

Competition and Markets Authority

Decision

Hydrocortisone tablets

**Excessive and unfair pricing
and
Anti-competitive agreements**

Case 50277

15 July 2021

1. CONTENTS

1.	Introduction and summary	7
A.	Addressees of this Decision	7
B.	Summary of the Infringements	11
I.	The context of the Infringements.....	12
II.	Auden/Actavis charged excessive and unfair prices	13
III.	Auden/Actavis entered into anti-competitive agreements with Waymade and AMCo.....	15
IV.	Auden/Actavis continued to charge excessive and unfair prices after entry occurred	17
V.	The parties' representations on the case	22
C.	The penalties the CMA is imposing	30
2.	The investigations	31
3.	Facts	39
A.	Key companies and individuals	39
I.	Key companies	39
II.	Key individuals	48
B.	The drug lifecycle and the place of hydrocortisone tablets in it	49
I.	The pre-launch period: stage 1	52
II.	The market exclusivity period: stage 2	53
III.	The post-exclusivity period: stage 3.....	54
IV.	Prescribing, dispensing and funding	57
V.	Price regulation	59
VI.	'Niche' generics.....	62
VII.	Hydrocortisone tablets as niche generics	67
C.	Adrenal insufficiency and the drugs that treat it.....	71
I.	Adrenal insufficiency and hydrocortisone.....	71
II.	Hydrocortisone tablets	72
III.	Plenadren	74
IV.	Other forms of hydrocortisone medicine	77
V.	Other steroids	78
D.	Bioequivalence and full and skinny label hydrocortisone tablets	79

I.	Bioequivalent medicines	79
II.	Marketing authorisations	82
III.	Orphan medicinal products and full and skinny label hydrocortisone tablets	82
E.	Supply and demand for hydrocortisone tablets	87
I.	Pricing framework for hydrocortisone tablets	87
II.	The supply chain for hydrocortisone tablets in the UK	94
III.	Prescribing and dispensing of hydrocortisone tablets	101
IV.	Demand for hydrocortisone tablets	113
V.	Developments in the supply of hydrocortisone tablets	141
F.	Conduct under investigation	164
I.	Facts relevant to the Unfair Pricing Abuses	164
II.	Facts relevant to the 20mg Agreement	167
III.	Facts relevant to the 10mg Agreement	189
4.	Market definition and dominance	293
A.	Overview of key market definition and dominance findings	293
I.	The CMA's findings	293
II.	Representations on consistency between market definition and dominance	299
B.	Market definition	300
I.	Legal framework for market definition	300
II.	The CMA's assessment of market definition	304
C.	Dominance	358
I.	Legal framework for dominance	358
II.	The CMA's assessment of dominance	373
5.	THE UNFAIR PRICING ABUSES	415
A.	Conclusions	415
B.	Legal framework	420
I.	Overview	420
II.	The Excessive Limb of the <i>United Brands</i> Test: is the price 'excessive'?	423
III.	The Unfair Limb of the <i>United Brands</i> Test: is the price unfair?	426
IV.	Other methodologies	433

C.	Auden/Actavis's prices were excessive	434
I.	Conclusion	434
II.	Auden/Actavis's prices	435
III.	Costs plus a reasonable rate of return (Cost Plus)	437
IV.	Auden/Actavis's prices were excessive.....	470
V.	The parties' representations on whether Auden/Actavis's prices were excessive	484
D.	Auden/Actavis's prices were unfair.....	493
I.	Conclusion	493
II.	Auden/Actavis's prices were unfair in themselves	493
III.	Auden/Actavis's prices were unfair when compared to competing products	512
IV.	Economic value.....	529
V.	The parties' representations on whether Auden/Actavis's prices were unfair.....	535
E.	Exclusions	544
6.	THE AGREEMENTS.....	545
A.	Summary	545
I.	The 20mg Agreement	545
II.	The 10mg Agreement	546
B.	The burden and standard of proof	548
I.	Legal framework	548
II.	Application in this case	550
III.	The parties' representations on the burden and standard of proof	551
C.	Legal and economic context.....	556
I.	Legal framework relevant to potential competition	556
II.	The legal and economic context to the Agreements	565
D.	Agreements restricting competition by object.....	630
I.	Legal framework	630
II.	Agreements for the purpose of the Chapter I prohibition	640
III.	The object of the Agreements.....	791
IV.	The parties' subjective intentions	805
7.	DURATION	811

8.	EFFECT ON TRADE	814
9.	UNDERTAKINGS AND ATTRIBUTION OF LIABILITY	815
A.	Legal framework for undertakings and attribution of liability	815
I.	Undertakings.....	815
II.	Attribution of liability	815
B.	The CMA's assessment of undertakings and attribution of liability	834
I.	Auden/Actavis	836
II.	Waymade.....	879
III.	AMCo.....	888
10.	THE CMA'S ACTION	948
A.	The CMA's decision.....	948
B.	Financial penalties.....	949
I.	The CMA's margin of appreciation in determining the appropriate penalty	949
II.	Intention and negligence	950
III.	Legal certainty.....	987
C.	Calculation of the financial penalties: the CMA's approach	991
I.	Liability to pay the financial penalties.....	993
II.	Specific deterrence and proportionality	995
III.	Financial benefits and deterrence	996
IV.	Considerable size of some of the undertakings	998
V.	The CMA's decision to impose separate penalties for separate infringements	999
VI.	Liability for multiple penalties for multiple infringements: avoiding 'double counting'	1000
VII.	Assessment of the penalties in aggregate	1001
D.	Penalty calculations.....	1003
I.	Step 1: starting point.....	1003
II.	Step 2: adjustment for duration	1013
III.	Step 3: adjustment for aggravating and mitigating factors	1015
IV.	Step 4: adjustment for specific deterrence and proportionality..	1034
V.	Step 5: adjustment to prevent maximum penalty from being exceeded and to avoid double jeopardy	1068

VI. In the round assessment of multiple penalties imposed on some of the undertakings	1072
VII. Step 6: application of reductions for leniency, settlement or voluntary redress.....	1075
VIII. Payment of penalty	1075

ANNEXES

Annex A: The Investigations

Annex B: Representations on DHSC/NHS countervailing buyer power

Annex C: Representations on 10mg hydrocortisone tablet product development

Annex D: Representations on demand for skinny label hydrocortisone tablets

Annex E: Summary penalty calculations

Annex F: Representations on step 4 of the penalties calculations

1. INTRODUCTION AND SUMMARY

A. Addressees of this Decision

1.1. This Decision of the Competition and Markets Authority (the '**CMA**') is addressed to the following legal entities:

- a. Accord-UK Limited (formerly known as Actavis UK Limited, company number 00079585) ('**Accord-UK**');¹
- b. Auden Mckenzie (Pharma Division) Limited (company number 03835531) ('**AM Pharma**');
- c. Allergan plc (formerly known as Actavis plc, registered in Ireland with company number 527629) ('**Allergan**');
- d. Accord Healthcare Limited (company number 04596349) ('**Accord**');
- e. Intas Pharmaceuticals Limited (registered in India with company number FC024249) ('**Intas**');
- f. Waymade plc (formerly known as Waymade Healthcare plc, company number 08156320);
- g. The '**Amdipharm Companies**':
 - i. Amdipharm UK Limited (company number 04606340);
 - ii. Amdipharm Limited (registered in Ireland with company number 364596); and
 - iii. Advanz Pharma Services (UK) Limited (formerly known as Amdipharm Mercury Company Limited, company number 04678629);
- h. The '**Cinven Entities**':
 - i. Cinven Capital Management (V) General Partner Limited (a non-cellular company limited by shares organised under the laws of Guernsey) ('**Cinven MGP**');
 - ii. Cinven (Luxco 1) S.A. (a *société anonyme* organised under the laws of Luxembourg) ('**Luxco 1**'); and

¹ This Decision may refer to a legal entity by the appropriate defined term or by its legal name at the time of the evidence or conduct being discussed. For example, Accord-UK Limited (formerly Actavis UK Limited) may be referred to as 'Accord-UK' or 'Actavis UK Limited'.

- iii. Cinven Partners LLP (a limited liability partnership registered under number OC366256) (**'Cinven Partners'**); and
 - i. Advanz Pharma Corp. Limited (formerly known as Advanz Pharma Corp. and Concordia International Corporation, incorporated in Jersey) (**'Advanz'**).
- 1.2. This Decision is issued to the persons listed in paragraph 1.1 above under section 31 of the Competition Act 1998 (the **'Act'**) and in accordance with rule 10(1) of the CMA's Rules under the Act.²
- 1.3. By this Decision, the CMA finds that:
 - a. The following legal entities form or formed part of an undertaking, referred to for the purposes of this Decision as **'Auden'** or **'Actavis'** (or **'Auden/Actavis'**) as appropriate in context:³
 - i. from 1 October 2008 to 28 May 2015: AM Pharma;
 - ii. from 29 May 2015 to 1 August 2016: AM Pharma, Accord-UK and Allergan;
 - iii. from 2 August 2016 to 8 January 2017: Accord-UK; and
 - iv. From 9 January 2017 to 31 July 2018: Accord-UK, Accord and Intas.
 - b. The following legal entities form or formed part of an undertaking, referred to for the purposes of this Decision as **'Waymade'**:
 - i. from 11 July 2011 to 30 October 2012: Waymade plc and Amdipharm UK Limited; and
 - ii. from 31 October 2012 to 30 April 2015: Waymade plc.
 - c. The following legal entities form or formed part of an undertaking, referred to for the purposes of this Decision as **'AMCo'**:

² SI 2014/458 *The Competition Act 1998 (Competition and Markets Authority's Rules) Order 2014* (the **'CMA's Rules'**).

³ Since (as explained in this Decision) AM Pharma sold hydrocortisone tablets until 31 August 2015, and Accord-UK (then known as Actavis UK Limited) took over its business from 1 September 2015, the CMA will refer to 'Auden' when discussing the undertaking until 31 August 2015, and to 'Actavis' when discussing the undertaking after that date. The CMA will refer to 'Auden/Actavis' when discussing the undertaking throughout the period covered by this Decision.

- i. from 31 October 2012 to 20 October 2015: the Amdipharm Companies and the Cinven Entities; and
- ii. from 21 October 2015 to 24 June 2016: the Amdipharm Companies and Advanz.

1.4. By this Decision, the CMA gives notice to the persons listed at paragraph 1.1 above that it has decided that:

- a. From 1 October 2008 to 31 July 2018, Auden/Actavis abused its dominant position by imposing excessive and unfair prices for **10mg** hydrocortisone tablets, thereby infringing the prohibition in section 18 of the Act (the '**Chapter II prohibition**') (the '**10mg Unfair Pricing Abuse**').
- b. From 1 October 2008 to 8 January 2017, Auden/Actavis abused its dominant position by imposing excessive and unfair prices for **20mg** hydrocortisone tablets, thereby infringing the Chapter II prohibition (the '**20mg Unfair Pricing Abuse**').
- c. From 11 July 2011 to 30 April 2015, Auden and Waymade entered into an agreement that had as its object the prevention, restriction or distortion of competition, thereby infringing the prohibition in section 2(1) of the Act (the '**Chapter I prohibition**'). In that agreement, Auden agreed to make substantial monthly payments to Waymade in exchange for Waymade agreeing not to enter the market independently with its own **20mg** hydrocortisone tablets (the '**20mg Agreement**').
- d. From 23 October 2012 to 24 June 2016 Auden/Actavis entered into another agreement that had as its object the prevention, restriction or distortion of competition, thereby infringing the Chapter I prohibition, first with Waymade and then with AMCo. In that agreement, Auden/Actavis agreed to make substantial monthly payments to Waymade and AMCo in exchange for each of Waymade and AMCo agreeing not to enter the market independently with its own **10mg** hydrocortisone tablets (the '**10mg Agreement**'). Specifically:
 - i. From 23 October 2012 to 30 October 2012, Waymade was party to the 10mg Agreement.
 - ii. On 31 October 2012, AMCo replaced Waymade as party to the 10mg Agreement and the agreement continued between Auden/Actavis and AMCo until 24 June 2016.

- 1.5. In this Decision, the CMA refers to the 10mg Unfair Pricing Abuse and the 20mg Unfair Pricing Abuse together as the '**Unfair Pricing Abuses**'; the CMA refers to the 20mg Agreement and the 10mg Agreement together as the '**Agreements**'; and the CMA refers to the Unfair Pricing Abuses and the Agreements together as the '**Infringements**'.
- 1.6. European Union ('**EU**') law no longer applies in the UK. This Decision does not therefore consider whether Articles 101 or 102 of the Treaty on the Functioning of the European Union ('**TFEU**') have been infringed. However, under section 60A of the Act, unless it considers it appropriate to act otherwise in light of specified factors, in reaching its findings in this Decision the CMA is required to act with a view to securing that there is no inconsistency between the principles that it has applied, and the decision it has reached, and the principles of EU law and judgments of the EU courts on corresponding issues that were made before 31 December 2020. The CMA must also have regard to relevant decisions or statements of the European Commission made before that date and not withdrawn.
- 1.7. The CMA has decided to impose financial penalties under section 36 of the Act on all the persons listed in paragraph 1.1 above (with the exception of AM Pharma⁴) in relation to the Infringements in which they participated.

⁴ As explained in section 9 below, the CMA has held Accord-UK liable for the conduct of AM Pharma prior to 1 September 2015 by application of the principle of economic continuity.

B. Summary of the Infringements

- 1.8. Hydrocortisone tablets are an essential, lifesaving medicine on which tens of thousands of patients depend for the treatment of adrenal insufficiency, which includes conditions such as the life-threatening Addison's disease. Prescriptions for these drugs are funded by the NHS, and ultimately the taxpayer. They are sold in two strengths: 10mg and 20mg. 10mg tablets make up 96% of all hydrocortisone tablets dispensed.⁵
- 1.9. This Decision relates to the prices charged by Auden/Actavis as the incumbent supplier of hydrocortisone tablets in the UK from 1 October 2008 to 31 July 2018, and the anti-competitive agreements it entered into with Waymade and AMCo, two potential competitors, during that period.
- 1.10. Between 2008 and 2016 Auden/Actavis increased prices by **over 10,000%**: from less than £1 per pack (the price charged under the drug's previous owner, which had sold the drug since 1955) to **£72** per pack. As a result, NHS spending on hydrocortisone tablets rose from around £500,000 per year in 2007 to over **£80 million** per year in 2016.
- 1.11. Until 2015, Auden/Actavis was the sole supplier of hydrocortisone tablets. When two other suppliers prepared to enter and threatened its position, Auden/Actavis entered into market exclusion agreements with them. Under these agreements, Auden/Actavis made monthly payments to its potential competitors. Auden/Actavis paid:
- a. Waymade a total of **£1.8 million** in return for which Waymade agreed to stay out of the market with its own **20mg** hydrocortisone tablets from 11 July 2011 to 30 April 2015; and **£70,000** in return for which Waymade agreed to stay out of the market with its own **10mg** hydrocortisone tablets during October 2012; and
 - b. AMCo a total of **£21 million** in return for which AMCo agreed to stay out of the market with its own **10mg** hydrocortisone tablets (which it acquired from Waymade at the end of October 2012) from 31 October 2012 to 24 June 2016.
- 1.12. These agreements aimed to prevent or delay the arrival of competition, and the consequent likely price falls, and to preserve Auden/Actavis's monopoly position and associated ability to charge very high prices. A portion of the resulting profits was shared with Waymade and AMCo.

⁵ Based on volumes of packs. NHS BSA data.

- 1.13. After other suppliers eventually entered the market and Auden/Actavis's prices started to fall, it continued profitably to charge prices significantly above those of its competitors, as a result of a quirk in the regulatory regime which afforded it the benefit of a protection given to a different drug supplied by a different firm, which had the unforeseen and unintended consequence of also protecting Auden/Actavis's drugs. This gave Auden/Actavis an assured base of customers it could continue to exploit.
- 1.14. As a result, Auden/Actavis overcharged the NHS over **ten years**.
- 1.15. The CMA has decided to fine:
- a. Auden/Actavis **£155.2 million** for the Unfair Pricing Abuses and **£66.0 million** for its participation in the Agreements;
 - b. Waymade **£2.5 million** for its participation in the Agreements; and
 - c. AMCo **£42.8 million** for its participation in the 10mg Agreement.

I. The context of the Infringements

- 1.16. The fact that hydrocortisone tablets are an essential medicine does not entail that they should be expensive. They were first sold in the UK in 1955, under the brand name *Hydrocortone*. Any patents granted to reward innovation by their originator expired at the latest during the 1970s. Being long off-patent, hydrocortisone tablets were in the third stage of the drug lifecycle,⁶ when the price of even essential drugs is expected to be kept low by the potential for competitive entry and competition. In 2007, over 50 years after they were first sold, the price of hydrocortisone tablets was less than **70 pence** per pack of 10mg tablets and **£1** per pack of 20mg tablets.⁷ Prices had remained at that level for years. The NHS spent around £500,000 per year on the drug. At its peak during the Infringements, NHS spending on the drug was over £80 million per year. In 2020, after competition eventually brought prices down, the NHS still spent £9.6 million on the drug.
- 1.17. In April 2008, Auden bought the licences for hydrocortisone tablets from the company that had brought them to market in 1955 and had sold them since, for £200,000. Within days Auden discontinued the brand and launched generic versions under those licences.

⁶ The first stage of the drug lifecycle concerns the invention of new drugs while the second stage concerns patent protection and recovery of research and development associated with the invention of a new drug: see section 3.B below.

⁷ These are reimbursement prices (the prices paid by the NHS to pharmacies for fulfilling prescriptions). The actual selling prices were lower.

- 1.18. This 'de-branding' removed the drugs from the price regulation provisions within the PPRS scheme. As a result of these steps hydrocortisone tablets became fully genericised and Auden had the freedom to set whatever prices it chose (subject to competition).
- 1.19. During the period covered by this Decision, the prices of generic drugs were unregulated in the UK. Whereas the profits made from branded drugs are often constrained by regulation, the historical assumption is that once a drug moves to the third stage of the drug lifecycle (when patents have expired and competitors are free to enter with generic versions of a drug), its suppliers should no longer be able to charge high prices. By this point, the cost of the drug's invention should long since have been recouped and any innovation rewarded. The public interest in lowering the price of medicines subsequently eclipses the public interest in incentivising innovation, which has been achieved by the patent regime. At this point competition between suppliers may normally be expected to keep prices low, even for essential drugs.
- 1.20. Relying on competition may normally be expected to be an effective means of securing value for money for the NHS. However, the assumption that the market will regulate generic drug prices only holds good where competition works, and is neither ineffective nor artificially prevented, restricted or distorted. For some generic drugs, competition is impeded or delayed. This could be because of market features (such as barriers to entry or expansion or where the market is too small to attract entry) or because of artificial or deliberate acts such as anti-competitive collusion.
- 1.21. Hydrocortisone tablets proved to be such generic drugs, with competition not working properly, as a result of the agreements and regulatory circumstances described in this Decision. Specifically, the CMA has found that when Auden/Actavis's price increases made the market more attractive to entrants the drugs were shielded from effective entry by anti-competitive collusion (see section 6 below); and that after entry eventually took place Auden/Actavis's market power was sustained by a regulatory windfall that gave it an assured customer base that it could continue to exploit with appreciable freedom from constraint (see section 4.C.II.c below).

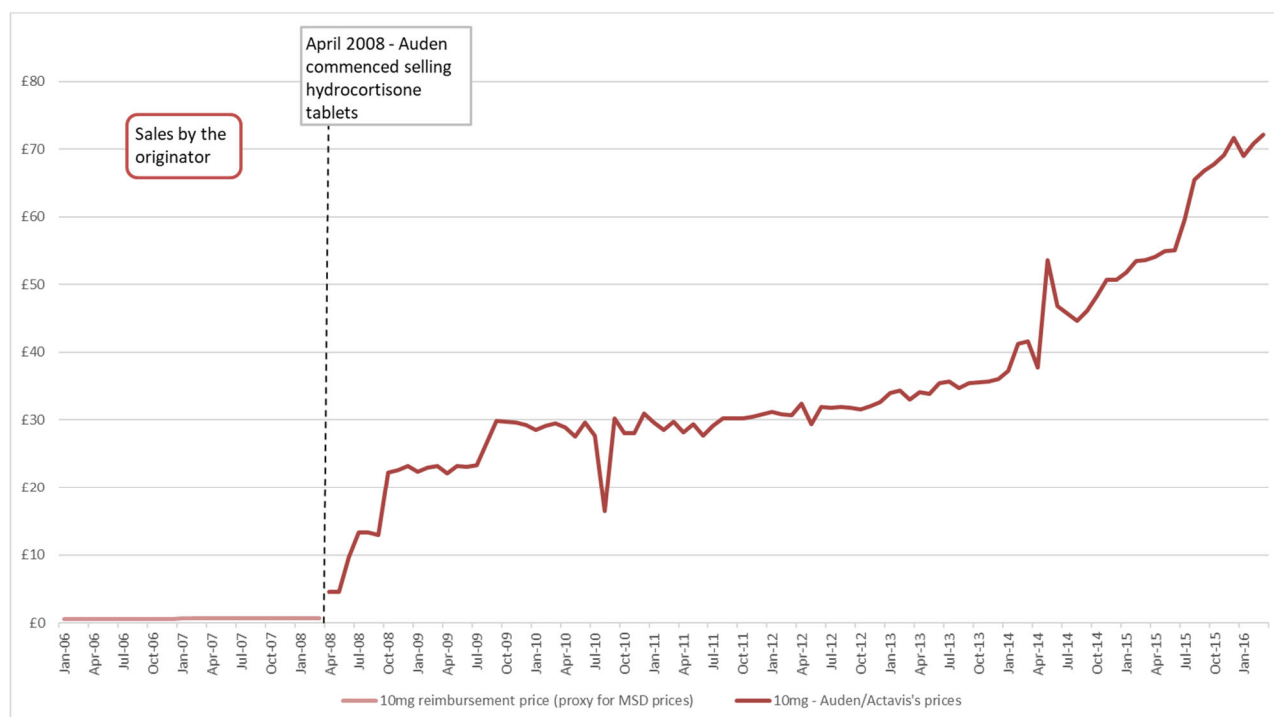
II. Auden/Actavis charged excessive and unfair prices

- 1.22. Over the eight years following its April 2008 decision to de-brand hydrocortisone tablets (for the majority of which it was the sole supplier), Auden/Actavis increased the prices by over 10,000% relative to the prices charged before it acquired the licences. At their highest (March 2016 for

10mg, October 2015 for 20mg), Auden/Actavis's selling prices reached **£72** per pack. In March 2016, the NHS paid **£88** per pack for 10mg tablets and **£103** per pack for 20mg tablets.⁸

1.23. Auden/Actavis's price increases are illustrated in figures 1.1 and 1.2 below.

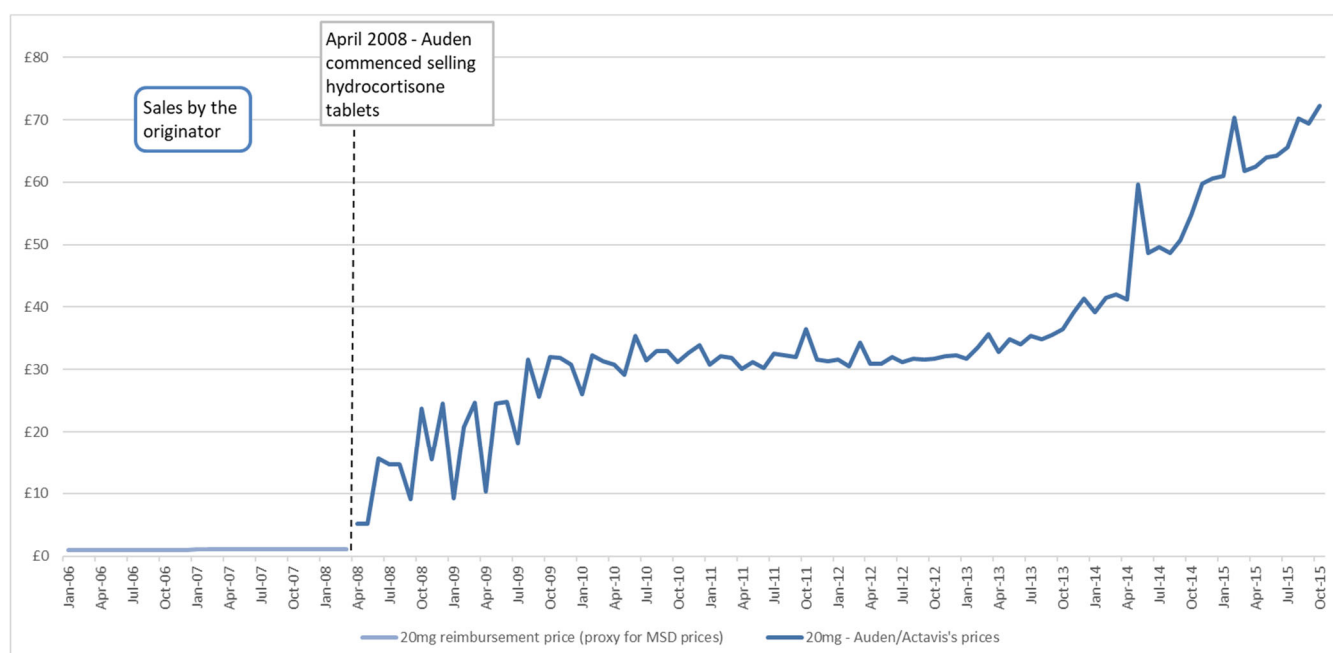
Figure 1.1: 10mg hydrocortisone tablet prices between January 2006 and March 2016



Source: CMA analysis based on data submitted by Auden/Actavis and NHS BSA data.

⁸ These are reimbursement prices, which peaked in March 2016.

Figure 1.2: 20mg hydrocortisone tablet prices between January 2006 and October 2015



Source: CMA analysis based on data submitted by Auden/Actavis and NHS BSA data.

- 1.24. The price increases did not reflect any increase in Auden/Actavis's costs. Moreover, Auden/Actavis did not make any investment or produce any innovation in relation to hydrocortisone tablets that might justify these price increases. Auden/Actavis did not invent, improve or even manufacture the drug. It simply exploited the absence of effective constraints to increase prices.
- 1.25. The CMA has found that Auden/Actavis's prices were excessive and unfair. The CMA has exercised its discretion to determine its administrative priorities and has not prioritised investigating Auden/Actavis's prices where they were below **£20 per pack**.⁹ The CMA has made no finding as to whether prices below that level were excessive or unfair. It has found that, in context, prices for this drug above that level were clearly excessive and unfair.

III. **Auden/Actavis entered into anti-competitive agreements with Waymade and AMCo**

- 1.26. Auden's increasing prices made hydrocortisone tablets more attractive to other suppliers, which could see that there were now significant profits to be made. Others therefore began to prepare to launch their own generic versions, with the intention of competing with Auden's generic versions. This

⁹ This decision determined the start date of both Unfair Pricing Abuses and the end date of the 10mg Unfair Pricing Abuse. The end date of the 20mg Unfair Pricing Abuse (8 January 2017) reflects the fact that the CMA has not prioritised investigating whether Actavis held a dominant position for 20mg hydrocortisone tablets after that date.

competition would normally be expected to result in price decreases to the benefit of the NHS.

- 1.27. However, such competition was deliberately prevented. Auden/Actavis bought off the first two of its potential competitors: Waymade and AMCo. It paid them, and in exchange they agreed not to enter the market. Auden/Actavis's high prices were therefore sustained and extended by anti-competitive agreements that enabled it to continue exploiting its market power.
- 1.28. The first agreement related to 20mg tablets and was reached with Waymade in July 2011. In response to the competitive threat posed by Waymade's licence for 20mg tablets, Auden gave Waymade a monthly cash payment initially of £24,000 (increasing over time) and supplied Waymade with 200 packs of 20mg tablets per month at **an 87% discount** compared to Auden's other customers. The cash payment was masked by an arrangement in which Auden 'sold' 800 packs to Waymade (at the same 87% discount), which it then immediately 'bought back' at prevailing market prices, without the product ever leaving Auden's warehouse. In total, from 11 July 2011 to 30 April 2015 Auden paid Waymade **£1.8 million**. In exchange, Waymade agreed to stay out of the market with its own 20mg hydrocortisone tablets.
- 1.29. From July 2011 onwards, while Waymade worked to obtain a 10mg licence, it bought 10mg tablets from Auden at market rate: **more than £30** per pack. On 27 September 2012, Waymade obtained its 10mg licence. In October 2012 (at the latest by 23 October), in response to the competitive threat posed by that licence, Auden again agreed to supply Waymade with a fixed volume of 10mg tablets each month at **a 97% discount** compared to Auden's other customers. The discounted volume of packs Waymade was given in October 2012 was worth **£70,000** at market rate. In exchange, Waymade agreed to stay out of the market with its own 10mg hydrocortisone tablets.
- 1.30. On 31 October 2012, Waymade sold its Amdipharm group to the Cinven private equity house. Cinven combined Amdipharm with another group, Mercury, to create Amdipharm Mercury or AMCo. From 31 October 2012 onwards Auden supplied AMCo with a heavily discounted fixed volume of 10mg tablets each month. Over the next three and a half years Auden/Actavis continued to give AMCo **a 97% discount** compared to its other customers, enabling AMCo to make significant profits selling its volumes in the market. The supply deal was renegotiated at certain points, each time resulting in an increase in AMCo's monthly volumes. In total, between November 2012 and June 2016 Auden/Actavis paid AMCo **£21**

million in relation to 10mg tablets. In exchange, AMCo agreed to stay out of the market with its own 10mg hydrocortisone tablets.

- 1.31. None of the parties or individuals involved has explained why Auden/Actavis was willing to supply Waymade and AMCo at a discount of 87% and 97% (respectively) to its prices to other customers, or to make cash payments to Waymade, if not to buy off their entry. It is not credible that Auden/Actavis expected nothing in return, or that Waymade and AMCo did not understand what was expected. Businesses do not pay their competitors considerable sums each month for nothing.
- 1.32. These market exclusion agreements were aimed at preserving Auden/Actavis's monopoly position and associated ability to charge very high prices. A portion of the resulting proceeds was shared with Waymade and AMCo through the profits they made on the heavily discounted volumes given to them (and, in Waymade's case, through cash payments). Waymade and AMCo were therefore able to share in Auden/Actavis's high and increasing prices while agreeing to delay the process of competition for hydrocortisone tablets and the savings for the NHS that this should have created.
- 1.33. The CMA has found that these agreements had the object of preventing, restricting or distorting competition.

IV. Auden/Actavis continued to charge excessive and unfair prices after entry occurred

- 1.34. Auden/Actavis was unable to delay competitive entry indefinitely. Other suppliers eventually began to enter the market from July 2015 (and especially March 2016) onwards. Prices began to fall as the process of competition began.
- 1.35. However, Auden/Actavis's market power did not vanish overnight. Despite entry, Auden/Actavis continued profitably to charge prices significantly in excess of those charged by its competitors while maintaining significant market shares.
- 1.36. Auden/Actavis's ability to sustain its market power following entry derived primarily from a quirk of the regulatory system: legal protection given to a different drug to reward innovation by a different firm.
- 1.37. In 2011 a licence was granted for a drug called Plenadren, a different form of hydrocortisone sold by Shire Pharmaceuticals. Plenadren benefits from an 'orphan designation', which is designed to incentivise research into serious

conditions affecting very small numbers of patients that otherwise might not attract investment by providing legal protection for a 'therapeutic indication' (ie for a specified use of a drug).

- 1.38. This orphan designation of Plenadren meant that, for ten years from November 2011, any **new** licences granted for drugs containing the active substance hydrocortisone could not specify that they were for treating adrenal insufficiency '*in adults*'. These licences are known as '**reduced indication**' or '**skinny label**'.
- 1.39. The by-product of this was that Auden gained a windfall regulatory benefit. Because Auden already had licences for hydrocortisone tablets in November 2011 (ie before the grant of the licence to Plenadren), it could continue marketing its drugs for adrenal insufficiency in adults. Its licences were '**full indication**' or '**full label**'. In contrast, any suppliers who obtained a **new** licence for hydrocortisone tablets after November 2011 were legally prevented from marketing their drug for the protected indication: they could only have a skinny label licence (such that they could not specify that they were for treating adrenal insufficiency in adults).
- 1.40. This was an unforeseen and unintended consequence of the regulatory regime that had no basis in innovation by Auden. The orphan designation granted to Plenadren reflected the difference between Plenadren and hydrocortisone tablets (Plenadren releases hydrocortisone into the body gradually, in contrast to hydrocortisone tablets, which release it instantly). It was meant to protect Plenadren and to recognise the innovation that led to that difference, which is a genuine clinical difference.
- 1.41. The orphan designation was not, however, intended to prevent suppliers of hydrocortisone tablets from competing with one another for all volumes, or to give a competitive advantage to Auden/Actavis simply because it happened to hold licences when Plenadren received protection. When applied to competing suppliers of hydrocortisone tablets, the orphan designation does not reflect any pharmaceutical or qualitative difference between products – only the date on which the supplier obtained its licence.
- 1.42. All entrants into the market were nonetheless affected by the orphan designation, except for Waymade in relation to 20mg hydrocortisone tablets, for which through circumstance it already held a licence.
- 1.43. Because prescriptions for hydrocortisone tablets specify the drug only (and not the supplier or the therapeutic indication), pharmacists are free to dispense any licensed hydrocortisone tablets to fulfil the prescription. This

means that pharmacists can dispense skinny label hydrocortisone tablets to an adult, although they are not indicated for the treatment of adrenal insufficiency in adults. This is known as dispensing '**off-label**' (and should not be confused with 'unlicensed' dispensing: all skinny label tablets had a licence and were therefore licensed for sale in the UK).

- 1.44. Although off-label dispensing is subject to guidance, in the case of hydrocortisone tablets all suppliers' tablets contain the same amount of the same active substance, meet the same standards and have essentially the same efficacy and safety (known as 'bioequivalence'). They are homogeneous, fungible commodities. Pharmacists are incentivised to dispense the cheapest product available (as they then make more profit when they are reimbursed by the NHS).
- 1.45. This has led to widespread off-label dispensing of hydrocortisone tablets and the NHS has benefited from the resulting price falls. Wholesalers and pharmacies accounting for **around 50% of total volumes** of hydrocortisone tablets have switched their business to suppliers of skinny label tablets.
- 1.46. The regulatory windfall from the orphan designation nonetheless gave Auden/Actavis an assured base of customers it could continue to exploit after entry. Pharmacies accounting for **around 50% of total volumes** of hydrocortisone tablets did not switch to skinny label tablets based mainly on their assessment of a potential regulatory risk to dispensers from off-label dispensing, rendering those volumes incontestable to skinny label suppliers and captive to Auden/Actavis as the only supplier of full label hydrocortisone tablets on the 10mg strength (which accounts for 96% of all hydrocortisone tablets dispensed) and one of only two suppliers of full label hydrocortisone tablets on the 20mg strength.
- 1.47. The effects of Auden/Actavis's market power persisted beyond entry in other ways (in addition to the regulatory windfall described above). When competitors eventually entered the market, they charged prices inflated by Auden/Actavis's price increases over the previous eight years. Competition took time to erode prices. Deficiencies in the way the reimbursement price of hydrocortisone tablets was calculated meant that Actavis's prices were further shielded from the impact of competition. This, combined with the regulatory windfall of the orphan designation, enabled Auden/Actavis to continue to impose prices which were significantly above those of its competitors. However, the process of competition over the next five to six years (together with a change in how the reimbursement price was calculated) resulted in the prices charged for competing hydrocortisone tablets returning in 2021 to levels similar to the price of *Hydrocortone* back in

2008 and Auden/Actavis's own prices returning to levels significantly below the prices Auden first set when launching its generic versions in April 2008.

1.48. This is set out in table 1.3 below.

Table 1.3: prices of hydrocortisone tablets over time

	10mg	20mg
Price of Hydrocortone from 2006 to 2008*	<£0.70	<[£1-£4]
Price charged by Auden when launching generic hydrocortisone tablets in April 2008	£4.54	£5.14
Auden/Actavis's prices during the Unfair Pricing Abuses	£20 - £72.14	£20 - £72.19
Average price of skinny label tablets (Feb to April 2021)	£1.34	£1.85
Average price of Waymade's full label tablets (May to July 2020**)	N/A	[£1-£4]
Actavis's prices (Feb to April 2021)	[£1-£4]	[£1-£4]***

* As explained above, these are NHS reimbursement prices. The originator's selling prices were lower.

** Waymade made no sales after July 2020.

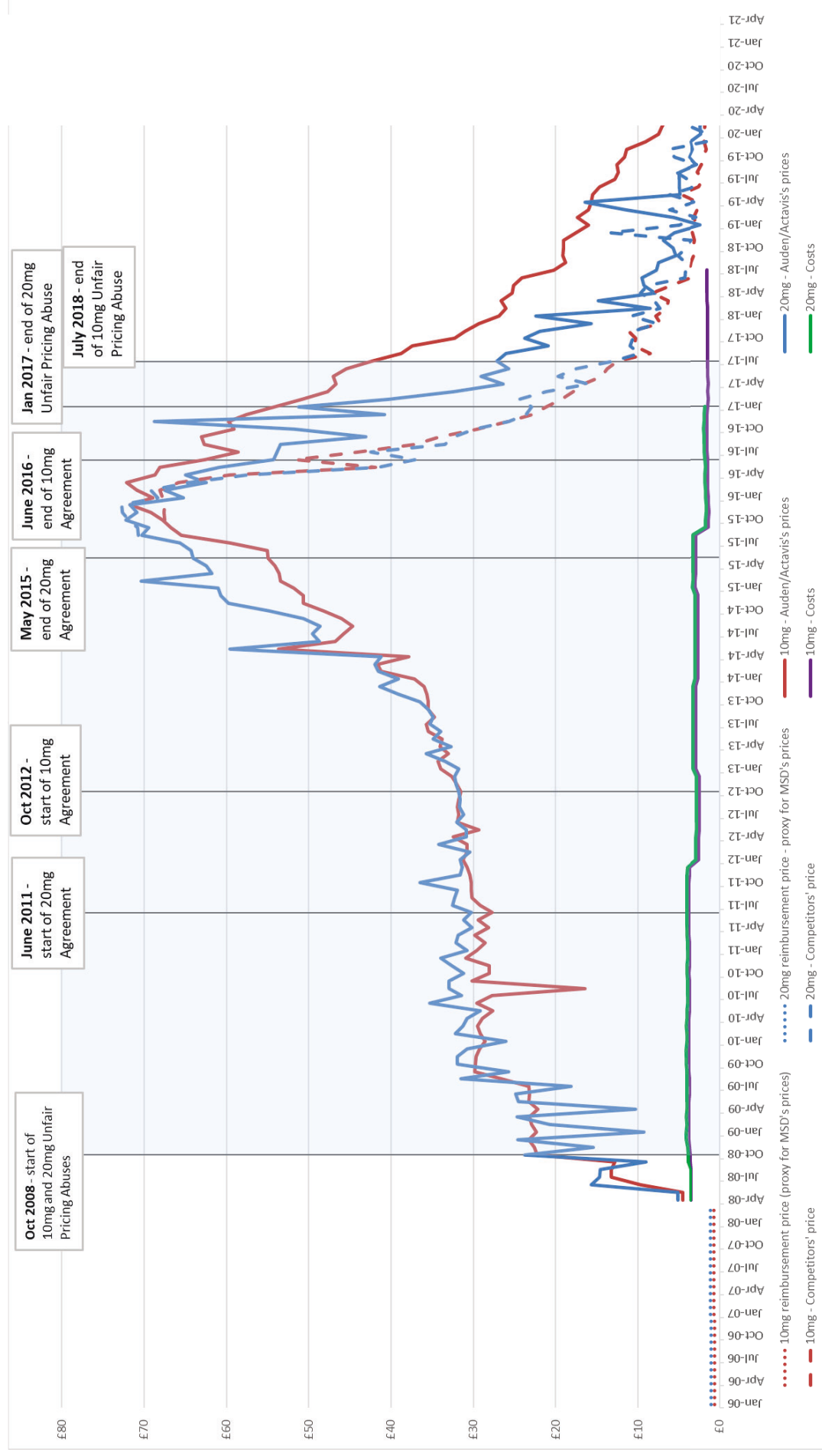
*** For 20mg tablets competition was more effective owing to the presence of another supplier (Waymade) that also benefited fortuitously from the orphan designation and could therefore market to all patients.

1.49. Table 1.3 demonstrates that, notwithstanding their status as an essential medicine (ie their **therapeutic value** to patients), the **economic value** of hydrocortisone tablets – what they are ‘worth’, whether determined by their price prior to de-branding, on generic launch or following a process of competition – provided no justification for the prices charged during the Unfair Pricing Abuses.

1.50. The process of competition ultimately restored the price of hydrocortisone tablets to a level that closely approximates their cost of production – as is to be expected with a generic drug first sold in 1955. It is only now, more than thirteen years after Auden took over sales of the drug and after more than five years of competition, that prices are back down to the low levels that would be expected from well-established and long off-patent generic drugs.

1.51. This is illustrated in figure 1.4 below.

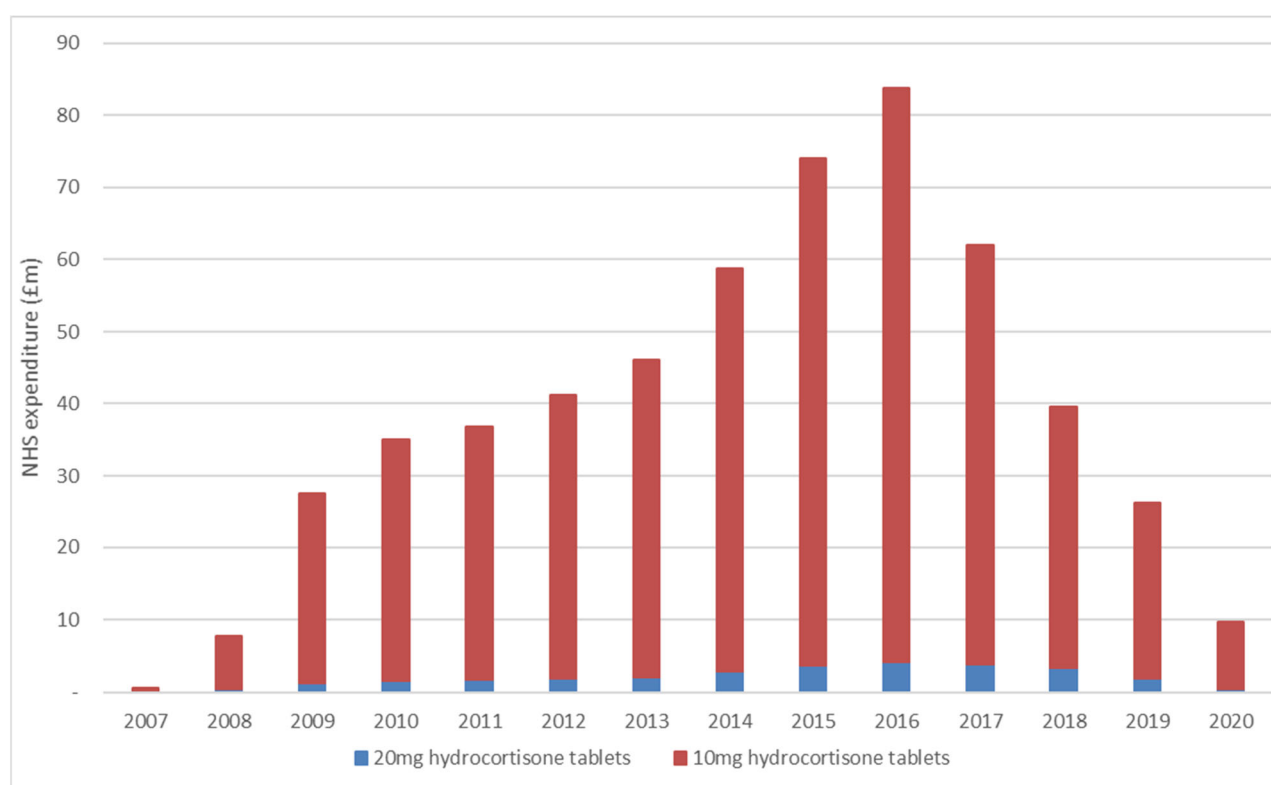
Figure 1.4: Prices and costs of hydrocortisone tablets between January 2006 and April 2021



* Note: the CMA has exercised its discretion to determine its administrative priorities and has not prioritised investigating Auden/Actavis's prices below £20 per pack. The CMA has made no finding as to whether prices below this level were excessive or unfair.

- 1.52. During the period covered by this Decision (shaded in figure 1.4 above) Auden/Actavis made profits of **at least £145 million** from the drug, at the ultimate expense of the NHS.¹⁰ The increased costs that the NHS incurred as a result of the price increases have not been recouped as a result of the price falls that followed entry: those price falls simply mean the NHS is only now paying what it should always have been paying for the drug.
- 1.53. This is illustrated in figure 1.5 below.

Figure 1.5: NHS annual UK expenditure on hydrocortisone tablets (£m)



Source: NHS BSA data

V. The parties' representations on the case

- 1.54. The parties' representations on the CMA's provisional findings in this case are addressed in the relevant sections of this Decision and in Annexes B to E.
- 1.55. Many of the parties' representations (summarised in paragraphs 1.57 to 1.72 below) ultimately centred on a single issue: the extent of competitive interaction between full label and skinny label hydrocortisone tablets. This

¹⁰ This figure gives Auden/Actavis's profit compared to the £20 threshold at which the CMA has not prioritised investigating Auden/Actavis's prices. If Auden/Actavis's profits are assessed against the costs of hydrocortisone tablets plus a reasonable rate of return (Cost Plus), the true figure is closer to £270 million

issue is equally central to the CMA's findings, and the CMA has analysed it in detail. The CMA has found that:

- a. Full and skinny label hydrocortisone tablets are **in the same relevant product market**, as demonstrated in particular by the widespread off-label dispensing following entry which resulted in customers accounting for around 50% of volumes switching their business to suppliers of skinny label tablets and consequent falls in both full and skinny label tablet prices prompted by skinny label entry. See section 4.B (*Market definition*).
- b. Waymade and AMCo were **potential competitors of Auden/Actavis** with their skinny label 10mg hydrocortisone tablets. Although the **extent** of demand for skinny label tablets was uncertain before suppliers entered the market, there was never any doubt that there would be **some** demand, as demonstrated in particular by the consistent projections of skinny label sales by each of Waymade, AMCo and Auden/Actavis and by the investment Waymade and AMCo (and others) made in developing their products. See sections 3.E.IV (*Demand for hydrocortisone tablets*) and 6.C.II.b (*Potential competition*) and Annex D.
- c. Auden/Actavis and each of Waymade and AMCo opted to substitute the certainty of cooperation for the uncertainty of competition between full and skinny label tablets by **entering into the 10mg Agreement**: the parties reached a common understanding that it was better to cooperate than to take the risks of genuine competition and the resulting price falls. See section 6.D.II (*Agreements*).
- d. After competitors entered the market, a significant proportion of pharmacies, especially the larger pharmacy chains (accounting for around 50% of total volumes) reached the view that they could not switch to skinny label tablets because of a perceived regulatory risk from off-label dispensing. This gave Auden/Actavis **an assured customer base** that was the key factor in its **continued dominance post-entry**. See sections 4.B.II (*Market definition*) and 4.C.II.c (*Dominance in the Post-Entry Period*).
- e. Full label hydrocortisone tablets have **no greater economic value** than skinny label tablets: the products are in all material respects the same. The only relevant difference between them is the indications specified on the packaging, which is solely a function of whether the supplier's

licence was granted pre- or post-November 2011. See section 5.D.IV (*Economic value*).

1.56. Given that the issue of the extent of competitive interaction between full and skinny label hydrocortisone tablets is pervasive across a number of areas of this Decision, the CMA summarises here its responses to the parties' representations on this issue.

a. Consistency between the CMA's findings on market definition and dominance

1.57. The parties submitted that the CMA's approach to market definition – which recognises that skinny label hydrocortisone tablets posed a sufficient competitive constraint on full label tablets to be included in the same relevant market – was inconsistent with its provisional finding that Auden/Actavis held a dominant position during the Unfair Pricing Abuses.¹¹

1.58. As explained in sections 4.B.II (*Market definition*) and 4.C.II (*Dominance*), the CMA's findings on market definition are not inconsistent with its findings on dominance:

a. The test for market definition is that a product imposes **a sufficient constraint** on the focal product to be considered part of the same relevant market. Skinny label tablets imposed such a constraint on full label tablets. Following independent entry, around 50% of the market by volume switched to skinny label tablets and prices fell across the market.

b. The test for dominance is that an undertaking is able to act **to an appreciable extent** independently of its competitors, customers and ultimately consumers. Auden/Actavis met that test throughout the Unfair Pricing Abuses. In particular, Auden/Actavis was able to maintain a significant price premium relative to skinny label tablets¹² because of its assured base of customers (around 50% of the market by volume that had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets), thereby sustaining Auden/Actavis's market power.

1.59. These tests are not mutually exclusive. An entrant's product may sufficiently compete with an incumbent's to be included within the same relevant

¹¹ Document 204922, AMCo's RSSO, paragraphs 4.62, 4.72 and 4.86. Document 204967, Cinven's RSSO, paragraphs 5.14-5.16 and 5.46-5.48. Document 204903, Waymade's RSSO, paragraph 8.128. Document 205212, Intas/Accord-UK's RSSO, paragraphs 31-33.

¹² And relative to competitor's prices (including Waymade's full label tablets) on 20mg tablets.

market, but not to the extent that it deprives the incumbent of the ability to behave to an appreciable extent independently. If this were not the case, dominance would only be possible in single-product markets. That is clearly wrong.

- 1.60. It is uncontroversial to have differentiated products in the same relevant market as one another: there is a distinction between identifying substitutability between products that are differentiated and finding the ability to hold market power over those differentiated products. What matters is the degree of the competitive constraint and whether the degree of constraint is sufficient to prevent an undertaking acting appreciably independently of its competitors, customers and consumers.

b. Whether skinny label hydrocortisone tablets compete with full label hydrocortisone tablets

- 1.61. The counterparties to the 10mg Agreement – Waymade and AMCo – submitted that skinny label hydrocortisone tablets do not compete with full label hydrocortisone tablets and that the two are therefore in separate markets. They argued that this entailed that they could not have been potential competitors of Auden/Actavis with their skinny label product.¹³
- 1.62. In contrast, Auden/Actavis agreed with the CMA that skinny label hydrocortisone tablets compete with full label tablets.¹⁴
- 1.63. However, as explained in sections 4.B.II (*Market definition*), 4.C.II (*Dominance*), 6.C.II.b (*Potential competition*) and 6.D.II (*The 10mg Agreement*), the argument that skinny and full label hydrocortisone tablets do not compete is unsustainable given that, following entry, suppliers of skinny label tablets have taken around 50% of total volumes from Auden/Actavis's full label tablets. Dispensing of skinny label tablets is widespread. In any event, whether or not full and skinny label tablets were in the same relevant market there was clearly a competitive interaction between them for the purposes of the 10mg Agreement, as demonstrated in particular by AMCo's use of the competitive threat posed by its skinny label product as leverage to secure increased payments from Auden/Actavis.

¹³ Document 204903, Waymade's RSSO, paragraphs 8.4(d) and 8.118-8.129. Document 204922, AMCo's RSSO, section 4 (in particular paragraphs 4.93-4.97) and paragraph 6.52.

¹⁴ Document 205217, Auden/Actavis's RSSO, paragraphs 3.12 and 3.20-3.38.

c. Demand for skinny label tablets prior to entry

- 1.64. AMCo and Cinven submitted that there was no demand for skinny label hydrocortisone tablets until April 2016.¹⁵ They submitted that this meant AMCo could not have been a potential competitor to Auden/Actavis because no one in the market place was prepared to purchase its skinny label product until that date and that this was why AMCo renewed the 10mg supply deal in June 2014. AMCo and Cinven submitted that there was a change in market conditions in April 2016, when customers indicated for the first time that they would be willing to buy skinny label tablets. They submitted that this – and not the 10mg Agreement – was the reason AMCo did not launch its product until May 2016, even after receiving market-ready stock.¹⁶
- 1.65. However, as explained in sections 3.E.IV (*Demand for hydrocortisone tablets*), 4.B.II (*Market definition*), 6.C.II.b.iii and 6.C.II.b.iv (*10mg potential competition*) and 6.D.II (*The 10mg Agreement*) and in particular in Annex D:
- a. There is no contemporaneous documentary evidence suggesting that any of the parties believed skinny label hydrocortisone tablets could not successfully enter the market or that there was no demand for the product.
 - b. In contrast, there is a substantial amount of consistent contemporaneous evidence showing that throughout the period prior to the first entry of skinny label tablets in October 2015, there was an expectation in the market that there would be demand for skinny label tablets once they were launched – and that all the parties understood this during the 10mg Agreement. For example:
 - i. AMCo invested in bringing its own product to launch-readiness over several years (as well as investigating other possibilities for entry with skinny label tablets). AMCo consistently projected that it could sell at least between 10,000 and 12,000 packs of its skinny label product a month: between 13% and 16% of total volumes.
 - ii. In the first half of 2014 Auden launched a project designed to influence stakeholders not to purchase or dispense skinny label tablets. This was expressly stated to be a response to its perception that AMCo's launch was imminent and an attempt to protect Auden's market share from erosion as a result of AMCo's

¹⁵ Document 204967, Cinven's RSSO, paragraphs 1.14(f) and 3.2(c)-(d). Document 204922, AMCo's RSSO, paragraphs 3.245 and 3.681. See further Annex D to this Decision.

¹⁶ Document 204922, AMCo's RSSO, section 3.L. Document 204967, Cinven's RSSO, paragraphs 1.14(i), 3.2(a), 3.54, 3.70(d), 3.95-3.96 and 10.7(b). See further Annex D to this Decision.

skinny label tablets being dispensed off-label in place of Auden's full label tablets. However, its project received lukewarm reception, with NHS England's Chief Pharmaceutical Officer responding that he saw no reason for action given that the products were bioequivalent.

- iii. AMCo then used the competitive threat its skinny label product posed to Auden/Actavis as leverage to secure better terms under the 10mg Agreement in June 2014. This strategy could only have succeeded if the parties shared a belief that AMCo's skinny label tablets could win market share from Auden/Actavis.
 - iv. When the first entrant (Alissa Healthcare) entered the market with its own skinny label product in October 2015 it immediately found that there was substantial demand for its product. Alissa's success demonstrates that there was demand for skinny label tablets prior to April 2016 but that this could only materialise once skinny label tablets became available.
- c. Following the parties' representations, the CMA approached market participants to clarify their previous responses to questions in the course of the investigations and contemporaneous documents. They confirmed that the market would have reacted in the same way had skinny label tablets been launched earlier than October 2015. This *ex post* evidence corroborates the contemporaneous evidence.
- d. There is also a substantial amount of contemporaneous evidence stating expressly that the reason AMCo decided not to launch its 10mg product in June 2014 (when it believed that it was launch-ready) was not a belief that there was no demand for it (AMCo continued to project selling 10,000 packs of its own product per month), but the fact that it had renewed the 10mg Agreement with increased volumes. For example, a summary of a meeting of AMCo's most senior management on 25 June 2014 stated: '**Why** [original emphasis] *New supply agreement signed with Auden. Will not be able to sell our own product (produced at Aesica) in the UK*'.¹⁷ AMCo's June 2014 monthly report stated: '*Hydrocortisone 10mg batches manufactured and ready for sale ... however, these won't be sold due to a deal extension being signed with Auden McKenzie*'.¹⁸

¹⁷ Document 200124, email from [AMCo Senior Employee 5] to AMCo management dated 25 June 2014.

¹⁸ Document 200192, AMCo strategic development report for June 2014.

- 1.66. The weight of evidence therefore overwhelmingly supports the CMA's findings rather than AMCo's and Cinven's alternative version of events. In fact, what led AMCo ultimately to launch its product in May 2016 was that the scale of independent entry to the market undermined the 10mg Agreement and left AMCo with no other option. This was the explanation [AMCo Senior Employee 3] gave to staff in contemporaneous documents: in light of further entry he reached the view in March 2016 that '*we may need to act April-June with volumes*'.¹⁹ He described these market developments in negative, not positive terms: as an '*imperfect storm*' that left AMCo with no other option but to launch: '*We cannot delay any longer*'.²⁰
- 1.67. In any event, the fact that the **extent** of demand for skinny label tablets was uncertain until suppliers entered the market and started to make sales cannot provide any justification for substituting the certainty of cooperation for the uncertainty inherent in genuine competition. There was never any doubt that there would be **some** demand for skinny label tablets, as the number of suppliers that invested in their own products in order to enter the market (including AMCo) attests. In the circumstances it was not open to AMCo to opt for cooperation with Auden/Actavis over the uncertainty of competition.

d. Demand for skinny label tablets following entry

- 1.68. Auden/Actavis and Intas/Accord-UK submitted that widespread entry, including from skinny label tablets, resulted in Auden/Actavis's prices inexorably declining on an irreversible and rapid trajectory. The reimbursement (or 'Drug Tariff') price mechanism (which uses market prices to determine the level at which pharmacies are reimbursed for prescriptions, with the intention of reflecting competition) also exerted downward pressure on Auden/Actavis's prices. As a result, Auden/Actavis and Intas/Accord-UK submitted that following entry Auden/Actavis was not dominant.²¹
- 1.69. However, as explained in sections 4.B.II (*Market definition*) and 4.C.II (*Dominance*), although many customers switched to skinny label tablets, that switching stalled because of the barrier created by the orphan designation. A significant proportion of customers, especially the larger pharmacy chains (accounting for around 50% of total volumes), determined that they could not or should not switch to skinny label tablets because of their assessment of a potential regulatory risk from off-label dispensing. This gave Auden/Actavis

¹⁹ Document 202845, email from [AMCo Senior Employee 3] to [AMCo Employee] and [AMCo Senior Employee 5] dated 1 March 2016.

²⁰ Document 202765, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.

²¹ Document 205217, Auden/Actavis's RSSO, paragraphs 1.6.3 and 3.75-3.78; Document 205212, Intas/Accord-UK's RSSO, paragraphs 9-11, 13, 41-56, 93-98 and 112-121.

an assured customer base that enabled it to maintain prices significantly in excess of those charged by its competitors while maintaining significant market shares.

- 1.70. The constraint on Auden/Actavis's prices from the Drug Tariff price was also limited because it did not take into account all suppliers' prices; a fact that Actavis itself drew to the Department of Health and Social Care's ('DHSC') attention in December 2017 when it suggested that the DHSC request information on supply prices from all suppliers to use in formulating the Drug Tariff price for 10mg hydrocortisone tablets, which '*would quickly lower the latter and reinforce the competitive process*'.²²

e. Whether customers were readily willing to pay a premium for full label tablets following entry

- 1.71. Auden/Actavis and Intas/Accord-UK argued that, following entry to the market, those customers that continued to purchase full label hydrocortisone tablets did so out of free choice, and that this reflected their ready willingness to pay a premium for full label tablets.²³
- 1.72. However, as explained in sections 4.C.II (*Dominance*) and 5.D.IV (*Economic value*), Auden/Actavis's full label hydrocortisone tablets have no greater economic value than its competitors' skinny label tablets. The premium at which Auden/Actavis's full label tablets were sold reflected Auden/Actavis's market power and the assured customer base it benefited from because of the orphan designation, rather than customers readily and 'willingly' paying Auden/Actavis's higher prices. This is demonstrated by the facts that, following a prolonged period of competition:
- a. The prices charged by Waymade, Auden/Actavis's only full label competitor (on 20mg tablets), fell to levels below the average of competing skinny label tablets.
 - b. Auden/Actavis's higher prices have belatedly proven not to be durable. If (some) customers valued full label tablets more highly than skinny label tablets, Auden/Actavis's premium would be expected to endure.

²² Document 02194, Intas letter to the DHSC dated 7 December 2017.

²³ Document 205217, Auden/Actavis's RSSO, paragraph 4.74; Document 205212, Intas/Accord-UK's RSSO, paragraphs 19, 156 and 158-166.

C. The penalties the CMA is imposing

- 1.73. The CMA has decided to impose the following penalties on the undertakings subject to this Decision:
- a. Auden/Actavis is fined **£155.2 million** for the Unfair Pricing Abuses.
 - b. Auden/Actavis is fined **£66.0 million** for the Agreements.
 - c. Waymade is fined **£2.5 million** for the Agreements.
 - d. AMCo is fined **£42.8 million** for the 10mg Agreement.
- 1.74. The legal entities liable for these fines and the amounts they must pay are set out in sections 9 and 10.
- 1.75. In setting the fines at these levels the CMA has in particular taken into account that:
- a. Auden/Actavis made a profit of at least **£145 million** from the Unfair Pricing Abuses;²⁴
 - b. Waymade made a profit of around **£2 million** from the Agreements; and
 - c. AMCo made a profit of around **£22 million** from the 10mg Agreement.
- 1.76. In order effectively to penalise and deter, the CMA considers that the fines imposed for the Infringements should exceed these profits by a material amount. It is not enough simply to eliminate the parties' gains from the Infringements. The CMA has also borne in mind that these were serious infringements of competition law and that these profits were ultimately made at the expense of the NHS, which should have benefited from competition.

²⁴ This figure gives Auden/Actavis's profit compared to the £20 threshold at which the CMA has not prioritised investigating Auden/Actavis's prices. If Auden/Actavis's profits are assessed against the costs of hydrocortisone tablets plus a reasonable rate of return (Cost Plus), the true figure is closer to **£270 million**.

2. THE INVESTIGATIONS

- 2.1. This Decision is the culmination of over five years' investigation. It is important to consider this in context. It reflects in particular: the manner and time in which relevant information came to light; changes to relevant law resulting from judgments of the Competition Appeal Tribunal ('**CAT**') and Court of Appeal; and procedural challenges (including in the High Court) from the parties.
- 2.2. This section summarises the key events in the CMA's investigations of the Infringements (the '**Investigations**'). The detailed procedural steps are set out in Annex A to this Decision.
- 2.3. In March 2016 the CMA opened an investigation into a suspected abuse of dominance by Auden/Actavis by charging excessive and unfair prices for hydrocortisone tablets (Case 50277-1).
- 2.4. In April 2016 the CMA opened an investigation into a suspected anti-competitive agreement involving AMCo and Auden/Actavis relating to 10mg hydrocortisone tablets (Case 50277-2).
- 2.5. These investigations were opened *ex officio*: there was no complainant, leniency applicant or informant.
- 2.6. In October 2016 the CMA received an anonymous submission, accompanied by contemporaneous documentary evidence. The submission stated:

'HYDROCORTISONE TABLETS

[Auden Senior Employee 1], and [Auden Senior Employee 5], [REDACTED] for Auden Mckenzie, had surpressed [sic] the entry on Waymade/Soveriegn's [sic] Generic Hydrocortisone tabs 20mg by paying them a monthly 'marketing' fee. This was to ensure that whilst [Waymade Senior Employee 1] and [Waymade Employee] of Waymade/Sovereign got their share of the profits, prices for Hydrocrtisone [sic] tablets remained high at the expense of the NHS and Tax Payer.

[Auden Senior Employee 1] and [Auden Senior Employee 5], [REDACTED] for Auden Mckenzie also had a similar arrangement with Waymade/Soveriegn [sic] AND then AMCO regarding the Hydrocortisone tabs 10mg. By supplying a limited amount of stock to

*AMCO, prices were kept very high at the expense of the NHS and Tax Payer.*²⁵

- 2.7. The CMA issued a Statement of Objections ('**SO**') in Case 50277-1 on 16 December 2016, provisionally finding that Auden/Actavis had abused its dominant position by imposing excessive and unfair prices for hydrocortisone tablets.²⁶
- 2.8. The CMA issued an SO in Case 50277-2 on 3 March 2017 (the '**March 2017 SO**').
- 2.9. In the March 2017 SO the CMA provisionally found that **the supply agreements** for 10mg hydrocortisone tablets entered into between Auden/Actavis and AMCo between January 2013 and June 2016 in themselves had an object restrictive of competition. In so doing the CMA adopted the framework used by the European Commission in its *Fentanyl* 'pay for delay' decision.²⁷ In that decision the Commission found that a supply agreement had an object restrictive of competition, having regard in particular to its findings that the agreement involved payments from the incumbent to a potential competitor; and that due to the agreement, the potential entrant limited, for the duration of the agreement, its independent efforts to enter the market with its own product.²⁸
- 2.10. The CMA also provisionally found that in making payments to its potential competitor AMCo in order to prevent or delay its entry to the market, Auden/Actavis engaged in an exclusionary abuse of its dominant position.
- 2.11. Notwithstanding its provisional findings in the March 2017 SO, the CMA continued to have reasonable grounds to suspect that Auden/Actavis and AMCo had been party to a traditional market exclusion agreement, in which Auden/Actavis had paid AMCo and in exchange AMCo had agreed not to enter the market with its own 10mg hydrocortisone tablets.
- 2.12. After issuing the March 2017 SO, the CMA received further information of relevance to the Investigations.²⁹ As a result of this information, the CMA had reasonable grounds to suspect that certain evidence had not been submitted by AMCo in response to formal information requests and that if the CMA were to request such evidence again, AMCo would conceal or destroy

²⁵ Document 201140, anonymous submission received in October 2016.

²⁶ This SO was subsequently reissued on 5 April 2017 and 9 August 2017 to include additional addressees.

²⁷ Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.

²⁸ Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 219.

²⁹ This information is protected by public interest immunity, as confirmed by Marcus Smith J in his 12 December 2018 judgment in *The Competition and Markets Authority v Concordia International Rx (UK) Ltd*, [2018] EWHC 3448 (Ch).

it. The CMA also had reasonable grounds to suspect that further evidence may be held by certain individuals and that, if the CMA were to request such evidence from them, they would conceal or destroy it. On 6 October 2017 the CMA obtained warrants from the High Court under sections 28 and 28A of the Act to inspect the premises of:

- a. AMCo (then named Concordia);
- b. [Auden Senior Employee 1]; and
- c. [AMCo Senior Employee 1].

- 2.13. These warrants were executed between 10 and 13 October 2017. In October 2017 the CMA also opened an investigation into suspected anti-competitive agreements between Waymade and Auden/Actavis relating to 10mg and 20mg hydrocortisone tablets (Case 50277-3).
- 2.14. On 10 October 2017 Concordia applied to have the warrant in respect of its premises set aside. Pending determination of that challenge, the CMA refrained from reviewing the evidence obtained under that warrant. In the meantime the CMA continued to progress its investigation in Case 50277-3.
- 2.15. On 7 June 2018, the CAT issued its judgment in the *Phenytoin* appeal.³⁰ The CAT disagreed with the CMA's application of the legal test for excessive and unfair pricing in that case and remitted the case to the CMA. The CMA appealed to the Court of Appeal.
- 2.16. Following a series of hearings in the High Court and the Court of Appeal, the CMA's warrant relating to AMCo's premises was ultimately upheld by the High Court on 16 January 2019. In his judgment, Marcus Smith J held that *'there were certainly reasonable grounds for suspecting that'* AMCo's methodology for replying to previous formal information requests issued by the CMA was *'framed with a view to ensuring that certain types of document and certain custodians were excluded from the search'* and that there were reasonable grounds for the CMA to suspect that those personnel at AMCo who managed the responses to the CMA's requests ought to have known that those responses were incomplete. Marcus Smith J therefore upheld the warrant, finding that there were reasonable grounds to suspect that if the CMA were to require the missing documents under its formal powers, they

³⁰ *Flynn Pharma Limited and Flynn Pharma (Holdings Limited) and Pfizer Inc and Pfizer Limited v Competition and Markets Authority* [2018] CAT 11.

would not be produced but would be concealed, removed, tampered with or destroyed.³¹

- 2.17. The CMA issued an SO in Case 50277-3 on 28 February 2019 (the '**February 2019 SO**'). In that SO the CMA provisionally found that Auden/Actavis and Waymade had been party to anticompetitive agreements relating to 20mg and 10mg hydrocortisone tablets. The CMA provisionally found that Auden/Actavis and Waymade were party to traditional market exclusion agreements, in which Auden/Actavis had paid Waymade and in exchange Waymade had agreed not to enter the market with its own hydrocortisone tablets. In the alternative, the CMA provisionally found that if no such common understanding could be established, the supply agreements between Auden/Actavis and Waymade would in themselves amount to restrictions of competition by object, applying the *Fentanyl* framework. The CMA also provisionally found that in making payments to its potential competitor Waymade to prevent or delay its entry Auden/Actavis engaged in an exclusionary abuse of its dominant position.
- 2.18. Following the conclusion of AMCo's unsuccessful challenge to the warrant relating to its premises, the filtering of the evidence obtained under that warrant and correspondence with AMCo's legal advisers, the CMA began reviewing the evidence obtained under the warrant in April 2019.
- 2.19. Between 3 April and 17 May 2019 the CMA reviewed a significant volume of emails and hard copy documents obtained under the warrant in the presence of AMCo's legal advisers. The CMA's review produced new evidence relevant to the Investigations.
- 2.20. On 1 May 2019 Waymade wrote to the CMA expressing concerns about the membership of the Case Decision Group. The CMA responded to these concerns on 8 May and 20 June 2019 and took the precautionary step of replacing a member of the Case Decision Group [REDACTED].
- 2.21. In June 2019 the CMA reviewed the mobile devices it had obtained under the warrant relating to AMCo's premises. However, the CMA was unable to obtain mobile device material from the periods of AMCo's involvement in the Infringements as older devices had not been retained and the devices of [Auden Senior Employee 1] and [AMCo Senior Employee 1] could not be unencrypted and/or were password protected, with the individuals unable to recall the passwords. It is clear from other evidence the CMA obtained that

³¹ *The Competition And Markets Authority v Concordia International Rx (UK) Ltd*, [2019] WLR(D) 20, [2019] Bus LR 1000, [2019] EWHC 47 (Ch) (16 January 2019) (see www.bailii.org/ew/cases/EWHC/Ch/2019/47.html) (see paragraphs 33 and 34).

representatives of Auden and AMCo communicated with each other via text messages during those periods.³² Those text messages, while an important target of the 2017 warrants, were therefore ultimately not unearthed.

- 2.22. On 29 May 2019 Waymade wrote to the CMA expressing concerns that the CMA had failed to provide Waymade with all documents relevant to the allegations against it (in particular since it considered that, owing to the procedural history, such documents may have been placed on the case file for Case 50277-2 but not transferred to the file for Case 50277-3) and that the case was creating a disproportionate burden for '*a relatively small company*' such as Waymade plc.
- 2.23. On 20 June 2019 the CMA informed all parties that it would progress all three cases on a joint basis. The further evidence that the CMA had obtained since issuing its SOs confirmed that the Infringements were closely connected: for example, that the collusion between Auden and its potential competitors began with the 20mg Agreement and then extended to the 10mg Agreement; and that the 10mg Agreement itself began with Waymade and passed to AMCo with the sale of the Amdipharm group. Given the close relationship between the facts and allegations in the existing SOs, the CMA began to prepare a supplementary statement of objections ('SSO') with the aim of setting out in a single document a comprehensive statement of the CMA's provisional findings in relation to hydrocortisone tablets and providing all case parties with an opportunity to respond to that single document both in written and in oral representations.
- 2.24. AMCo claimed that the CMA had no power to combine the three cases or issue an SSO in a series of six letters between 1 July and 7 November 2019. The CMA responded to each letter explaining its reasons. AMCo did not identify any respect in which its rights of defence might be prejudiced by the issue of an SSO and did not refer the matter to the Procedural Officer.
- 2.25. AMCo claimed legal professional privilege over the email and hard copy materials relating to [AMCo Senior Employee 8] obtained under the warrant. This meant that a separate review was conducted by Independent Counsel to determine issues of legal professional privilege. The CMA's review of materials determined not to be privileged began in July 2019 and finished on 10 February 2020.
- 2.26. On 12 February 2020 the CMA issued the SSO to the parties, bringing together all three cases and developing the CMA's allegations of excessive

³² For example, Document 00149, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 28 May 2014: '*Many thanks for your text over the weekend*'.

and unfair pricing, anti-competitive agreements and exclusionary abuses. In the cover letter accompanying the SSO, the CMA responded to Waymade's concerns expressed in its letter of 29 May 2019, noting that the combination and disclosure of the three case files with the SSO neutralised any concern about insufficient disclosure, and that the case against Waymade had not significantly changed in the SSO when compared to the SO in Case 50277-3, such that responding to the SSO would not impose a disproportionate additional burden on Waymade.

- 2.27. The SSO reflected material changes in the nature of the CMA's provisional findings in the SOs. These included, for example:
- a. Explaining how the 20mg Agreement formed a template for the 10mg Agreement.
 - b. Extending AMCo's liability for the 10mg Agreement to begin with the purchase of the Amdipharm group.
 - c. Adjusting the legal characterisation of the Agreements. The CMA no longer provisionally found that **the supply agreements** between Auden/Actavis and its potential competitors Waymade and AMCo in themselves amounted to restrictions of competition by object, applying the *Fentanyl* framework. The CMA provisionally found that the evidence set out in the SSO amounted to a clear, traditional market exclusion agreement between potential competitors: Auden/Actavis agreed to make substantial payments to Waymade and AMCo and in exchange, Waymade and AMCo agreed not to enter the market with their own hydrocortisone tablets. In doing so, the CMA characterised the supply agreements between the parties as a sham, meaning that their true purpose was for Auden/Actavis to pay Waymade and AMCo, rather than simply to give them product to sell as in a genuine bona fide distribution deal.³³
 - d. Altering the relevant periods of the Unfair Pricing Abuses as a result of the CMA's prioritisation decisions. The CMA made a decision not to prioritise investigating whether Auden/Actavis's prices were excessive and unfair below £20 per pack or whether Actavis continued to hold a dominant position in relation to 20mg tablets after January 2017.
 - e. Updating the CMA's analysis of the Unfair Pricing Abuses in light of the CAT's *Phenytoin* judgment, the CMA's SSO in case 50395 (excessive

³³ Compare *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 179 to 180, and *GSK v CMA* [2021] CAT 9, paragraph 47.

and unfair pricing of liothyronine tablets by AMCo) and factual developments since the December 2016 SO was issued.

- f. Updating the case on the liability of Cinven to reflect additional evidence gathered and developments in case 50395 (in which Cinven was also provisionally held liable as former parent of AMCo).
- 2.28. On 10 March 2020 the Court of Appeal handed down its judgment on the CMA's and Flynn's appeal in the *Phenytoin* case.³⁴ The Court of Appeal clarified the legal test for excessive and unfair pricing and agreed with the CMA that it was not necessary to establish a hypothetical benchmark price or range that would have existed in conditions of normal and sufficiently effective competition.
- 2.29. Following the Court of Appeal's judgment, the CMA issued a revised version of section 5 (*The Unfair Pricing Abuses*) of the SSO on 16 June 2020.³⁵
- 2.30. On 6 July 2020 Waymade wrote to the CMA stating that it had decided not to exercise its right to an oral hearing on the SSO, because of its '*confidence in the strength of its written submissions, which address the CMA's allegations in full*';³⁶ its limited resources; and its loss of confidence in the CMA's process. Waymade cited in this regard what it portrayed as the CMA's failure to disclose contemporaneous manuscript notes of meetings relating to the 20mg Agreement,³⁷ which it stated were '*ultimately disclosed only at Waymade's insistence*' after the SO in Case 50277-3 was issued. Waymade suggested that the inclusion of these manuscript notes in the SSO, without a resulting material change to the CMA's provisional findings, indicated that the CMA was determined to reach an infringement finding irrespective of the strength of Waymade's submissions. Waymade also suggested that the presence of the CMA's Chief Executive and Senior Legal Director, Cartels and Consumer, on the Case Decision Group gave rise to confirmation bias.

³⁴ *Flynn Pharma v CMA* [2020] EWCA Civ 339.

³⁵ Following Intas/Accord-UK's hearing on the SSO on 21 September 2020 and a letter from Intas/Accord-UK dated 30 October 2020 (Document 205689), the CMA clarified its use of the phrases '*skinny label market*' and '*effectively competitive market*' at places in the SSO in a letter dated 20 November 2020 (Document 206685). As the CMA explained, when read in context these phrases did not imply that the CMA had found a separate relevant product market for skinny label hydrocortisone tablets, or that the market as a whole (including Auden/Actavis's prices) was effectively competitive in 2019 (the latest data available at the time of the SSO). The CMA provided Intas/Accord-UK with two further opportunities to make representations in light of this clarification, but Intas/Accord-UK declined to do so. The CMA clarified these points to the other parties to the excessive and unfair pricing case (Auden/Actavis and Allergan) in its letter of facts dated 7 May 2021, providing them (and Intas/Accord-UK a further time) with an opportunity to make representations on the point.

³⁶ Notwithstanding this statement Waymade made no attempt in its written representations to explain: why Auden gave it an 87% and 97% discount for 20mg and 10mg hydrocortisone tablets respectively, the highly unusual Buyback arrangement in the 20mg Agreement, or the 'RAMA clause' in the 20mg Agreement.

³⁷ Documents 00752 and 00751, [Auden Senior Employee 2]'s handwritten notes of telephone call on 21 June 2011 and meeting on 4 July 2011.

- 2.31. The CMA responded to Waymade's letter on 25 September 2020, noting that the CMA had already taken steps on a precautionary basis to address points Waymade previously raised about the composition of the Case Decision Group; that the burden on Waymade from the CMA's investigations was not disproportionate compared either to the burden placed on other parties to the investigations or to the gravity of the allegations against it; that Waymade plc remained a substantial undertaking with a turnover of £21 million despite its owners' decision to transfer many of its activities and resources out of Waymade plc intra-group; and that the manuscript notes Waymade referred to were not deliberately withheld from Waymade but overlooked as a result of human error when the February 2019 SO was prepared and immediately disclosed to Waymade when this error was pointed out.³⁸
- 2.32. The CMA subsequently made a decision not to prioritise investigating the alleged exclusionary abuses by Auden/Actavis and informed the parties of this on 6 May 2021.

³⁸ As explained in section 6.D.II.c.i below, that the content of the contemporaneous manuscript notes did not change the CMA's findings reflects the fact that they contain little positive evidence – not any determination to fit evidence to a predetermined narrative.

3. FACTS

3.1. This section sets out the facts relevant to the Infringements and is structured in the following way.

- a. First, it sets out and describes the key companies and individuals associated with each of the undertakings for the purposes of this Decision (section 3.A).
- b. Second, it describes the drug lifecycle, how drug prices are regulated, 'niche' generics and hydrocortisone tablets' status as niche generic drugs (section 3.B);
- c. Third, it describes adrenal insufficiency and the drugs that treat it, including hydrocortisone tablets (section 3.C).
- d. Fourth, it explains the notion of bioequivalence, and the role of marketing authorisations and orphan medicinal products (section 3.D).
- e. Fifth, it describes supply and demand of hydrocortisone tablets (section 3.E), including in particular the supply chain (section 3.E.II), how hydrocortisone tablets are prescribed and dispensed (section 3.E.III), and demand for hydrocortisone tablets (section 3.E.IV).
- f. Sixth, it describes facts relevant to the Infringements (section 3.F).

A. Key companies and individuals

3.2. This section sets out a description of the key companies and individuals associated with Auden/Actavis, Waymade and AMCo.

I. Key companies

a. Auden/Actavis

i. AM Pharma

3.3. AM Pharma focused on the development, licensing and marketing of niche generic medicines and proprietary brands in the UK and across Europe. It was engaged in the sale of hydrocortisone tablets in the UK from April 2008 until 31 August 2015.

3.4. Until 29 May 2015 AM Pharma was wholly owned and managed by [REDACTED].³⁹

³⁹ Directly until 31 October 2012; through a holding company, Auden Mckenzie Holdings Limited, from 1 November 2012 until 29 May 2015.

3.5. [REDACTED].⁴⁰ [REDACTED].⁴¹

ii. Allergan (formerly Actavis)

3.6. On 29 May 2015, the global pharmaceutical company Actavis plc indirectly acquired the entire issued share capital of AM Pharma.⁴²

3.7. In June 2015 Actavis plc changed its name to Allergan plc.⁴³

3.8. [REDACTED].⁴⁴ [REDACTED].⁴⁵ [REDACTED].⁴⁶

3.9. On 8 May 2020 Allergan was acquired by AbbVie.⁴⁷

iii. Accord-UK (formerly Actavis UK Limited)

3.10. After Allergan acquired AM Pharma, AM Pharma's trading activities, including the business of selling hydrocortisone tablets, were transferred intra-group to an existing wholly-owned subsidiary of Allergan, Actavis UK Limited.⁴⁸

3.11. From 1 September 2015 onwards, Actavis UK Limited took over the business of supplying hydrocortisone tablets in the UK.⁴⁹

3.12. Actavis UK Limited was renamed Accord-UK Limited on 5 March 2018.⁵⁰

⁴⁰ [REDACTED].

⁴¹ [REDACTED].

⁴² Document 00686, response to question 11, AM Pharma's response to the CMA's section 26 notice dated 24 August 2016. See also the Auden Mckenzie Holdings Limited accounts for the year ended 31 March 2015, as filed at Companies House on 10 January 2016.

⁴³ www.allergan.com/news/news/thomson-reuters/actavis-plc-is-now-allergan-plc.

⁴⁴ [REDACTED].

⁴⁵ [REDACTED].

⁴⁶ [REDACTED].

⁴⁷ <https://news.abbvie.com/news/press-releases/abbvie-completes-transformative-acquisition-allergan.htm>

⁴⁸ Document 00686, response to question 12, AM Pharma's response to the CMA's section 26 notice of 24 August 2016.

⁴⁹ Document 00686, response to question 12, AM Pharma's response to the CMA's section 26 notice dated 24 August 2016. See also Document 00639, response to questions 1 and 8, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016. See, for example, AM Pharma's accounts for the year ending 31 December 2015, page 2: 'With effect from 1 September 2015, the company transferred its activities to Actavis UK Limited [now Accord-UK], a fellow group company'. Accord-UK took over the purchasing of hydrocortisone tablets from Tiofarma: Document 00412, minutes of a meeting with Tiofarma dated 11 August 2015, refer to purchase orders for hydrocortisone tablets being raised by Accord-UK from 13 August 2015. Accord-UK purchased closing stocks of hydrocortisone tablets from AM Pharma around the time sales transitioned across to Accord-UK (Document 00639, response to question 8, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016).

⁵⁰ Companies House filings.

iv. Teva

- 3.13. In July 2015, Teva, a pharmaceutical company based in Israel, announced its intention to acquire Allergan's generics division (then still known as Actavis Generics).⁵¹
- 3.14. The sale to Teva completed on 2 August 2016 and Teva became the indirect owner of 100% of the shares of Accord-UK and AM Pharma.⁵² However, in order to secure merger control clearance for the purchase of Actavis Generics from the European Commission, Teva was required to divest the UK generics business.⁵³
- 3.15. As a result, from 10 March 2016 until 1 August 2016 (under Allergan's ownership) and from 2 August 2016 onwards (under Teva's ownership) Accord-UK was held separate under commitments given to the European Commission, pending divestment to a third-party purchaser.⁵⁴
- 3.16. In January 2018, Teva and Allergan entered into a settlement agreement and mutual releases for which Allergan made a one-time payment of \$703 million to Teva to settle the working capital adjustments under a Master Purchase Agreement dated 26 July 2015. In the context of this settlement agreement Teva indemnified Allergan against losses arising from the CMA's investigation into hydrocortisone tablets.⁵⁵ [X].
- 3.17. As of the date of this Decision, Teva remains the 100% owner of AM Pharma. AM Pharma no longer trades and has no market-facing activities that generate income and no employees.⁵⁶

v. Intas/Accord

- 3.18. Intas is a privately-owned pharmaceutical company based in Ahmedabad, India.

⁵¹ www.tevapharm.com/news/teva-to-acquire-allergan-generics-for-40-5-billion-creating-a-transformative-generics-and-specialty-company-well-positioned-to-win-in-global-healthcare-07-15.aspx.

⁵² Document 00686, response to questions 11 and 13, AM Pharma's response to the CMA's section 26 notice dated 24 August 2016.

⁵³ <http://pharmaphorum.com/news/tevas-allergan-acquisition-goes-ahead/>.

⁵⁴ Document 00686, response to question 14, AM Pharma's response to the CMA's section 26 notice dated 24 August 2016. Separately, Teva has run its own hydrocortisone tablets business. Teva sourced hydrocortisone tablets from Resolution Chemicals from 24 May 2016 until 14 February 2017 and launched hydrocortisone tablets under its own licence on 7 February 2017. Document 01646, Teva's response to the CMA's section 26 notice dated 19 May 2016.

⁵⁵ See for example Teva's quarterly report to the US Securities and Exchange Committee for the quarterly period ending 30 September 2019, Notes 3 and 16 (see in particular page 35).

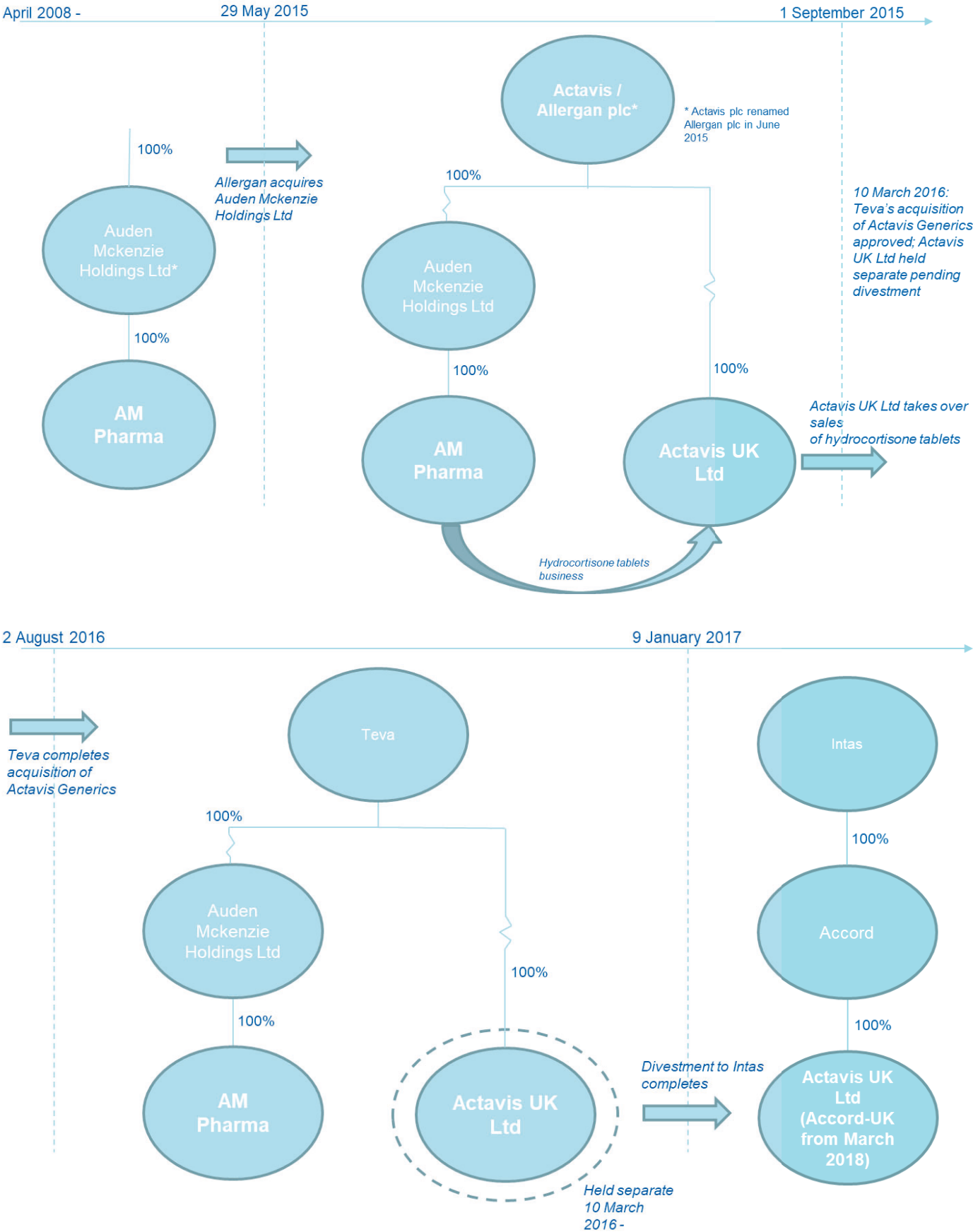
⁵⁶ AM Pharma's accounts for the year ending 31 December 2015, page 2; and its latest available accounts (for the year ended 31 December 2019).

- 3.19. On 9 January 2017 Intas (through its 100% subsidiary Accord) became the indirect owner of 100% of the shares of Actavis UK Limited, which it later renamed Accord-UK.⁵⁷
- 3.20. Since 9 January 2017 Accord-UK has continued the business of selling hydrocortisone tablets in the UK under Intas's indirect ownership.⁵⁸
- 3.21. The corporate history of Auden/Actavis is summarised in the following diagram.

⁵⁷ The shares in AM Pharma remained with Teva.

⁵⁸ Document 01568, responses to questions 1 and 2, Intas' response to the CMA's section 26 notice dated 3 May 2017.

Figure 3.1: corporate history of Auden/Actavis



b. Waymade

3.22. Waymade was founded in 1984 by [X], as a pharmaceutical wholesaler and distributor.

i. Waymade plc

3.23. Waymade plc was named Waymade Healthcare plc until 12 October 2012.⁵⁹ It was originally a pharmaceutical importer and wholesaler, though it also sold generic drugs through its 'Sovereign Generics' trading name.⁶⁰

3.24. On 25 November 2013, another generic pharmaceutical company called Atnahs Pharma UK Limited ('**Atnahs**') was incorporated under the control of [X].

3.25. On 31 December 2014, Waymade plc sold a significant proportion of its business – '*circa 90% of its operations which included parallel exports, third party generics and specials*'⁶¹ – to a third party for proceeds of over £15 million.⁶² Since that date Waymade plc has focused on its Sovereign Generics business.⁶³

3.26. In December 2014 Waymade plc also divested a property subsidiary, Sovereign House Properties Limited (formerly Waymade UK plc) for proceeds of £1.4 million,⁶⁴ at which point control was transferred from Waymade plc to [X].

3.27. Waymade plc and Sovereign House Properties Limited remain part of a larger group controlled by [X] and run by the [X]. Waymade plc describes itself as '*the pharmaceutical division of Waymade Capital, the Family Office of [X]. Waymade Capital encompasses the four pillars of Pharma, Property, Private Equity and Philanthropy.*'⁶⁵

3.28. On 8 August 2019 Atnahs was sold to the private equity firm Triton, prior to which it was also part of Waymade Capital.⁶⁶

⁵⁹ Companies House filings.

⁶⁰ Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016, paragraph 16.

⁶¹ Waymade plc financial statements for the financial year ending 31 March 2015.

⁶² £15 million purchase price plus deferred consideration of up to £2.3 million. Laxmico Limited Annual Accounts for the financial year ending 31 March 2015.

⁶³ Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016, paragraph 18.

⁶⁴ Waymade plc Annual Report and Financial Statements for the financial year ending 31 December 2018.

⁶⁵ <https://www.waymade.co.uk/>

⁶⁶ <https://www.atnahs.com/triton-completes-acquisition-of-a-majority-stake-in-atnahs/>

ii. **Amdipharm UK Limited and Amdipharm Limited**

3.29. Until 30 October 2012, Waymade included a generic drugs business called the **Amdipharm group**. The Amdipharm group included Amdipharm UK Limited and Amdipharm Limited. On 31 October 2012, Waymade sold the Amdipharm group to the private equity house **Cinven**.

c. **AMCo**

i. **The AMCo group**

3.30. On 31 August 2012, Cinven completed its acquisition of the Mercury Pharma group, a pharmaceutical group focused on niche generic medicines [✂], from the private equity house HgCapital. The Mercury Pharma group included Mercury Pharma Management Services Limited.

3.31. On 31 October 2012, Cinven completed its acquisition of the Amdipharm group from [✂].

3.32. Cinven combined the Amdipharm group with the Mercury Pharma group to create **Amdipharm Mercury Companies**, or the **AMCo** group, [✂]. Mercury Pharma Management Services Limited was later renamed Amdipharm Mercury Company Limited.

ii. **Concordia/Advanz**

3.33. On 21 October 2015, Cinven sold its stake in the AMCo group to the Canadian pharmaceutical company **Concordia Healthcare** Corp. Concordia Healthcare Corp. subsequently changed its name to Concordia International Corp.; and in 2018, to **Advanz Pharma Corp Ltd.**⁶⁷ Amdipharm Mercury Company Limited was renamed Concordia International Rx (UK) Limited and later Advanz Pharma Services (UK) Limited.

3.34. Since 21 October 2015, the Amdipharm Companies have been wholly owned by Advanz. Advanz is a global pharmaceutical company focused on niche established medicines.⁶⁸

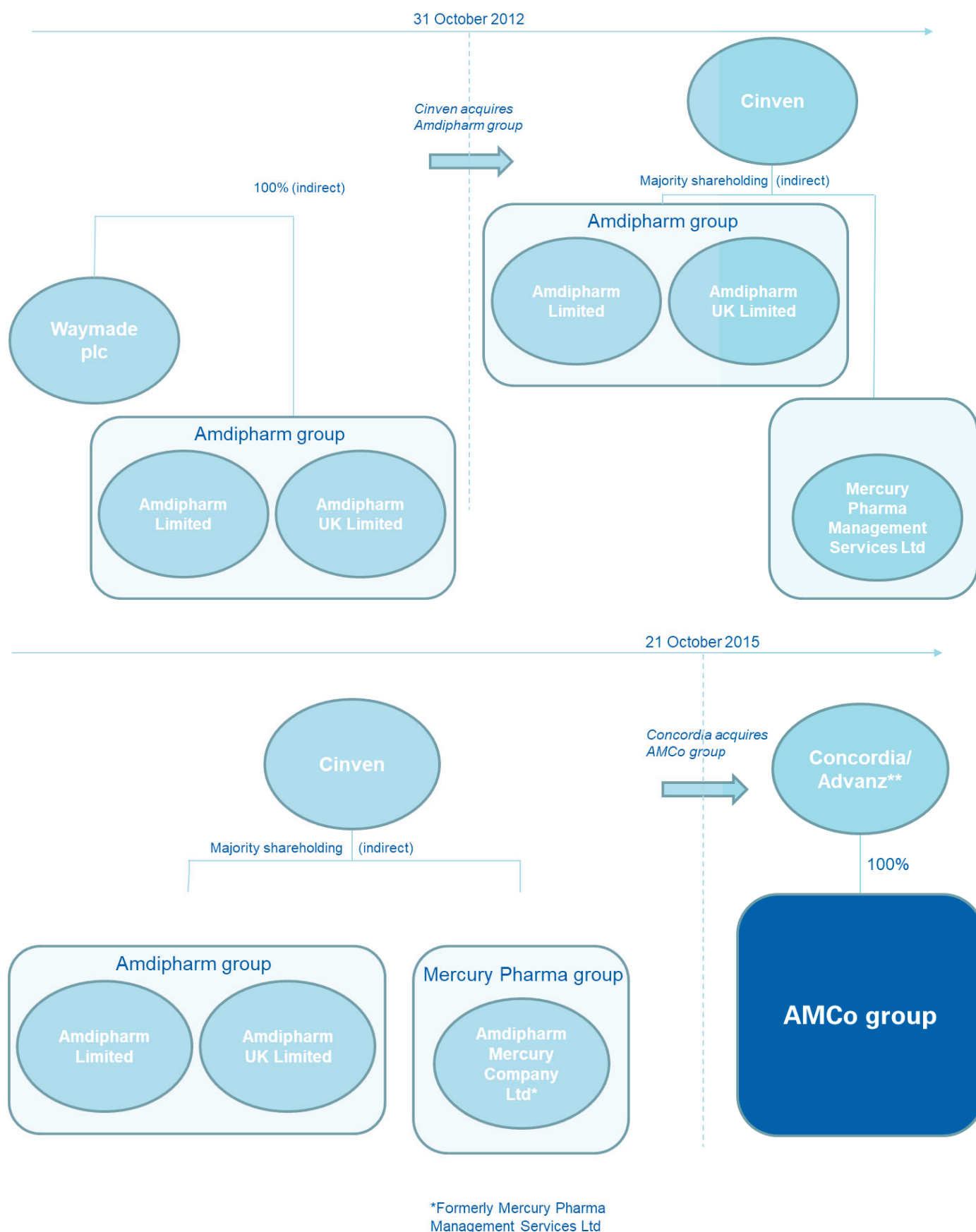
⁶⁷ Document PAD068, Concordia: '*Completes AMCo acquisition*'. Concordia Healthcare Corp. announced its name change to Concordia International Corp. on 28 June 2016: Document PAD069, Prnewswire: '*Concordia Healthcare Corp. Announces Name Change to Concordia International Corp. and Comments on Brexit's Impact on the Company's Business*'. Concordia International Corp. announced its name change to Advanz Pharma Corp. on 29 November 2018: www.prnewswire.com/news-releases/concordia-international-corp-announces-name-change-to-advanz-pharma-corp-300757781.html.

⁶⁸ www.advanzpharma.com/.

- 3.35. On 1 June 2021, Advanz was acquired by the private equity firm Nordic Capital.⁶⁹
- 3.36. The corporate history of Waymade and AMCo is summarised in figure 3.2.

⁶⁹ www.advanzpharma.com/news/2021/nordic-capital-acquires-specialty-pharmaceutical-company-advanz-pharma-in-deal-worth-846-million

Figure 3.2: corporate history of Waymade and AMCo



II. Key individuals

- 3.37. As explained above, each of the undertakings involved in the Infringements has a complex corporate history involving successive parent entities, restructurings and name changes. These are explained in most detail in the section of this Decision attributing liability for the Infringements to specific legal entities (section 9).
- 3.38. However, this Decision is fundamentally about the conduct of a few key individuals, who retained relationships with one another despite the corporate changes of the undertakings they worked for.
- 3.39. For example:
- a. Auden was from its creation in 1999 until its sale to Allergan in May 2015 [REDACTED].⁷⁰ Auden's commercial decisions relating to hydrocortisone tablets – in particular, prices charged – ultimately fell to [Auden Senior Employee 1] for seven of the ten years covered by this Decision. After AM Pharma was sold to Allergan and its business transferred to Actavis UK Limited, Actavis UK Limited (now Accord-UK) continued the strategy set by [Auden Senior Employee 1] of price increases and anticompetitive agreements.
 - b. Since its creation in 1984, Waymade has been [REDACTED].⁷¹ Until 31 October 2012, the Amdipharm group (which included Amdipharm UK and Amdipharm Limited) was also [REDACTED]. [REDACTED].
 - c. The 20mg Agreement was negotiated in June and July 2011 by [Amdipharm Senior Employee] (among others) for Waymade, under [Waymade Senior Employee 1]'s supervision, and by [Auden Senior Employee 2] for Auden, under [Auden Senior Employee 1]'s supervision.
 - d. The 10mg Agreement was negotiated in October 2012, again by [Amdipharm Senior Employee] for Waymade, under [Waymade Senior Employee 1]'s supervision, and by [Auden Senior Employee 1] for Auden.
 - e. On 31 October 2012, the Amdipharm group was sold to Cinven. [Amdipharm Senior Employee], as well as other key staff, went with it. Cinven, led by its '[REDACTED]' [Cinven Senior Employee 1] and [Cinven Senior Employee 2], proceeded to combine the Amdipharm group with the

⁷⁰ [REDACTED].

⁷¹ [REDACTED].

Mercury Pharma group (which included Advanz Pharma Services (UK) Limited) to create the AMCo group.

- f. [X] of the Mercury Pharma group prior to Cinven's ownership was [AMCo Senior Employee 1]. [AMCo Senior Employee 1] became [X] of the combined AMCo group under Cinven's ownership. [X] held a minority stake in the AMCo group and sat on the board of its holding company until the end of July 2014.
 - g. From January 2013 onwards, the volumes given by Auden to AMCo under the 10mg Agreement tripled. This increase was negotiated by [Amdipharm Senior Employee] for AMCo, under the supervision of [AMCo Senior Employee 1], and by [Auden Senior Employee 1] for Auden. The negotiation was set up by [Waymade Senior Employee 1]. Although the Amdipharm Companies had become part of a broader group under new ownership, the core individuals who had been dealing with one another on hydrocortisone tablets since mid-2011 were the same.
 - h. In early 2014, AMCo and Auden negotiated a formal, written supply contract for 10mg hydrocortisone tablets. The negotiations were led by [Amdipharm Senior Employee] for AMCo, under the supervision of [AMCo Senior Employee 1], and by [Auden Senior Employee 1] for Auden. They resulted only in a largely retrospective contract documenting the arrangement that had been in place since January 2013.
 - i. In mid-2014, AMCo and Auden negotiated a further, forward-looking two-year supply agreement for 10mg hydrocortisone tablets, under which the volumes given to AMCo doubled. The negotiations were led by [AMCo Senior Employee 1] for AMCo ([Amdipharm Senior Employee] having left AMCo's employment) and [Auden Senior Employee 1] for Auden.
- 3.40. Despite the complex corporate history of the parties, therefore, the conduct and agreements in this case were driven by a handful of individuals who dealt with one another on a consistent basis. This should be borne in mind when reading the legal analysis of the Infringements in this Decision, which necessarily refers to undertakings and legal entities.

B. The drug lifecycle and the place of hydrocortisone tablets in it

- 3.41. The drug lifecycle is a central feature of the pharmaceutical sector and important context for understanding the pricing of drugs and the nature of

competition between suppliers of drugs in the UK. In order to assess the legality of drug pricing under competition law, it is important to understand the broader context in which prices were charged and in which any price increase was imposed. It is also important to understand the context when assessing whether anti-competitive collusion has taken place. The position of hydrocortisone tablets within the drug lifecycle is therefore one of a number of important factual elements relevant to the CMA's assessment of the Infringements.

- 3.42. Most drugs follow a common, relatively long, lifecycle that has three distinct stages. In summary, and as explained further below, this comprises:⁷²
- a. The pre-launch period. This covers the development of new and innovative drugs to launch by an 'originator' (a company that carries out research into new pharmaceuticals) and is characterised by substantial investments in research and development ('R&D'), with no guarantee of commercial success.
 - b. The market exclusivity period. This covers the initial launch and sale of new and innovative drugs, which typically benefit from patent protection. The public interest in incentivising ongoing innovation in pharmaceuticals allows for the originator to obtain time-limited exclusivity in order to allow it to recoup the cost of R&D. A patent generally lasts for up to 20 years (with scope for limited extensions), though the patent is typically obtained prior to launch, so that the market exclusivity period is shorter. The drug is typically sold under a brand name during this period.
 - c. The **post-exclusivity period**. Products sold by originator companies are largely patent protected during the first two stages of the drug lifecycle. The third stage of the lifecycle commences when, following patent expiry and loss of exclusivity, other pharmaceutical companies can enter the market with generic versions of an originator drug.⁷³ This is when price competition is typically expected to take place. Competition at this stage is primarily focused on price because both the originator drug and generic versions of that drug are effectively identical and interchangeable with each other and with the originator drug,

⁷² See European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009 (available at [Pharmaceutical Sector Inquiry \(europa.eu\)](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/summary_en.pdf)), paragraphs 91, 128 to 168, and 169 to 247. See also Commission Communication, Executive Summary of the Pharmaceutical Sector Inquiry Report 2009 (available at [EN \(europa.eu\)](https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/summary_en.pdf)), pages 7 to 9, section 2.1. See also The Milbank Quarterly, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending, 2017* (available at www.ncbi.nlm.nih.gov/pmc/articles/PMC5594322/).

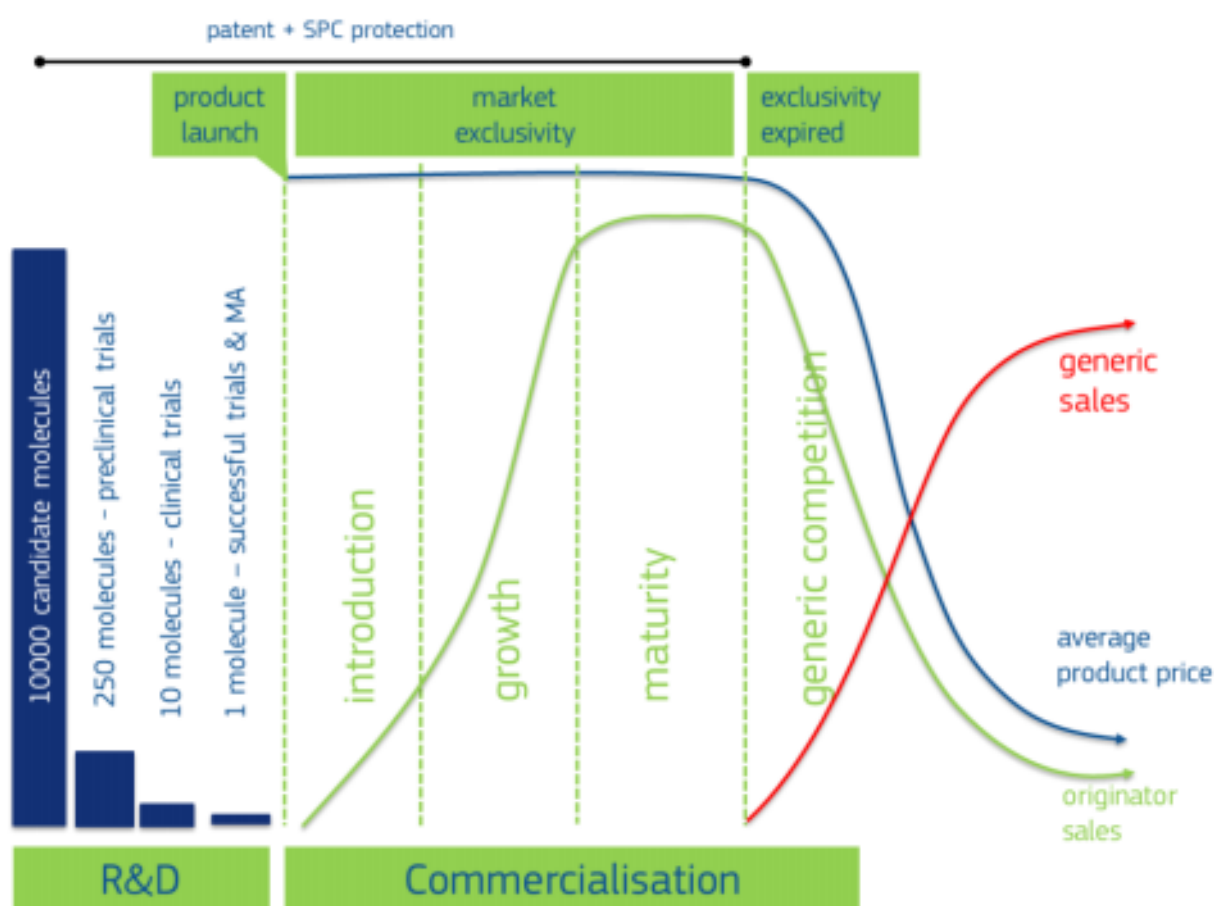
⁷³ Generic drugs are bioequivalent replicas of originator drugs. See section 3.D.V (*Bioequivalent medicines*) below.

making price the key differentiating factor. Generic drugs are typically sold at a substantially lower price than the originator drug was sold at during the second stage of the drug life cycle. This is possible for two key reasons:⁷⁴

- i. it is relatively cheap to bring a generic drug to the market as R&D costs are lower;⁷⁵ and
- ii. the market for the drug and brand value already exists which reduces marketing expenses.

3.43. These three stages are summarised in figure 3.3.

Figure 3.3: pharmaceutical product lifecycle



Source: European Commission, Competition enforcement in the pharmaceutical sector (2009-2017), 28 January 2019 (available at [kd0718081enn.pdf \(europa.eu\)](#)), page 16

⁷⁴ The Milbank Quarterly, *Comparing Generic Drug Markets in Europe and the United States: Prices, Volumes, and Spending*, 2017.

⁷⁵ Most of the required testing for a drug is not necessary for a generic version because it can rely on the originator test results and needs to only show bioequivalence to the originator drug.

I. The pre-launch period: stage 1

- 3.44. During the pre-launch period, innovation in pharmaceuticals typically requires significant investment in R&D with no guarantee of commercial success. Some of these drugs will be developed successfully and so will be granted a marketing authorisation ('MA') (following the necessary testing) and sold on the market. The development of other drugs will be unsuccessful, despite originator companies sometimes having incurred heavy expenditure on research, development and testing.
- 3.45. Competition between originators to develop a new drug and win a patent award may occur during the pre-launch period. There are several stages in this period.⁷⁶ At the final stage, medicines must pass the MA process in order to prove that they have a positive benefit-risk ratio as regards safety and efficacy, and are of good quality, before they can be placed on the market.⁷⁷
- 3.46. The costs to the originator company of bringing a new medicine to the market will vary between drugs. The European Commission's Pharmaceutical Sector Inquiry report in 2009 found that the cost of developing a new medicine from basic research to launch ranged between \$450 million and \$1 billion.⁷⁸ Irrespective of the exact cost, it is widely accepted that producing new pharmaceuticals requires a significant amount of investment with no guarantee of success.
- 3.47. To recoup the significant costs involved in bringing the product to market, an originator company will typically obtain a patent during or following extensive R&D. Patents effectively grant the originator freedom from direct competition on the same molecule for a certain period of time. The patent does not automatically equate to a monopoly because there may be some degree of competition between the molecule invented and other drugs. However, it is likely to result in limited price competition in the second stage of the drug life cycle.
- 3.48. A primary (or compound) patent is one that is used for new molecules which have a therapeutic use. The molecule will have never been disclosed previously, and so the primary patent will be the first ever patent to cover a

⁷⁶ These stages include identification of molecular targets that are associated with the disease, testing to find the molecules which have the greatest potential to be developed into a safe and effective medicine and assessment of the safety and efficacy of the drug.

⁷⁷ European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraphs 134 to 138. In the UK the MHRA is responsible for considering and approving marketing authorisations.

⁷⁸ European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 149.

particular active pharmaceutical ingredient ('API').⁷⁹ A primary patent in the EU and in the UK usually lasts for 20 years from the patent application.^{80,81} However, given that the patent is usually applied for at this initial stage, the 20-year period generally starts a long time before an MA for the drug is obtained and the drug enters the market. In addition, a manufacturing patent can be acquired that protects the manufacturing process used to create the drug.

- 3.49. The granting of patent protection is essential to ensure that originator companies are willing to invest the significant amounts of money and time required to develop new drugs. Without the patent, and the consequent ability to charge prices above competitive levels for a period of time, there would be little incentive to invest heavily in R&D. This is particularly true because, once a new drug has been developed, it is relatively easy (and less costly) for rival companies to copy it.⁸²

II. The market exclusivity period: stage 2

- 3.50. During the second stage of the drug lifecycle the originator begins to commercialise its drug. This is the first time that potential generic entrants will be able to begin to assess the success of a drug to determine whether to enter the market. However, in addition to any patent it may have obtained, the originator has:
- a. eight years of 'data exclusivity' during which a generic entrant cannot refer to the information the originator submitted to obtain the original MA to support its own MA application;⁸³ and
 - b. ten years of 'market exclusivity' from the date the original MA was granted, during which generic medicines typically cannot enter the market and compete with the originator medicine.⁸⁴

⁷⁹ European Commission, *Pharmaceutical Sector Inquiry - Annexes*, Annexes to Chapter B – Part III (available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part2.pdf), paragraphs 133 and 134.

⁸⁰ The time between filing an application for the first compound patent to the launch of the product varies significantly. It can take between two to ten years for a potential medicine to go through the three clinical trial phases, with an average of five years. European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 142.

⁸¹ Supplementary Protection Certificates provide additional patent-related protection by extending the period of patent protection by up to 5 years. These are used to compensate for the period of exclusivity lost by the originator due to the time required to obtain the MA.

⁸² European Commission, *Competition enforcement in the pharmaceutical sector (2009-2017)*, 28 January 2019, page 20.

⁸³ European Commission, *Competition enforcement in the pharmaceutical sector (2009-2017)*, 28 January 2019, page 16. See also European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, page 6.

⁸⁴ Competition between generic and originator companies may begin before patent expiry if the generic company finds a way of entering the market without infringing the patent protecting the originator product, or if the patent

- 3.51. Further, 'orphan' drugs (those developed for rare diseases: see section 3.D.VI below) benefit from a period of ten years of market exclusivity in which no similar medicine to treat the same disease (whether generic or originator) can be marketed.⁸⁵
- 3.52. The process of developing a generic drug can begin several years prior to patent expiry, starting with an ongoing 'horizon-scanning' exercise to monitor which products will come off patent up to ten years in the future.⁸⁶ This means that while the originator is in the commercialisation phase and benefitting from market exclusivity, potential generic entrants will be assessing the success of the drug and determining whether, and when, they want to enter the market.
- 3.53. Upon deciding to develop a generic version of a drug, generic entrants will begin to develop a bioequivalent medicine (see section 3.D.V below) to an economically successful originator product. While generic medicines are subject to the same requirements of quality, safety and efficacy, generic suppliers do not need to run pre-clinical tests and clinical trials as they can rely (once the data exclusivity period has expired) on the clinical data from the originator drug.⁸⁷

III. The post-exclusivity period: stage 3

- 3.54. Once the patent and period of market exclusivity have expired, generic suppliers can, in principle, produce and sell medicines containing the molecule in question. The original patent application covering the molecule must indicate how the invention can be reproduced. This allows others to freely reproduce the invention after patent expiry and acts as a return for guaranteeing the inventor an initial period of exclusive use.⁸⁸
- 3.55. The final stage of the drug lifecycle occurs when generic entry can begin. During this stage, competition initially takes place between the originator and the first generic entrant(s), and subsequently between these companies and any further generic entrants. This process and, in particular, the development of competition in the market, is expected to lead to drug prices which are significantly below the historic originator price. Competition

relied upon by the originator company is not valid. European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 April 2009, paragraph 464.

⁸⁵ European Commission, Competition enforcement in the pharmaceutical sector (2009-2017), 28 January 2019, page 16.

⁸⁶ Oxera, *The supply of generic medicines in the UK*, 26 June 2019 (available at [The operation of the generic medicines market in the UK \(oxera.com\)](https://www.oxera.com/en/insights/publications/2019/06/the-supply-of-generic-medicines-in-the-uk)), paragraph 3.8.

⁸⁷ European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 91.

⁸⁸ CMA, *Paroxetine decision*, case CE-9531/11, 12 February 2016, paragraph 3.68.

between generic suppliers is then expected to ensure that generic prices remain low.

- 3.56. Usually, generic entry into the market is phased.⁸⁹ Initially, there may be competition between generic entrants to be the first to enter.⁹⁰ It is expected that the first generic entrant will obtain the highest profits as it only needs to price slightly below the incumbent, assuming that the incumbent does not compete on price straight away. Other generic entrants might enter the market at a later stage, and it is typically with subsequent entry, and the initiation of price competition in a market with multiple generic entrants, that price competition becomes fiercer.
- 3.57. Generic companies have different cost structures from originators given that they typically do not have to research as heavily (although the cost of research will depend on the complexity of the product) and therefore incur lower R&D costs.⁹¹ Generic companies also do not have to incur the high levels of marketing expenditure incurred by the originator in order to build brand value or the market for the drug.
- 3.58. The primary focus of competition for suppliers of generic medicines is the price offered to wholesalers and pharmacies. This competition causes the average drug price to gradually fall towards the cost level. Research in the sector indicates that competition from generic drugs typically results in significant price falls. For example:
- a. the European Commission's pharmaceutical sector inquiry found that, in the EU, the price at which generic companies entered the market was on average 25% lower than the price of the originator medicines prior to the loss of exclusivity. Two years after entry, prices of generic medicines were on average 40% below the former originator price;⁹²
 - b. the UK trade association for generic manufacturers, the British Generics Manufacturers Association ('**BGMA**'), states that competition between generic manufacturers '*drives down prices, often leading to a reduction of 90% or more within a few weeks*';⁹³ and

⁸⁹ European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, Figure 17.

⁹⁰ Some generic companies will have begun to develop the drug prior to the expiration of patents with the aim of being able to launch the product as soon as the patent on the originator's product expires, as can be seen in Figure 3.3 above.

⁹¹ Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 3.5; and European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 103.

⁹² European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, paragraph 1560.

⁹³ British Generic Manufacturers Association, *About generics* (available at: www.britishgenerics.co.uk/about-generics.html).

- c. a study by the economics consultancy Oxera for the BGMA found that prices charged by generic suppliers of a sample of products within Scheme M (see section 3.D.IV.h below) in the six months after loss of exclusivity were on average 70% lower than the originator's branded price before the loss of exclusivity, falling to 80-90% lower four years after generic entry.⁹⁴
- 3.59. Following the entry of generic suppliers, the originator typically has three strategies it can employ to continue making profits:⁹⁵
- a. Option one: compete on price to protect its sales. The originator is likely to maintain larger sales volumes when generics enter if it lowers its price and competes with the generic manufacturers;
 - b. Option two: choose not to compete on price and instead maintain a higher price for its branded product. The originator would continue to receive a higher price for any patients who are dispensed its product while accepting that it is likely to lose other patients to generic competitors charging a lower price;⁹⁶ or
 - c. Option three: choose not to compete on price and instead maintain a higher price for its branded product and introduce a generic version of the drug at a lower price. This would allow the originator to receive a higher price for any patients who are dispensed the branded drug but also allow it to protect some of its sales via the lower priced generic version. Some originators decide to introduce a 'branded' generic⁹⁷ (a generic drug that still carries the manufacturer's name rather than simply the chemical name) if they wish to differentiate their generic product offering on the value and recognition of the company.
- 3.60. The strategy adopted by the originator may vary over time depending on the pace and strength of generic entry. However, each of these strategies involves retaining the brand as there may be some value in it due, for example, to patient or prescriber preference built up during the market exclusivity period.

⁹⁴ Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 1.13.

⁹⁵ Compare Eelco Kappe, *Pharmaceutical lifecycle extension strategies* (available at [Literature Combination Drugs \(psu.edu\)](#)), pages 17-25.

⁹⁶ Originators can also enter into brand equalisation deals where they provide a discounted, blended price on the condition that the customer purchases all its requirements, generic and branded, from the same supplier.

⁹⁷ Branded generics are known as off-patent branded medicines (ie branded drugs which are no longer covered by patent protection due to, for instance, the expiry of the patent). See, for example, [Branded generics : PSNC Main site](#).

- 3.61. However, if several suppliers enter the market, generic medicines usually become 'commoditised', meaning that suppliers of generic medicines are not able to use brand value or product quality to differentiate themselves. The products are homogenous.⁹⁸ This is the case even for essential medicines. For example, [AMCo Senior Employee 2] noted in a published paper that:

*'generic products with the same active ingredient have to be identical and as such can be considered "commodities" ... The demand for long-established pharmaceutical products where patients have been stabilised on a particular drug is mostly price inelastic. As a result, micro-economic theory explains that in countries where generic prices are set by market forces, for example in the UK, as the volume of supply increases, the price falls by a greater percentage.'*⁹⁹

IV. Prescribing, dispensing and funding

- 3.62. The clinical decision to prescribe a patient a medicine is typically taken by that patient's GP or a specialist healthcare professional.
- 3.63. A prescriber can choose how prescriptive they are when writing a prescription, which in turn has implications for the degree of choice that a dispenser (typically a pharmacy) has when fulfilling a prescription. A prescriber may choose to write:
- a. a 'generic' or '**open**' prescription for a medicine which only specifies the active ingredient,¹⁰⁰ or specifies the active ingredient together with one or more of the medicine's forms,¹⁰¹ its strength,¹⁰² and dose;¹⁰³ or
 - b. a '**closed**' prescription for a medicine which specifies the particular brand, manufacturer or supplier.¹⁰⁴
- 3.64. Prescribers are generally encouraged to write open prescriptions using a medicine's generic name, eg '*hydrocortisone tablets*', regardless of whether a generic product is actually available, unless there are specific clinical reasons not to do so.¹⁰⁵ For example, in cases where products are not

⁹⁸ Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 3.21.

⁹⁹ [§].

¹⁰⁰ For example, 'hydrocortisone'.

¹⁰¹ For example, 'tablets'.

¹⁰² For example, '10mg' or '20mg'.

¹⁰³ For example, 'to be taken twice daily'.

¹⁰⁴ For example, in the past, this may have been 'Hydrocortone'. A closed prescription may, as with an open prescription, typically also specify the medicine's form, strength and dose.

¹⁰⁵ The NHSEI explained to the CMA that it has '*been encouraging GPs to prescribe generically for many years. If the GP prescribes generically then community pharmacists can dispense either a branded or a generic drug, but will only be reimbursed for the generic. If the GP prescribes a branded drug then community pharmacists should dispense that brand*'. See Document 206557, note of call between the NHSEI and the CMA of 22 March 2021, paragraph 5.2.

interchangeable from a patient safety perspective, the Medicines and Healthcare products Regulatory Agency (the '**MHRA**') would generally require the use of a brand name (even for a generic product) so that product can be more easily distinguished.¹⁰⁶

- 3.65. During the second stage of the drug lifecycle (the market exclusivity period), even where prescriptions are open, in practice pharmacies have only one choice of product to dispense because there will be only one supplier of the drug.
- 3.66. However, during the third stage of the drug lifecycle, open prescriptions give pharmacies the option of dispensing any supplier's product because there can be multiple suppliers of the same drug.
- 3.67. Pharmacies purchase medicines from wholesalers and manufacturers (in some cases, they are vertically integrated with their own wholesaling arm, see section 3.E.V below). They then fulfil prescriptions by dispensing the medicines they have purchased.
- 3.68. Pharmacies are then reimbursed for the prescriptions they fulfil by the patient's local NHS clinical commissioning group ('**CCG**').¹⁰⁷
- 3.69. A pharmacy's profit margin is the difference between the price it paid to purchase the product and the amount it is reimbursed:
 - a. The amount pharmacies are paid for the drugs they dispense is set by the price of the product listed in what is called the Drug Tariff: a list of reimbursement prices for specific drugs compiled by the DHSC (less any discount) (see section 3.E.I below).
 - b. The same reimbursement price is paid to the pharmacy irrespective of which supplier's product they dispensed or the price that the pharmacy paid for the drug (eg the reimbursement price for a pack of 10mg hydrocortisone tablets is the same regardless of which supplier's product the pharmacy dispenses and regardless of the price that the pharmacy bought the product for).
- 3.70. Pharmacies therefore have an incentive to purchase the cheapest medicine available, in order to maximise their profit margin.¹⁰⁸ This system is designed

¹⁰⁶ Document 206640, note of call between the MHRA and the CMA of 31 March 2021, paragraph 4.4.

¹⁰⁷ CCGs are the relevant purchaser in England. The purchasing entities differ in Scotland, Wales and Northern Ireland, but the CMA considers that this does not materially impact on the findings in this Decision.

¹⁰⁸ Subject to the clawback which regulates a pharmacy's overall profit.

to encourage price competition, as suppliers are then incentivised to offer lower prices than their competitors in order to win business.

- 3.71. Once the prescribing decision is taken by the GP or specialist healthcare professional, the NHS – in the form of the patient's local CCG – has no option but to fund the product.
- 3.72. The NHS is principally funded by UK taxpayers.¹⁰⁹ Within the NHS's overall budget, there are budgets allocated to certain activities, such as prescribing medicines. Each year, NHS England sets each CCG a prescribing budget and GP practices are expected to prescribe within this budget.¹¹⁰ Increases in the price of any drug invariably result in a consequent decrease in the financial resources available to fund other healthcare services.¹¹¹ Notwithstanding the significant scale of the NHS budget, legitimate demands for healthcare will always exceed its levels and resources have to be prioritised.¹¹²

V. Price regulation

a. Branded drugs

- 3.73. The prices of branded drugs are typically (directly or indirectly through profit caps) subject to regulation.
- 3.74. In the UK, this purpose was served during the Infringements by the Pharmaceutical Price Regulation Scheme (the '**PPRS**').
- 3.75. The PPRS was a voluntary agreement between the DHSC and the Association of the British Pharmaceutical Industry ('**ABPI**') which applied to manufacturers and suppliers of branded medicines to the NHS.¹¹³ The PPRS aimed to ensure '*safe and effective medicines are available on reasonable terms to the National Health Service*' and '*a strong, efficient and profitable*

¹⁰⁹ See www.nhs.uk/NHSEngland/thenhs/about/Pages/overview.aspx. The NHS also derives some revenue from user charges – for example prescription payments.

¹¹⁰ See www.nhsbsa.nhs.uk/PrescriptionServices/3996.aspx and bma-focus-on-excessive-prescribing-feb-2018.pdf.

¹¹¹ See, for example, Document 01604, response to question 6, Coastal West Sussex CCG's response to the CMA's section 26 notice dated 16 May 2017.

¹¹² In recent years, the NHS has also been required to find significant efficiency savings. In the period from 2010 to 2015, for example, the NHS Efficiency Policy (also known as the Quality, Innovation, Productivity and Prevention Plan) tasked the NHS to make up to £20 billion of efficiency savings by 2015 in order to make more funds available to treat patients. See www.gov.uk/government/publications/2010-to-2015-government-policy-nhs-efficiency/2010-to-2015-government-policy-nhs-efficiency. While the NHS's overall funding is being increased, the need to continue to find efficiencies and savings continues to be important. The NHS expected there to be a potential unmitigated gap of around £30 billion in its total funding by 2020/21. See www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf. To help address this funding gap, the NHS was to receive approximately £8 billion in extra funding, but was expected to make up the remaining £22 billion in efficiency savings. See, for example, www.england.nhs.uk/wp-content/uploads/2016/05/fyfv-tech-note-090516.pdf.

¹¹³ Section 261(2) of the NHS Act 2006; see also the 2014 PPRS, paragraph 3.14.

pharmaceutical industry'.¹¹⁴ The PPRS did this by regulating *'the profits that companies can earn on sales of branded products to the NHS, rather than regulating prices directly'*.¹¹⁵

- 3.76. The PPRS applied to branded drugs, whether patented or 'branded generics'.
- 3.77. A company was able to choose not to become a member of the PPRS, and could be excluded by the Secretary of State. In such circumstances, a statutory pricing scheme would have applied to the company's branded products (but not to its non-branded generic drugs). See section 3.D.I.d below.
- 3.78. The 2014 PPRS expired on 31 December 2018 and was replaced by the 2019 Voluntary Scheme for Branded Medicines Pricing and Access, which operates broadly in the same way as the 2014 PPRS – a profit control scheme capping income from sales of drugs at an agreed level of growth – and also applies to branded drugs, whether patented or 'branded generics'.¹¹⁶ Companies that choose not to join the voluntary scheme remain subject to the statutory pricing scheme.¹¹⁷

b. Generic drugs

- 3.79. Once a drug becomes generic, the expectation is that the cost of the R&D that led to its creation has been recouped and the price should fall, as explained in section 3.B above.
- 3.80. The prices of generic drugs are therefore generally unregulated in the UK on the assumption that competition between suppliers in the third stage of the drug lifecycle will keep prices low. Typically, if the price of a given drug was significantly above the competitive price during the third stage then it would be expected that the high price would act as a signal and incentivise new entrants to the market.¹¹⁸ The market price should then correct as the introduction of more competitors supplying generic medicines will inevitably lead to more intense price competition. This should be true both for a price that is already high and a price that starts to increase. The DHSC's policy

¹¹⁴ See the 2014 PPRS, page 9, paragraph 1.2.

¹¹⁵ ABPI's 'Understanding the 2014 Pharmaceutical Price Regulation Scheme 2014', (www.abpi.org.uk/media/1561/understanding_pprs2014.pdf), page 1.

¹¹⁶ See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/761834/voluntary-scheme-for-branded-medicines-pricing-and-access-chapters-and-glossary.pdf.

¹¹⁷ Now established under the Branded Health Service Medicines (Costs) Regulations 2018, as amended from time to time.

¹¹⁸ Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 5.22 entry barriers and long-term dynamics.

during the Infringements was therefore to rely on competition to control generic drug selling prices.¹¹⁹

- 3.81. In the majority of cases, this is believed to be an effective means of securing value for money for the NHS. For example, the BGMA states that:

'Generic medicines make the drugs bill affordable and promote innovation. When an original branded drug loses its patent protection, generic equivalents are launched, typically by many manufacturers. The competition between these manufacturers drives down prices

...

Generic medicines cost 20% to 90% less than the original price of their brand-name equivalents. In addition, competition from rival generic products forces originators to reduce their own prices after – or sometimes before – patent expiry ... When we use generic medicines, our national healthcare systems save considerable sums of money'.¹²⁰

c. De-branding

- 3.82. In addition to the three options described at paragraph 3.59 above, originators also have the option of 'de-branding' their drug. This means that the brand name is discontinued. The originator may then choose to sell its drug solely under a generic name (eg hydrocortisone tablets). As a result, all prescriptions will be open (ie using the generic drug name rather than a brand).
- 3.83. De-branding removes the drug from the framework of price regulation. As explained above, in most cases competition is expected to prevent significant or sustained price increases as a result.
- 3.84. However, this assumption does not apply to all drugs. As AMCo's management explained to investors in 2012:

'Products not covered by the PPRS which are essentially non-branded have free pricing due to NHS's approach to allow competition to check prices, which is indeed the best approach to optimise pricing across the overall £11bn drug budget

¹¹⁹ See www.gov.uk/government/publications/health-service-medical-supplies-costs/health-service-medical-supplies-costs-bill-factsheet.

¹²⁰ www.britishgenerics.co.uk/about-generics.html.

- Management actively identifies branded products where the Company has exclusive or semi-exclusive positions, and deliberately 'de-brands' them, thus freeing the product from the PPRS pricing regime

- Because the Company has exclusive or semi-exclusive positions, there is no / limited competition for its products¹²¹

3.85. In such cases de-branding creates an opportunity for exploitative pricing.¹²²

VI. 'Niche' generics

3.86. While the majority of drugs follow each stage of the drug lifecycle set out in sections 3.B.I to III above, there are some drugs for which the generic competition that typically occurs during the third stage is impeded or delayed. This could be because of market features (such as barriers to entry or expansion or where the market is too small to attract entry) or because of anti-competitive collusion. The suppliers of such drugs could find themselves in a position of holding significant market power in relation to very old medicines which, although essential to patients, have not been subject to any recent innovation or investment and are shielded from competition. For these drugs, commonly referred to as 'niche' generics, the assumption that competition between suppliers will keep prices low in the third stage of the drug lifecycle breaks down. The freedom of pricing that arises due to a lack of regulation of generic drug pricing in the UK can then be exploited by suppliers to increase prices.

3.87. Identifying markets for particular drugs which other manufacturers will be less likely to enter allows a firm to enter a market where it has both the capacity to produce enough of a drug to meet market demand and the power to dictate the drug's price.¹²³

3.88. Some suppliers have used this market power and the window before effective competition materialises to increase prices, with negative consequences for the NHS, which has no option but to continue funding prescriptions for the drugs. For example, the former Secretary of State for Health has stated in Parliament:

¹²¹ Document LIO0242, AMCo rating agency presentation dated November 2012, slide 27.

¹²² Compare Document 202327, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 1] dated 12 October 2012: 'If there is anything you want him [[Waymade Senior Employee 1] to do with Amdipharma's] portfolio post-signing (eg de-brand XYZ so we have a few months before you start raising prices) you should feel free to ask him direct of course'. See also Document 202506, final due diligence report prepared for Cinven on the Amdipharma business dated 23 October 2012, slide 31: 'One aspect of Management's strategy is to debrand products, thus taking them out of PPRS, and increasing prices. This strategy has been successfully deployed by other players in the market ... e.g. Mercury Pharma'.

¹²³ OECD, *Excessive Prices in Pharmaceutical Markets*, 3 October 2018 (available at [https://one.oecd.org/document/DAF/COMP\(2018\)12/en/pdf](https://one.oecd.org/document/DAF/COMP(2018)12/en/pdf)), paragraph 109.

'We rely on competition in the market to keep the prices of these drugs down. That generally works well and has, in combination with high levels of generic prescribing, led to significant savings. However, we are aware of some instances where there is no competition to keep prices down, and companies have raised their prices to what looks like an unreasonable and unjustifiable level ... there are companies that appear to have made it their business model to purchase off-patent medicines for which there are no competitor products. They then exploit a monopoly position to raise prices.

...

a handful of companies appear to be exploiting our freedom of pricing for unbranded generic medicines where there is no competition in the market, leaving the NHS with no choice but to purchase the medicine at grossly inflated prices'.¹²⁴

- 3.89. The DHSC introduced legislation partly in order to address the problem identified by the Secretary of State. On 7 August 2017, the Health Service Medical Supplies (Costs) Act 2017 entered into force (see section 3.E.I.d below).¹²⁵ In introducing the legislation, the Secretary of State stated that there was a need to:

'close the loophole of de-branding medicines. Although the Government's existing powers allow us to control the price of any health service medicine, they do not allow controls to be placed on unbranded generic medicines where companies are members of the voluntary PPRS scheme'.¹²⁶

- 3.90. This category of generic drugs – niche generics – is widely recognised in the pharmaceutical industry. Certain drug suppliers (and their investors) have identified the opportunities that niche generics provide to generate revenue that would not normally be expected of a drug in the third stage of its lifecycle.
- 3.91. For example, Auden described itself as *'focused on the development, licensing and marketing of niche generic medicines and proprietary brands in*

¹²⁴ See [https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies\(Costs\)Bill](https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies(Costs)Bill).

¹²⁵ By virtue of the Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017.

¹²⁶ See [https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies\(Costs\)Bill](https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies(Costs)Bill).

the UK and across Europe'.¹²⁷ Due diligence materials prepared for the sale of AM Pharma's business in 2015 described it as:

- a. *'highly cash generative selling niche, high margin drugs'*;
- b. and noted that its *'niche portfolio of products reduces the ability of customers to source alternative suppliers'*.
- c. They also noted that Auden's *'business model is relatively straightforward and "virtual" with manufacturing and distribution outsourced and sales channels through large distributors'*.¹²⁸

3.92. Auden's prospective buyer identified that *'Auden's competency is in identifying semi-exclusive products for the UK market and then optimizing the price / volume mix to maximize revenue/profits'*.¹²⁹

3.93. In 2012, Cinven acquired the Amdipharm group (originally part of Waymade) and the Mercury Pharma group, and combined them to create Amdipharm Mercury, or AMCo. Cinven described the groups as *'two complementary niche pharmaceutical companies'* and noted that: *'Our Healthcare sector team identified off-patent, niche pharmaceuticals as a particularly attractive sub-sector.'* Cinven therefore combined the two groups to create in AMCo *'a global force in niche pharmaceuticals'* and *'a real global leader in the niche pharmaceutical space'*.¹³⁰

3.94. The investment recommendation for Cinven's acquisition of the Mercury Pharma group stated:

'Approximately 40% of the generics market in the UK is unbranded

- *The pricing of these unbranded products is not regulated because competition suppresses pricing across the market as a whole*
- *However, for smaller, niche formulations, the competitive forces may not work to suppress prices as efficiently as for larger volume products and create room for price growth*

¹²⁷ See [Auden McKenzie \(Pharma Division\) Ltd \(archive.org\)](http://audenmckenzie.com/about), (<http://audenmckenzie.com/about> as archived on 28 October 2018).

¹²⁸ Document 00681, Project Apple due diligence report dated 11 December 2014, pages 7, 10 and 19. The due diligence report also noted that *'The Company operates from a relatively low cost base, and the main expense is R&D'*; but the compilers of the report had not been provided with supporting information for R&D costs; and that although AM Pharma had claimed R&D tax relief, *'the company lacks detailed reports to support recent claims'* (pages 23 and 55). [§].

¹²⁹ Document 00679, Project Apple presentation dated December 2014, slide 11. See also document 00706, Project Apple presentation dated January 2015, slide 5.

¹³⁰ Document LIO7766, Cinven 2012 annual review, case study on AMCo, pages 8 and 9.

...

*Mercury therefore operates below the radar and capitalises on opportunities to achieve volume and pricing growth even in such a heavily regulated market*¹³¹

3.95. It also stated:

*'The primary growth levers for Amdipharm are very similar to Mercury: capitalise on the relatively favourable UK drug pricing regime for niche branded / unbranded generic portfolios of this nature to drive price increases'*¹³²

3.96. AMCo explained how niche generics could be exploited to investors with the following diagram.

¹³¹ Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012', pages 6 and 8.

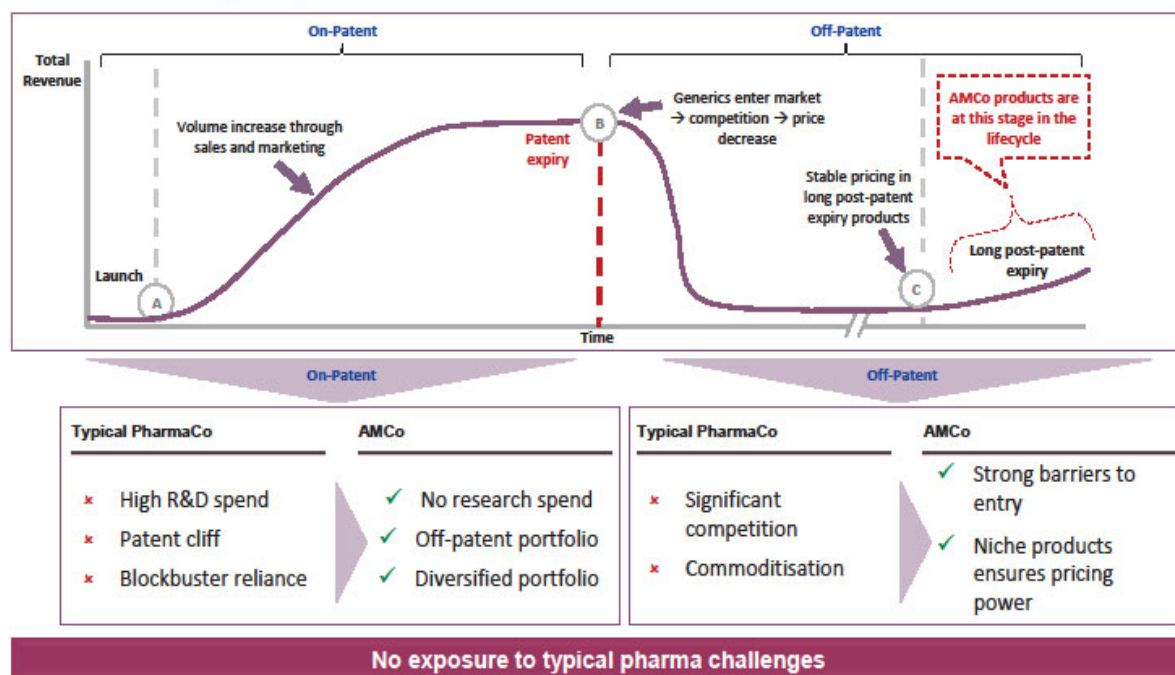
¹³² Document LIO6490.4, 'Annex 2.2 - memorandum to the IC titled 'Amdipharm - initial investment recommendation' dated 9 July 2012', page 4.

Figure 3.4: AMCo diagram presented to lenders in October 2014

LIO0458

We focus on niche off-patent pharmaceutical products

Pharmaceutical Drug Lifecycle



Strictly Confidential

Page 9

Source: Document LIO0458, AMCo lenders presentation dated 15 October 2014, slide 9.

- 3.97. As this diagram shows, the strategy involves identifying products in the third stage of the drug lifecycle that are '*Long post-patent expiry*' and subject to '*Strong barriers to entry*'. The niche status of such drugs '*ensures pricing power*', contrary to the conventional assumption that the prices of drugs in this stage will be kept low by competition. This allows the supplier to increase prices without constraint. The strategy requires no R&D ('*No research spend*'), this having long since been recouped by the originator during the first two stages of the drug lifecycle. Like Auden (see paragraph 3.91.c above), AMCo was described by Cinven as having '*a purely virtual business model*', with no in-house manufacturing or distribution.¹³³

¹³³ Document LIO6492.6, AMCo Q3 Portfolio Review Committee paper dated September 2013, page 4. Compare Document LIO0231, Mercury Pharma lenders' presentation dated September 2012, notes to slide 12: AMCo has '*No R&D spend or patent cliff*'. See also Document LIO6490.4, investment recommendation for Cinven's acquisition of the Amdipharm group, page 3: '*Like Mercury, Amdipharm is a virtual company, i.e. it outsources its manufacturing to third parties*'.

- 3.98. At the Jefferies Healthcare Conference in November 2012, [AMCo Senior Employee 1] and [AMCo Senior Employee 2] delivered a presentation.¹³⁴ The presentation listed ‘*key strategic elements*’ of the merger between Amdipharm and Mercury, two of which were as follows:

‘Limited and stable competitive dynamics around key products:

- *Strong barriers to entry due to relatively small size of individual product markets by country, combined with geographic and SKU diversity and requirement for separate marketing authorisations by country.*
- *Provides recurring revenues*

Favourable position in UK regulatory framework:

- *Portfolio comprises low-cost, off-patent products which are not the main focus of healthcare cost reduction initiatives*
- *UK is an attractive market owing to unrestricted pricing on unbranded products*¹³⁵

- 3.99. These contemporaneous documents demonstrate that for niche generics, the ability to generate a higher than average gross margin is not due to the importance of the drug or its essential features, but rather the underlying market features that limit the likelihood and strength of generic entry: the combination of ‘*Limited and stable competitive dynamics*’ and a ‘*Favourable position in the UK regulatory framework*’.

VII. Hydrocortisone tablets as niche generics

- 3.100. During the Infringements, hydrocortisone tablets were niche generic drugs.
- 3.101. Hydrocortisone tablets are very old drugs. They were first sold in the UK in **1955** and have been long off-patent. Accordingly, hydrocortisone tablets have been in the third stage of the drug lifecycle for a long time. At this stage, prices are expected to remain low due either to generic competition or the threat of such competition if prices start to increase (and therefore make entry more attractive), as explained above.

¹³⁴ Document 202401, AMCo conference presentation dated 13 November 2012.

¹³⁵ Document 202401, AMCo conference presentation dated 13 November 2012, slide 11.

- 3.102. For 53 years, hydrocortisone tablets were sold by their originator, Merck Sharp & Dohme ('MSD'), under the brand name '*Hydrocortone*'.¹³⁶ As branded drugs, the profits MSD made from hydrocortisone tablets were regulated. By April 2008 MSD was selling at prices of £0.70 per pack of 10mg tablets and [£1-£4] per pack of 20mg tablets.¹³⁷
- 3.103. On 21 April 2008,¹³⁸ MSD sold the brand and MAs to Auden. Auden immediately de-branded the drug: it discontinued the *Hydrocortone* brand, removing the drug from the profit regulation of the PPRS,¹³⁹ and launched its own generic versions at initial prices of £4.54 per pack of 10mg tablets and £5.14 per pack of 20mg tablets. Auden then exploited the absence of price regulation for generic drugs and its status as sole supplier until July 2015 to increase prices, reaching as high as £72 per pack for each strength.¹⁴⁰
- 3.104. As a result of the price increases, hydrocortisone tablets became the key drug in Auden's portfolio. When the business was sold to Allergan in 2015, due diligence materials noted that:
- a. *'The hydrocortisone product has been the foundation of the business and supported the development and acquisition of other niche products ... it remains the key product contributing 46% of total LTM15 gross profit'*.¹⁴¹
 - b. *'Hydrocortisone is the key product line, upon which the Company is heavily reliant in order to sustain current sales and profitability. We also understand that this has Orphan drug status in the UK and minimal competition'*.¹⁴²
 - c. Hydrocortisone tablets generated the highest absolute gross margin of any product in the business's portfolio.¹⁴³
- 3.105. The due diligence materials explained that these price increases were possible because of Auden's position as sole supplier of the drug and the regulatory circumstance of the orphan designation from which it benefited:

¹³⁶ The '*Hydrocortone*' trademark was registered (730276) in the UK on 17 May 1954 (Document 00561, response to question 1, MSD's response to the CMA's section 26 notice dated 22 June 2016).

¹³⁷ Document 00561, response to questions 1, 3 and 4, MSD's response to the CMA's section 26 notice dated 22 June 2016.

¹³⁸ Document 00558, 'Divestment of Hydrocortone 10mg and 20mg tablets (hydrocortisone)'.

¹³⁹ Document 00618, Department of Health's response to the CMA's section 26 notice dated 5 August 2016, response to question 2.

¹⁴⁰ Auden's 20mg price reached £72.19 in October 2015 and its 10mg price reached £72.14 in March 2016.

¹⁴¹ Document 00681, Project Apple due diligence report dated 11 December 2014, page 7.

¹⁴² Document 00681, Project Apple due diligence report dated 11 December 2014, page 16.

¹⁴³ Document 00681, Project Apple due diligence report dated 11 December 2014, page 22.

'significant price increases have been achieved in Hydrocortisone largely due to the orphan status that it holds in the UK and the current lack of competition'.¹⁴⁴

3.106. The materials also stated that: *'Price increases across the Hydrocortisone and other SKUs ... are within the maximum price dictated by the Government's drug tariff and have to be negotiated with their customers'.¹⁴⁵* However, this failed to recognise that since Auden was the sole supplier:

- a. Auden's price increases were driving the Drug Tariff up, rather than the Drug Tariff constraining Auden's prices. See section 3.D.IV.d below.
- b. Its customers had no countervailing buyer power to exert in such 'negotiations'. See section 4.C.d below.

a. Anti-competitive agreements

3.107. The *'current lack of competition'* identified in the 2015 due diligence materials is attributable to the anti-competitive agreements Auden/Actavis entered into with its potential competitors Waymade and AMCo.

3.108. Auden's conduct in de-branding hydrocortisone tablets and dramatically increasing their prices made the market more attractive to potential entrants. Less than six months after Auden de-branded hydrocortisone tablets, [Waymade Senior Employee 1] noted, *'hydrocortisone tabs 20mg we have a license and I want to launch. the brand by MSD has been discontinued'*.¹⁴⁶ [Waymade Senior Employee 3] explained in interview:

*'The holy grail within the generic sector is to find these little nuggets, as the commercial guys would see it, where there is limited competition and therefore the price is high.'*¹⁴⁷

3.109. [Waymade Senior Employee 3] went on to say: *'with a product like hydrocortisone where the margins were, would appear to be quite generous ... this was going to be one of those nuggets that I referred to.'*¹⁴⁸ [Waymade

¹⁴⁴ Document 00681, Project Apple due diligence report dated 11 December 2014, pages 7, 16, 17 and 22.

¹⁴⁵ Document 00681, Project Apple due diligence report dated 11 December 2014, page 17.

¹⁴⁶ Document 300705, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 3] dated 2 September 2008.

¹⁴⁷ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 18, lines 1 to 4.

¹⁴⁸ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 3, lines 15 to 21.

Senior Employee 2], [REDACTED], also described hydrocortisone tablets as ‘a gold nugget’.¹⁴⁹

3.110. Waymade therefore prepared to enter the market with its own hydrocortisone tablets. However, the CMA has found that:

- a. between 11 July 2011 and 30 April 2015, Auden bought off Waymade’s entry with 20mg tablets; and
- b. in October 2012, shortly after Waymade obtained an MA for 10mg tablets, Auden bought off Waymade’s entry. Waymade’s 10mg MA was then transferred to AMCo and between 31 October 2012 and 24 June 2016 Auden/Actavis bought off AMCo’s entry with 10mg tablets.

3.111. See section 6 (*The Agreements*) below.

3.112. These market exclusion agreements allowed Auden/Actavis to retain its pricing power. During the terms of the Agreements:

- a. Auden increased its price for 20mg hydrocortisone tablets by 92%, from £32.56 in July 2011 to £62.45 in April 2015, when the 20mg Agreement ended. Auden/Actavis’s price peaked at £72.19 a pack in October 2015.
- b. Auden/Actavis increased its price for 10mg hydrocortisone tablets by 99%, from £31.55 in October 2012 to £62.63 in June 2016, when the 10mg Agreement ended. Auden/Actavis’s price peaked at £72.14 a pack in March 2016.

b. The orphan designation

3.113. In January 2015, Actavis labelled hydrocortisone tablets a ‘*Near term cash cow*’.¹⁵⁰ This status was ‘*Near term*’ because Actavis and its analysts expected competitors to enter the market soon and erode its margins through the process of price competition.¹⁵¹

3.114. In fact, competitors began to enter the market from July 2015 onwards. However, prices remained high, inflated by Auden’s price increases over the previous seven years. Having taken over sales of hydrocortisone tablets

¹⁴⁹ Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018, part 2, page 7, line 9.

¹⁵⁰ Document 00706, Project Apple Presentation January 2015, Executive Summary and Hydrocortisone Background.

¹⁵¹ In January 2015 Actavis anticipated market share erosion of 60% and price erosion of 90% over a three-year period with the expectation that competitors would enter in 2015 ‘*without indication for adrenal insufficiency and being launched and dispensed off label*’. Document 00706, Project Apple Presentation January 2015, Hydrocortisone Background.

from Auden, Actavis was also able to maintain a premium over its competitors' prices.

- 3.115. This resulted from the orphan designation granted to Plenadren, which from November 2011 meant that no new licences (or extensions of existing licences) for hydrocortisone tablets could specify that they were for the treatment of '*adrenal insufficiency in adults*' (see section 3.D.III below). This unforeseen and unintended consequence of the regulatory regime, which had no basis in innovation by Auden, created a barrier to expansion once competitors began to enter the market and gave Actavis an assured base of customers who reached the view that they could not switch away from its hydrocortisone tablets. See sections 3.D.IV.c and 4.C.II (*Dominance*) below.

C. Adrenal insufficiency and the drugs that treat it

- 3.116. This section explains what adrenal insufficiency is and which medicines are used to treat it. In summary:
- a. Adrenal insufficiency is a lifelong and serious condition. It is treated in almost all cases with hydrocortisone tablets, which are considered to be the most appropriate steroid to replace the missing hormone in the body.
 - b. Other treatments are only used in exceptional circumstances or for marginal numbers of patients with specific needs.
 - c. Almost all prescriptions for hydrocortisone tablets are repeat prescriptions, creating a stable though steadily increasing customer base.

I. Adrenal insufficiency and hydrocortisone

- 3.117. Adrenal insufficiency¹⁵² is a chronic, rare condition that occurs when the adrenal glands fail to produce any or enough of the hormones the body needs. If untreated, it is life-threatening.¹⁵³ In almost all cases, it is a lifelong condition:^{154,155}

¹⁵² Adrenal insufficiency can also be referred to as Addison's disease or hypoadrenalism. However, as explained below, Addison's disease is only one of many causes of adrenal insufficiency.

¹⁵³ Document 00524, Boots guidance on hydrocortisone tablets.

¹⁵⁴ Only when the adrenal suppression is caused by exogenous glucocorticoid use for non-endocrine diseases, such as asthma or rheumatoid arthritis, can the treatment be discontinued once the patient is confirmed as no longer adrenal insufficient. Document 00603 and Document 00599, responses to questions 4 and 5, Society for Endocrinology's and the Royal College of Physicians' responses to the CMA's section 26 notice dated 20 June 2016.

¹⁵⁵ Document 00435, Auden McKenzie guide to adrenal insufficiency for patients; Document 00436, Auden McKenzie guide to adrenal insufficiency for pharmacists; and the Society for Endocrinology's [Adrenal Insufficiency Patient Booklet](#).

- a. **Primary** adrenal insufficiency occurs when the adrenal cortex, which produces cortisol, has been destroyed. In around 70% to 90% of all cases, this is caused by an autoimmune disorder. Primary adrenal insufficiency may also occur as a result of an infection, adrenal cancer, haemorrhage or rare hereditary diseases, such as congenital adrenal hyperplasia.¹⁵⁶
 - b. **Secondary** adrenal insufficiency describes the situation when the adrenal glands are affected by a condition or disease in another part of the body, most often a pituitary tumour. Damage to the pituitary gland affects its ability to produce another hormone, called adrenocorticotrophic hormone, which acts as a signal for adrenal glands to produce more cortisol. This disruption means cortisol production by the adrenal glands is no longer controlled properly.¹⁵⁷
- 3.118. Adrenal insufficiency is treated with steroids to replace the missing cortisol in the body.
- 3.119. Hydrocortisone is the first-line treatment for the replacement of cortisol in patients with primary or secondary adrenal insufficiency.¹⁵⁸ Hydrocortisone is considered to be the most appropriate steroid for the treatment of adrenal insufficiency as it is:
- a. the closest imitation of what the body normally produces;
 - b. absorbed into the body quicker than other steroids; and
 - c. easily measured in the bloodstream, making monitoring easier.¹⁵⁹

II. Hydrocortisone tablets

- 3.120. Hydrocortisone tablets are a prescription-only medicine used in primary and secondary care mainly to treat adrenal insufficiency.¹⁶⁰

¹⁵⁶ Document 00435, Auden Mckenzie guide to adrenal insufficiency for patients; Document 00436, Auden Mckenzie guide to adrenal insufficiency for pharmacists; and the Society for Endocrinology's [Adrenal Insufficiency Patient Booklet](#).

¹⁵⁷ Document 00436, Auden Mckenzie guide to adrenal insufficiency for pharmacists; and the Society for Endocrinology's [Adrenal Insufficiency Patient Booklet](#).

¹⁵⁸ Document 00603, response to question 1, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹⁵⁹ Document 00436, Auden Mckenzie guide to adrenal insufficiency for pharmacists; Document 00603 and Document 00599, responses to questions 1 and 3, Society for Endocrinology's and the Royal College of Physicians' responses to the CMA's section 26 notice dated 20 June 2016.

¹⁶⁰ Both the Royal College of Physicians and the Society for Endocrinology informed the CMA that hydrocortisone tablets are primarily used to treat adrenal insufficiency. Document 00603 and Document 00599, response to question 1, Society for Endocrinology's and the Royal College of Physicians' responses to the CMA's section 26 notice dated 20 June 2016; Document 02046.B, note of call between the CMA and [Professor of Endocrinology]

- 3.121. The Society for Endocrinology estimates that around **95% of all adult patients with adrenal insufficiency** are treated with hydrocortisone tablets.¹⁶¹
- 3.122. Hydrocortisone tablets are available in 10mg and 20mg strengths and are sold in packets of 30 tablets.
- 3.123. Hydrocortisone tablets are ‘**immediate release**’ drugs. This means that the hydrocortisone is rapidly absorbed into the bloodstream to deliver peak cortisol values in the blood approximately half an hour after administration.¹⁶²
- 3.124. For those taking hydrocortisone tablets as a replacement therapy, the standard adult daily dose ranges between 15mg to 25mg; however, higher doses might be needed when the patient is acutely unwell.¹⁶³ Hydrocortisone tablets often need to be taken two or three times a day in order to secure sufficient blood cortisol levels throughout the day (for example, 10mg on waking, 5mg at lunchtime, and 5mg in the late afternoon: the dosing regime aims to reflect the body’s natural rhythm, with cortisol levels highest in the morning).¹⁶⁴ Patients often achieve this by halving or quartering tablets.¹⁶⁵ Due to the frequent need to split the tablets into small doses (for example, 5mg or 2.5mg), 20mg hydrocortisone tablets are not commonly used in practice,¹⁶⁶ other than in specific cases when higher doses of hydrocortisone are required, usually on a short term basis.¹⁶⁷

dated 17 November 2017, response to question 7, page 5. Hydrocortisone tablets are also used in emergency situations for treatment of severe bronchial asthma, drug hypersensitivity reactions, serum sickness, angioneurotic oedema and anaphylaxis in adults and children: Document 00656, paragraph 1.2, AM Pharma’s response to the CMA’s section 26 notice dated 23 May 2016.

¹⁶¹ Document 00603, response to question 2, Society for Endocrinology’s response to the CMA’s section 26 notice dated 20 June 2016.

¹⁶² Document 00436, Auden Mckenzie guide to adrenal insufficiency for pharmacists.

¹⁶³ Document 00603, responses to questions 2 and 3, Society for Endocrinology’s response to the CMA’s section 26 notice dated 20 June 2016.

¹⁶⁴ Document 00603, response to question 2, Society for Endocrinology’s response to the CMA’s section 26 notice dated 20 June 2016; Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 1, page 2.

¹⁶⁵ Document 00437, page 2, Auden Mckenzie guide to the role of hydrocortisone in the treatment of primary and secondary disease; Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 1, page 2.

¹⁶⁶ Although the Society for Endocrinology reports that pharmacies sometimes dispense 20mg hydrocortisone tablets and advise patients to divide the tablets, 10mg hydrocortisone tablets are more practical for this purpose (Document 00603, responses to questions 2, 3, 6 and 10, Society for Endocrinology’s response to the CMA’s section 26 notice dated 20 June 2016; Document 00893B, response to question 2, Society for Endocrinology’s supplementary response to the CMA dated 20 July 2016). See also Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to questions 1 and 2, page 2.

¹⁶⁷ See document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 1, page 2.

- 3.125. As a result, 10mg hydrocortisone tablets are the most common strength of hydrocortisone tablets dispensed, accounting for around **96% of all packs of hydrocortisone tablets** dispensed between 2012 and 2017.¹⁶⁸
- 3.126. Most hydrocortisone tablets prescriptions are repeat prescriptions. Between 2013 and 2015, approximately **98% of prescriptions were repeat** and 2% of prescriptions were for new patients, with only a marginal number (less than 0.1%) issued for patients who switched to hydrocortisone tablets from another product.¹⁶⁹ This means that the overall customer base is steadily increasing over time, with a rate of annual growth in monthly packs dispensed of around 4% for 10mg tablets and being broadly stable for 20mg tablets.¹⁷⁰
- 3.127. The precise breakdown of the age range of patients on hydrocortisone tablets is unclear, as opinions vary:
- The Royal College of Physicians estimates that the proportion of patients taking hydrocortisone tablets that are children is approximately 5% for 10mg tablets; and 10% for 20mg tablets.¹⁷¹
 - Other estimates of the proportion of patients that are children by market participants include: 2% (Auden),¹⁷² 5% (Boots),¹⁷³ 8% (Wells Pharmacy),¹⁷⁴ 10% (Alissa),¹⁷⁵ and 20% (Resolution Chemicals).¹⁷⁶

III. Plenadren

- 3.128. Unlike hydrocortisone tablets, Plenadren is a branded product. It is a form of hydrocortisone available in 5mg and 20mg strengths and sold in bottles of 50 tablets by a single supplier, Shire Services BVBA and its UK subsidiary Shire Pharmaceuticals Limited ('**Shire**').¹⁷⁷ Plenadren is only approved for the treatment of **adrenal insufficiency in adults**.¹⁷⁸

¹⁶⁸ NHS BSA data.

¹⁶⁹ CMA analysis based on IMS data.

¹⁷⁰ CMA analysis based on NHS BSA data.

¹⁷¹ Document 00599, response to question 2, Royal College of Physicians' response to the CMA's section 26 notice dated 20 June 2016.

¹⁷² Document 00129, letter from Auden to [X] (MHRA) dated 14 April 2014.

¹⁷³ Document 02188, internal Boots email dated 11 January 2016.

¹⁷⁴ Document 03590, internal Wells email dated 16 December 2016.

¹⁷⁵ Document 206413, note of call between the CMA and [X] of 22 February 2021, paragraph 2.4.

¹⁷⁶ Document 206344, note of call between the CMA and Resolution Chemicals of 4 March 2021, paragraph 3.4.

¹⁷⁷ [All medicines for Takeda UK Ltd - \(emc\)](#). Plenadren was originally a DuoCort AB product. See section 3.C.III below for an account of the transfers in ownership that this product has undergone.

¹⁷⁸ It is not approved for any other indication, including adrenal insufficiency in children, as compared to all immediate-release hydrocortisone tablets which are licensed to treat adrenal insufficiency in children (Document 200320, response to question 4, Shire's response to the CMA's section 26 notice dated 20 June 2016).

- 3.129. Plenadren is a **modified-release** tablet formulation of hydrocortisone: a novel form of hydrocortisone that is designed to mimic closely the body's normal steroid production and its natural daily steroid profile. It releases hydrocortisone over a longer period of time than the conventional immediate-release method provided by other hydrocortisone tablets and is therefore administered only once daily. In recognition of this innovation, Plenadren was given 'orphan' drug status in 2011 (see section 3.D.VI below).
- 3.130. This modified-release innovation means Plenadren is potentially more beneficial for a particular subset of patients in terms of convenience and patient compliance than hydrocortisone tablets, which (as explained in paragraph 3.124 above) are usually taken two to three times a day.¹⁷⁹ Specifically, Plenadren is an option for patients experiencing '*severe compliance problems*' (and some CCGs) have made this a prerequisite for recommending prescribing Plenadren).¹⁸⁰
- 3.131. Plenadren is only given to a very small number of adrenal insufficiency patients. It is also not recommended or endorsed for use in Scotland or Wales.¹⁸¹
- 3.132. The largest number of Plenadren packs were dispensed in 2019, with 628 packs (including both 5mg and 20mg) dispensed on average per month, compared to 91,746 and 2,908 packs of 10mg and 20mg hydrocortisone tablets respectively. Since its introduction in 2012 Plenadren has always accounted for less than 1% of all hydrocortisone tablets (both immediate and modified-release) dispensed, as tables 3.1 and 3.2 show.¹⁸²

¹⁷⁹ Document 00603, responses to questions 2, 3 and 7, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016; and '[Hydrocortisone modified-release: Concise evaluated information to support the managed entry of new medicines in the NHS](#)'.

¹⁸⁰ NHS Calderdale Commissioning Statement [here](#) at www.calderdaleccg.nhs.uk; NHS East Surrey CCG, NHS Guildford & Waverley CCG, NHS North West Surrey CCG, NHS Surrey Downs CCG & NHS Surrey Heath CCG, NHS North East Hampshire & Farnham CCG and NHS Crawley, Horsham & Mid-Sussex CCG Prescribing Clinical Network [here](#) at <https://surreyccg.res-systems.net>; Dorset Medicines Advisory Group Commissioning Statement [here](#) at www.dorsetccg.nhs.uk; East and NHS North Hertfordshire CCG [here](#) at www.enhertscg.nhs.uk; and NHS Greater Huddersfield CCG Commissioning Statement [here](#) at www.greaterhuddersfieldccg.nhs.uk.

¹⁸¹ Document 01604, response to question 8, Coastal West Sussex CCG's response to the CMA's section 26 notice dated 16 May 2017. See also Scottish medicines 2016 press release and advice ([here](#) and [here](#)) and All Wales Medicines Strategy Group Statement of Advice ([here](#)).

¹⁸² Similarly, the Society for Endocrinology stated that Plenadren accounts for less than 1% of all hydrocortisone tablets and Plenadren volumes dispensed; Document 00603, response to question 2, response to the CMA's section 26 notice dated 20 June 2016 from the Society for Endocrinology.

Table 3.1: Average monthly number of packs of hydrocortisone tablets and Plenadren dispensed by tablet strength (2012 to 2020)

Packs dispensed (average per month)		2012	2013	2014	2015	2016	2017	2018	2019	2020
Plenadren	5mg	8	117	307	381	441	481	508	510	474
	20g	2	15	49	71	84	101	115	118	103
Hydrocortisone tablets	10mg	71,037	73,560	76,626	79,410	81,744	84,165	88,334	91,746	91,952
	20mg	3,357	3,384	3,409	3,426	3,543	3,515	3,197	2,908	2,851

Source: NHS BSA data

Note: Plenadren is dispensed in packs of 50 tablets, whereas hydrocortisone tablets are dispensed in packs of 30.

Table 3.2: Proportions of hydrocortisone tablets and Plenadren dispensed adjusted for tablet strength and pack size (2012 to 2020)

Overall proportion of all hydrocortisone tablets (%)	2012	2013	2014	2015	2016	2017	2018	2019	2020
Plenadren	0.02%	0.18%	0.50%	0.64%	0.72%	0.80%	0.84%	0.83%	0.75%
Hydrocortisone tablets	99.98%	99.82%	99.50%	99.36%	99.28%	99.20%	99.16%	99.17%	99.25%

Source: NHS BSA data

3.133. Low volumes of Plenadren are due to the following reasons:

- a. Notwithstanding the orphan designation recognising the innovation of Plenadren's modified release formulation (see section 3.D.III below), there are in practice few clinical advantages associated with taking Plenadren instead of hydrocortisone tablets other than for those patients that Plenadren is targeted at (ie those who have severe compliance problems) as the biological rhythm can be obtained by taking immediate-release hydrocortisone tablets two to three times a day.¹⁸³ Patients switching from hydrocortisone tablets to Plenadren also require closer monitoring as the amount of hydrocortisone absorbed systematically from Plenadren is about 20% less than from immediate-release hydrocortisone tablets, potentially leading to under-substitution.¹⁸⁴

¹⁸³ Document 00599, response to question 7, Royal College of Physicians' response to the CMA's section 26 notice dated 20 June 2016.

¹⁸⁴ Document 02365, Bedfordshire and Luton CCGs' New Medicine Review for Plenadren, April 2013; Document 02385, Calderdale CCG's Commissioning Statement on Plenadren, October 2016; Document 02419, Dorset Medicines Advisory Group's Commissioning Statement on Plenadren, April 2014; Document 02442, Greater Huddersfield CCG's Commissioning Statement on Plenadren, November 2016; Document 02428, Lancashire Medicines Management Group's New Medicine Recommendation for Plenadren, June 2013.

- b. Plenadren is not recommended by either the National Institute for Health and Care Excellence ('NICE') or the specialist clinical reference group ('CRG') for endocrinology;¹⁸⁵ and
- c. Prescribing restrictions are imposed on GPs by CCGs which materially limit the use of Plenadren: Plenadren is not generally included in CCG formularies.¹⁸⁶ By way of illustration, Plenadren was not included in prescribing formularies of South Devon and Torbay CCG,¹⁸⁷ Gloucestershire CCG¹⁸⁸ and Coastal West Sussex CCG.¹⁸⁹ Coastal West Sussex informed the CMA that it, along with several other groups representing 21 CCGs in England, does not include Plenadren and was also not aware of other CCGs that did include it.¹⁹⁰ These three CCGs also noted that the limited potential benefits of Plenadren are not significant enough to justify the considerable extra cost associated with prescribing Plenadren.¹⁹¹
- d. Having failed to achieve formulary status in primary and secondary care formularies,¹⁹² Shire changed its sales and marketing strategy *'from seeking to expand sales to only serving customers when they proactive seek orders'*.¹⁹³

IV. Other forms of hydrocortisone medicine

- 3.134. Other forms of hydrocortisone medicine are not used routinely as cortisol replacement therapy.
- 3.135. Injections are only used as cortisol replacement therapy in exceptional circumstances where oral medication is not tolerated, for example when a patient is going through an adrenal crisis, in cases of severe illness, pre- and

¹⁸⁵ Document 00603, responses to questions 3 and 7, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹⁸⁶ The Society for Endocrinology estimates that nearly 90% of GPs are not allowed to prescribe Plenadren. In some instances, Plenadren is recommended for hospital use only in patients who meet the following criteria: (i) have primary adrenal insufficiency; and (ii) have experienced at least two hospital admissions in the last 12 months due to unstable primary adrenal insufficiency (Document 00603, responses to questions 3 and 7, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016).

¹⁸⁷ Document 01638A, response to question 8, Torbay CCG's and South Devon CCG's responses to the CMA's section 26 notice dated 16 May 2017.

¹⁸⁸ Document 01612, Gloucestershire CCG's responses to the CMA's section 26 notice dated 16 May 2017.

¹⁸⁹ Document 01604, response to question 8, Coastal West Sussex CCG's response to the CMA's section 26 notice dated 16 May 2017

¹⁹⁰ Document 01604 response to question 8, Coastal West Sussex CCG's responses to the CMA's section 26 notice dated 16 May 2017.

¹⁹¹ See Document 01604 and Document 01612, response to question 8, Coastal West Sussex CCG's and Gloucestershire CCG's responses to the CMA's section 26 notice dated 16 May 2017.

¹⁹² Document 200320, response to question 6, Shire's response to CMA's s.26 notice dated 20 June 2016. Shire *'approached Leeds Area Prescribing Committee in 2017 as a pilot project'* but *'[t]he committee declined to proceed with the proposal, due to it not being attractive enough for them'*; Document 206381, response to question 1, Shire's response to CMA's s.26 notice dated 9 March 2021.

¹⁹³ Document 206381, response to question 1, Shire's response to CMA's s.26 notice dated 9 March 2021.

post-major procedures, or where the patient is 'Nil by Mouth'.¹⁹⁴ One such injection is 'Hydrocortistab', which is used primarily for certain arthritic conditions.¹⁹⁵ Injections are not used to treat long-term adrenal insufficiency.

- 3.136. Soluble hydrocortisone tablets, which are dissolved in water before being taken by a patient,¹⁹⁶ were launched in the UK in March 2019.¹⁹⁷ Like Plenadren, they are sold by a single supplier, Zentiva,¹⁹⁸ and are targeted at a particular subset of patients: those who have a preference or need for a liquid form of hydrocortisone. This includes patients suffering from dysphagia (difficulty swallowing) or very young children.¹⁹⁹

Table 3.3: Average monthly number of packs of hydrocortisone tablets and soluble hydrocortisone tablets dispensed by tablet strength (2019 and 2020)

Packs dispensed (average per month)		2019	2020
Soluble tablets	10mg	79	199
Hydrocortisone tablets	10mg	91,746	91,952
	20mg	2,908	2,851

Source: NHS BSA data

V. Other steroids

- 3.137. There are other synthetic steroids, such as prednisolone and dexamethasone, which may also be used for the treatment of adrenal insufficiency.²⁰⁰ However, these drugs are only prescribed in exceptional

¹⁹⁴ Document 00603, response to question 8, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹⁹⁵ The SPC states that Hydrocortistab is indicated for '*the local treatment, by intra-articular or periarticular injection, of arthritic conditions such as rheumatoid arthritis and osteoarthritis when few joints are involved. It is also suitable for symptomatic treatment, by local injection, of certain non-articular inflammatory conditions such as inflamed tendon sheaths and bursae. Hydrocortistab Injection is not suitable for the production of systemic effects*'. See SPC for Hydrocortistab Injection 25mg/ml:

www.medicines.org.uk/EMC/medicine/10796/SPC/Hydrocortistab+Injection+25+mg+ml/.

¹⁹⁶ Document 206315B, response to question 4.a, Colonis Pharma's response to the CMA's section 26 notice dated 9 March 2021.

¹⁹⁷ Document 206315B, response to question 4.c Colonis Pharma's response to the CMA's section 26 notice dated 9 March 2021 and Document 206279, response to question 1.b, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁹⁸ Document 206279, responses to question 8, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁹⁹ Document 206279, responses to question 1, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

²⁰⁰ Some sources (for example, [the Addison's Self-help Group](#)) also state that cortisone acetate may sometimes be used for the treatment of adrenal insufficiency. However, cortisone acetate is an older version of hydrocortisone and has largely been replaced by the latter, which is more readily absorbed by the body. Neither the Society for Endocrinology, nor the Royal College of Physicians, mentioned cortisol acetate as a potential substitute for Hydrocortisone Tablets (Document 00603, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016; Document 00599, Royal College of Physicians' response to the CMA's section 26 notice dated 20 June 2016). In any case, the volumes of cortisone acetate dispensed during the Infringements were very small and continued to decrease. Since 2012 only marginal volumes of cortisone acetate were dispensed.

circumstances, for example when a patient is intolerant or allergic to hydrocortisone or an alternative treatment is required due to patient non-compliance with multiple dosing. This is because:

- a. it is not possible to monitor drug levels in a patient's blood and therefore determine if the correct dose has been administered; and
- b. their longer half-life increases the likelihood of adverse metabolic and overtreatment-related side effects.²⁰¹

3.138. Further, other steroids such as prednisolone and dexamethasone may be unsuitable for young patients with adrenal insufficiency as they may cause growth retardation. Due to its limited effects on growth, hydrocortisone is the 'drug of choice' for treating children.²⁰²

3.139. The Society for Endocrinology estimates that **no more than 5%** of all patients with adrenal insufficiency are treated with other steroids.²⁰³

D. Bioequivalence and full and skinny label hydrocortisone tablets

I. Bioequivalent medicines

3.140. There are different degrees of 'equivalence' between generic medicines.

3.141. Medicinal products are **pharmaceutical alternatives** if they contain the '*same active substance*' but '*differ in chemical form*' of that substance or in the '*dosage form or strength*'.²⁰⁴

3.142. Medicinal products are **pharmaceutically equivalent** if they:

- a. contain the '*same amount of the same active substance*';
- b. in the '*same dosage forms*';
- c. that meet the '*same or comparable standards*'.²⁰⁵

²⁰¹ Document 00603 and Document 00599, responses to questions 2, 3 and 9, Society for Endocrinology's and the Royal College of Physicians' responses to the CMA's section 26 notice dated 20 June 2016; Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, responses to questions 5 and 7, pages 3 to 5.

²⁰² See, for example, <http://patient.info/health/congenital-adrenal-hyperplasia-leaflet>.

²⁰³ Document 00603, response to question 2, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

²⁰⁴ European Agency for the Evaluation of Medicinal Products – Committee for Proprietary Medicinal Products, *Note for guidance on the investigation of bioavailability and bioequivalence* (July 2001), paragraph 2.2. Available at: www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-investigation-bioavailability-bioequivalence_en.pdf

²⁰⁵ European Agency for the Evaluation of Medicinal Products – Committee for Proprietary Medicinal Products, *Note for guidance on the investigation of bioavailability and bioequivalence* (July 2001), paragraph 2.1. Available

- 3.143. A medicinal product is **therapeutically equivalent** with another product if it contains '*the same active substance*' and, clinically, shows '*the same efficacy and safety*' as that product, whose efficacy and safety has been established.²⁰⁶
- 3.144. Medicinal products can be therapeutically equivalent where they show similar '*extent*' of absorption but different '*rates*' of absorption. However, medicinal products are **bioequivalent** if they are:
- a. '*pharmaceutically equivalent or pharmaceutical alternatives*'; and
 - b. their *bioavailability* (the '*rate and extent*' at which the active substance is absorbed and becomes available in the body) after administration in the same dose are '*similar to such degree that their effects, with respect to both efficacy and safety, will be essentially the same*'.²⁰⁷
- 3.145. In practice, demonstration of bioequivalence is generally the most appropriate method of substantiating therapeutic equivalence between medicinal products, where they contain **excipients** (stabilising or bulking agents used alongside the active ingredient) generally recognised as not having an influence on safety and efficacy and comply with labelling requirements with respect to excipients.²⁰⁸
- 3.146. In summary:

at: www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-investigation-bioavailability-bioequivalence_en.pdf

²⁰⁶ European Agency for the Evaluation of Medicinal Products – Committee for Proprietary Medicinal Products, *Note for guidance on the investigation of bioavailability and bioequivalence* (July 2001), paragraph 2.6. Available at: www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-investigation-bioavailability-bioequivalence_en.pdf

²⁰⁷ European Agency for the Evaluation of Medicinal Products – Committee for Proprietary Medicinal Products, *Note for guidance on the investigation of bioavailability and bioequivalence* (July 2001), page 4. Available at: www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-investigation-bioavailability-bioequivalence_en.pdf

According to the World Health Organisation, the bioavailability of bioequivalent products, in terms of both rate and extent of absorption, is '*similar to such a degree that their effects can be expected to be essentially the same*'. See definition from WHO Expert Committee on Specifications for Pharmaceutical Preparations, 51st report. Annex 6: Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability (2017), page 186. Available at:

www.who.int/medicines/areas/quality_safety/quality_assurance/trs1003_annex6.pdf?ua=1

See also EMA Committee for Medicinal Products in Human Use (CHMP), *Guideline on the investigation of bioequivalence* (2010), page 4. Available at: www.ema.europa.eu/en/documents/scientific-guideline/guideline-investigation-bioequivalence-rev1_en.pdf

²⁰⁸ European Agency for the Evaluation of Medicinal Products – Committee for Proprietary Medicinal Products, *Note for guidance on the investigation of bioavailability and bioequivalence* (July 2001), page 4. Available at: www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-investigation-bioavailability-bioequivalence_en.pdf

- a. Pharmaceutically equivalent products may not necessarily be bioequivalent: differences in the excipients and/or manufacturing process can lead to faster or slower dissolution and/or absorption.
 - b. Therapeutically equivalent products may not necessarily be bioequivalent: they may have different rates of absorption.
 - c. Bioequivalent products have the same rate and extent of absorption. While bioequivalent products may contain different excipients and/or use different methods of manufacture, where bioequivalence can be demonstrated this is *'the widely accepted means of demonstrating that these differences have no impact on the performance of the formulation with respect to rate and extent of absorption'*.²⁰⁹
- 3.147. Bioequivalent medicines are therefore considered to be equivalent in terms of safety and efficacy when treating the same conditions.
- 3.148. Once the bioequivalence of a generic medicine to a 'reference' (or branded) originator product has been established through bioavailability studies, generic medicinal products can rely on data relating to the safety and efficacy of the reference product in their application for an MA.^{210, 211}
- 3.149. All immediate-release hydrocortisone tablets sold in the UK during the period covered by this Decision were bioequivalent regardless of which treatments were included in their MAs, which meant that they were all shown to be equivalent in terms of safety and efficacy when treating the same conditions, were to all intents and purposes the same product, and could be used interchangeably from a clinical perspective.²¹²

²⁰⁹ European Agency for the Evaluation of Medicinal Products – Committee for Proprietary Medicinal Products, *Note for guidance on the investigation of bioavailability and bioequivalence* (July 2001), paragraphs 2.1, 2.5 and 2.6. Available at: www.ema.europa.eu/en/documents/scientific-guideline/note-guidance-investigation-bioavailability-bioequivalence_en.pdf

²¹⁰ This also means that generics do not need to submit the same level of clinical data as the branded product. The EMA notes that: *'Since information on the **safety and efficacy** of the active substance(s) is already available from the reference medicine, companies producing generic medicines usually only need to: provide information on the **quality** of the medicine; demonstrate that the generic medicine produces the same levels of the active substance in the human body as the reference medicine.'* See European Medicines Agency, definition of 'Generic and hybrid medicines', available at: www.ema.europa.eu/en/human-regulatory/marketing-authorisation/generic-hybrid-medicines (emphasis in original).

²¹¹ There are also biosimilar products. The WHO has defined a biosimilar product (also known as a 'similar biotherapeutic product' or 'SBP') as *'a biotherapeutic product which is similar in terms of quality, safety and efficacy to an already licensed reference biotherapeutic product'*. See: WHO Expert Committee on Biological Standardization, *Guidelines on evaluation of similar biotherapeutic products (SBPs)*, 2009, p.4 (available at who.int). Whereas bioequivalent products are chemically identical, the natural variability of biological medicines means that biosimilar products are not regarded as generics of biological medicines. See definition from WHO Expert Committee on Specifications for Pharmaceutical Preparations: *51st report. Annex 6: Multisource (generic) pharmaceutical products: guidelines on registration requirements to establish interchangeability* (2017), page 186 (available at who.int)

²¹² Instead, immediate release hydrocortisone tablets would not be bioequivalent to modified-release hydrocortisone (e.g. Plenadren) as they have different absorption rates.

II. Marketing authorisations

- 3.150. To market and sell a pharmaceutical product, a company must obtain an MA from the national competent authority, which in the UK is the MHRA.²¹³ An MA will only be granted if the pharmaceutical product meets satisfactory standards of safety, quality and efficacy in treating the condition for which it is intended.
- 3.151. An MA sets out the terms under which the marketing of a medicinal product is authorised within the UK. An MA must contain a summary of the product characteristics ('**SmPC**') and the labelling and package leaflet.²¹⁴ The SmPC is a document describing the properties and the officially approved conditions of use of a medicine. SmPCs form the basis of information for healthcare professionals on how to use the medicine safely and effectively.²¹⁵ Amongst other clinical particulars, an SmPC includes a list of therapeutic indications which define the target disease(s) or condition(s) for the medicine. The SmPC also states the age groups for which the product is indicated.²¹⁶

III. Orphan medicinal products and full and skinny label hydrocortisone tablets

a. The exclusivity given by an 'orphan designation'

- 3.152. Regulation 141/2000²¹⁷ of the European Parliament and of the Council (the '**Orphan Medicinal Products Regulation**') outlines the European Union

²¹³ A company may also obtain a parallel import licence from the MHRA, which allows a medicine authorised in another EU Member State to be marketed in the UK, as long as the imported product has no therapeutic difference to the same UK product.

²¹⁴ European Commission Health and Food Safety Directorate-General, *Notice to Applicants Volume 2A Procedures for marketing authorisation* (July 2015), section 2.1. Available at:

https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-2/a/vol2a_chap1_201507.pdf

The MHRA's *Drug Safety Update* of April 2009 'defines a medicine's terms of use: its Summary of Product Characteristics outlines, among other things, the indications(s), recommended dose(s), contraindications, and special warnings and precautions for use on which the license is based, and it is in line with such use that the benefits of the medicine have been judged to outweigh the potential risks'. See 'Off-label or unlicensed use of medicines: prescribers' responsibilities' in *Drug Safety Update* Vol.2 issue 9 (April 2009), pages 6-7. Available at: <https://webarchive.nationalarchives.gov.uk/20141206163936/http://www.mhra.gov.uk/home/groups/pl-p/documents/publication/con043810.pdf>

²¹⁵ European Medicines Agency definition of 'summary of product characteristics', available at:

www.ema.europa.eu/en/glossary/summary-product-characteristics

²¹⁶ European Commission, *A Guideline on Summary of Product Characteristics (SmPC)* (September 2009), section 4.1. Available at: https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf

²¹⁷ Regulation (EC) No 141/2000 of the European Parliament and of the Council (adopted on 16 December 1999 and entered into force on 28 April 2000). See also Community Regulation (EC) No 847/2000 of 27 April 2000, which entered into force on 28 April 2000, which laid down implementing rules and established definitions for Regulation (EC) No 141/2000. Further clarification was provided in the Communication from the Commission on Regulation (EC) No 141/2000 of the European Parliament and of the Council on orphan medicinal products (2003/C 178/02), adopted on 29 July 2003.

('EU') procedure for the designation of products as orphan medicinal products and provides incentives for their research, development and sale.

- 3.153. A medicinal product may obtain an 'orphan designation' where its supplier or manufacturer can demonstrate that it is intended for the diagnosis, prevention or treatment of life-threatening or very serious conditions, where:
- those conditions affect no more than 5 in 10,000 people in the EU; or
 - it would be unlikely that the product would generate returns justifying the required investment without incentives.²¹⁸
- 3.154. In either case, the supplier or manufacturer must also demonstrate either that:
- there is no pre-existing treatment for the condition; or
 - where a pre-existing treatment exists, the new product '*will be of significant benefit*' to those affected by the condition.²¹⁹
- 3.155. A '*significant benefit*' is defined in an implementing regulation, Regulation 847/2000, as '*a clinically relevant advantage or a major contribution to patient care*'.²²⁰
- 3.156. Where an MA is granted to a medicinal product with an orphan designation, the EU and the EU Member States shall not, for a period of ten years,²²¹ accept another application for an MA, or accept an application to extend an existing MA:
- for '*the same therapeutic indication*';²²²
 - in respect of '*a similar medicinal product*'.²²³

²¹⁸ Article 3 of the Orphan Medicinal Products Regulation. Recitals 1, 2 and 8 explain that orphan designations are intended to provide incentives for industry to invest in the development of drugs to treat conditions that occur so infrequently the cost would otherwise not be recouped.

²¹⁹ Article 3 of the Orphan Medicinal Products Regulation.

²²⁰ Article 3(2) of Regulation 847/2000.

²²¹ This period can be reduced to six years, if at the end of the fifth year, it is established that the medicinal product no longer meets the orphan designation criteria.

²²² Article 8(3) of the Orphan Medicinal Products Regulation specifies exceptions when an MA may be granted for the same therapeutic indication, including when the holder of the MA for the original orphan medicinal product has given consent to the applicant.

²²³ '*Similar medicinal product*' is defined in the implementing regulation 847/2000, Article 3(b), as '*a medicinal product containing a similar active substance of [sic: or] substances as contained in a currently authorised orphan medicinal product, and which is intended for the same therapeutic indication*'. '*Similar active substance*' in turn means, according to Article 3(c), '*an identical active substance, or an active substance with the same principal molecular structural features ... and which acts via the same mechanism*'.

- 3.157. An orphan designation therefore affords different protection from a patent. Whereas a patent usually protects the drug (the molecule and its formulation) itself, the orphan designation protects the relevant **therapeutic indication** of a drug: ie its **use**.

b. The orphan designation and MA granted to Plenadren

- 3.158. On 22 May 2006, the European Commission granted an orphan designation to DuoCort AB for modified release hydrocortisone tablets (5mg and 20mg), in respect of the therapeutic indication *'for the treatment of adrenal insufficiency'*.²²⁴ Since a pre-existing treatment for the condition (immediate release hydrocortisone tablets) existed, DuoCort was required to demonstrate that Plenadren would be *'of significant benefit'* to patients suffering from adrenal insufficiency – ie that it offered *'a clinically relevant advantage or a major contribution to patient care'* as compared to immediate release hydrocortisone tablets.²²⁵ This *'clinically relevant advantage'* was the modified release formulation, which mimics more closely the natural level of cortisol in the body over the course of a day than immediate release tablets.²²⁶
- 3.159. The orphan designation was subsequently transferred to DuoCort Pharma AB in November 2008 and to Viropharma SPRL in February 2012.²²⁷ In November 2013, Shire plc acquired ViroPharma Inc. and its group of companies, including the Plenadren portfolio. In February 2016, ViroPharma SPRL changed its name to Shire Services BVBA. In January 2019, Takeda Pharmaceutical Company Limited acquired Shire plc (including Plenadren).²²⁸

²²⁴ EU/3/06/372.

²²⁵ See also Article 3 of Regulation 847/2000, which requires those applying for orphan designation to submit detailed justifications showing how their product meets the conditions.

²²⁶ The European Medicines Agency (EMA) noted: *'The sponsor has provided sufficient information to show that hydrocortisone (modified release tablet) might be of potential significant benefit for the treatment of adrenal insufficiency, because it is designed to mimic more closely the natural level of cortisol in the body, which has a variable profile over the day. In particular, it may improve the early morning fatigues and the patient's compliance of the treatment since it would be a single administration per day. This assumption will have to be confirmed at the time of marketing authorisation, in order to maintain the orphan status.'* EMA public summary of opinion on orphan designation, EMA/COMP/137594/2006 Rev. 4, page 2. As the EMA stipulated, this assumption was confirmed at the time Plenadren obtained its MA, when the Committee for Orphan Medical Products (COMP) concluded that Plenadren continued to offer significant benefit over existing treatments. EMA recommendation for maintenance of orphan designation at the time of marketing authorisation, EMA/729720/2011. In March 2016, the COMP again concluded that Plenadren continued to provide *'Significant benefit over existing treatments ... because based on clinical data its once-daily modified release formulation produces benefits in terms of body fat, control of blood sugar, and aspects of patients' quality of life compared with existing treatments. This was considered a major contribution to patient care'*. ['COMP assesses whether Plenadren still meets orphan designation criteria', EMA/COMP/263073/2016, dated 28 April 2016.](#)

²²⁷ EMA 'Public summary of opinion on orphan designation', EMA/COMP/137594/2006 Rev.4, page 1.

²²⁸ [Takeda Completes Acquisition of Shire, Becoming a Global, Values-based, R&D-Driven Biopharmaceutical Leader](#). See also Plenadren listed as Takeda's product [here](#).

- 3.160. On 3 November 2011, the EMA granted a centralised European MA for Plenadren (5mg and 20mg) in respect of the therapeutic indication '*for treatment of adrenal insufficiency in adults*'.²²⁹
- 3.161. The grant of Plenadren's MA and the orphan designation granted to modified release hydrocortisone tablets triggered a 10-year period within which no **new** MAs would be granted and no extensions of existing MAs would be accepted for the therapeutic indication '*adrenal insufficiency in adults*' in respect of a '*similar medicinal product*'.^{230,231}
- c. The impact of the orphan designation on hydrocortisone tablets: full and skinny label MAs**
- 3.162. The orphan designation granted to Plenadren and subsequent granting of MAs for Plenadren (in November 2011) had an impact on MAs granted for immediate release hydrocortisone tablets, which are '*similar medicinal products*' to Plenadren.²³² It meant that only those MAs granted before Plenadren obtained its MAs could include the indication '*adrenal insufficiency in adults*'.
- 3.163. There were just three hydrocortisone tablets MAs granted before Plenadren obtained its MAs:
- a. the 10mg and 20mg MAs held by Auden; and
 - b. the 20mg MA held by Waymade.
- 3.164. Because they include the full range of indications, these MAs (and the products they cover) are referred to as 'full label'.
- 3.165. All other MAs for hydrocortisone tablets postdate the Plenadren MAs and therefore do not include the indication '*adrenal insufficiency in adults*'. These MAs (and the products they cover) are referred to as 'skinny label'.

²²⁹ EU/1/11/715. Plenadren is authorised in the EU for the treatment of adrenal insufficiency in adults.

²³⁰ Orphan market exclusivity for the treatment of adrenal insufficiency, based on EU/3/06/372, started on 14 November 2011 and will expire on 14 November 2021, see [community register of medical products for human use](#).

²³¹ The transition period implementing the UK's departure from the EU ended on 31 December 2020 and the Orphan Medicinal Products Regulation is therefore no longer directly applicable in the UK. From 1 January 2021, a holder of an MA for an EU orphan drug can submit a GB-wide MA application (but not a UK-wide one) to the MHRA. As far as the CMA is aware, no GB orphan MA was granted between January 2021 and the date of this Decision. No supplier of hydrocortisone tablets has been granted a full label MA between January 2021 and the date of this Decision. These post-transition period facts do not have any impact on the market and regulatory context during the duration of the Infringements, which all took place while the Orphan Medicinal Products Regulation was applicable in the UK.

²³² Document 00625, response to question 3, the MHRA's response to the CMA's section 26 notice dated 7 July 2016.

- 3.166. This was an unintended consequence of the orphan designation regime when applied to hydrocortisone tablets. The recitals to the Orphan Medicinal Products Regulation state that *'in the interest of patients, the market exclusivity granted to an orphan medicinal product should not prevent the marketing of a similar medicinal product which could be of significant benefit to those affected by the condition'*.²³³ In practice, however, this was the result of the orphan designation granted to Plenadren when applied between competing suppliers of hydrocortisone tablets.
- 3.167. As explained above, the orphan designation granted to Plenadren recognised its *'clinically relevant advantage'* over hydrocortisone tablets – namely its modified release formulation, compared to hydrocortisone tablets' immediate release formulation. This is a genuine clinical difference between Plenadren and hydrocortisone tablets, and this was the innovation rewarded by the exclusivity period.
- 3.168. However, there is no clinical difference between full label and skinny label hydrocortisone tablets. All immediate-release hydrocortisone tablets, whether full or skinny label, are bioequivalent and therefore therapeutically equivalent. It is important to distinguish between skinny label tablets and unlicensed medicines: unlicensed medicines do not have an MA (ie they have not been through the same regulatory approval process) and can only be used in exceptional circumstances, while skinny label tablets do have an MA and have been carefully assessed and subject to regulatory approval by the MHRA.²³⁴
- 3.169. When applied between competing suppliers of hydrocortisone tablets, the orphan designation granted to Plenadren therefore created a labelling distinction between suppliers' products that was entirely an arbitrary function of when the licence was granted. This is demonstrated by the fact that while Waymade by chance held a full label 20mg MA, when it obtained a 10mg MA from the MHRA in 2012 it was only granted a skinny label MA. This was despite the fact that Waymade's 10mg MA was a 'line extension' from its 20mg MA, meaning it was intended simply to be a different strength of the same product.²³⁵

²³³ Recital 8 of the Orphan Medicinal Products Regulation.

²³⁴ For instance, a 'special' is a medicine without an MA which is manufactured and supplied to meet a patient's special clinical need. Specials are a category of unlicensed medicines which are subject to their own separate guidance.

²³⁵ [Amdipharm Senior Employee] of Waymade stated in interview with the CMA: *'We argued that it [the MHRA's refusal to grant Waymade a full label 10mg MA] was a nonsense in any event because the 20mg tablet, the authorisation for which pre-dated the orphan indication, that had the full indications. The 10mg was just a line extension, same product, just half the strength, but with different indications; we said this is a nonsense and it was and I think it still is. But they [the MHRA] were adamant that their hands were tied.'* Document 200348, transcript of interview with [Amdipharm Senior Employee] dated 4 August 2016, page 14, lines 9-14.

- 3.170. The arbitrariness of the distinction between full and skinny label hydrocortisone tablets is further illustrated by the fact that following the entry of competing suppliers from 2015 onwards, pharmacies accounting for around 50% of total volumes of hydrocortisone tablets dispensed switched their business to skinny label tablets. See section 3.E.IV.c below.
- 3.171. However, the unintended consequences of the orphan designation when applied to hydrocortisone tablets are illustrated by the fact that pharmacies accounting for around the remaining 50% of total volumes did not switch to skinny label tablets. This left Auden/Actavis as their only potential supplier of 10mg hydrocortisone tablets. See section 3.E.IV.c below.

E. Supply and demand for hydrocortisone tablets

I. Pricing framework for hydrocortisone tablets

a. The PPRS

- 3.172. Until April 2008, hydrocortisone tablets were sold in the UK under the brand name '*Hydrocortone*' by the originator, MSD, and fell under the PPRS.
- 3.173. AM Pharma was not a member of the PPRS, although Accord-UK (which took over sales of hydrocortisone tablets from 1 September 2015) was a member. However, since the PPRS only applied to branded products, it did not apply to hydrocortisone tablets as Auden de-branded these in April 2008 (as explained in section 3.B.V above).

b. The Drug Tariff

- 3.174. The Drug Tariff is the primary mechanism for determining how dispensers are reimbursed. It is produced on a monthly basis by NHS Prescription Services²³⁶ and governs the reimbursement price that pharmacies can claim from the NHS when fulfilling prescriptions (the '**Drug Tariff price**'). The reimbursement that pharmacies can claim is the Drug Tariff price subject to

²³⁶ See www.nhsbsa.nhs.uk/prescriptionservices.aspx. The DHSC's responsibilities in relation to Part IX of the Drug Tariff extend only to England. The National Assembly for Wales operates a common policy with the DHSC and therefore the Drug Tariff currently covers both England and Wales. Arrangements regarding Scotland and Northern Ireland are unchanged and both countries continue to maintain and publish separate Drug Tariffs. Part VII of the Scottish Drug Tariff is based on that used by the DHSC for Category M of the English Drug Tariff. This means that the English Category M price list is used in Scotland. See *Cost of relevant comparators* in the Detailed Advice from the Scottish Medicines Consortium (available at: www.scottishmedicines.org.uk/Submission_Process/Submission_guidance_and_forms/Templates-Guidance-for-Submission/Templates-Guidance-for-Submission).

any price concessions agreed between the DHSC and the Pharmaceutical Services Negotiating Committee²³⁷ (the '**NHS Reimbursement Price**').²³⁸

- 3.175. The Drug Tariff provides that a dispenser is reimbursed for medicines dispensed at a 'basic price' (less any clawback discount).²³⁹
- 3.176. From 21 April 2008, hydrocortisone tablets fell under Part VIIIA of the Drug Tariff.²⁴⁰
- 3.177. Medicines listed in Part VIIIA of the Drug Tariff fell into one of three different categories which determined how the Drug Tariff price was calculated:²⁴¹
- a. **Category A:** Prices were based on the list price (that is, the supplier's price before customer-specific discounts) of commonly used generics that are typically readily available from several sources. The price of a drug within Category A was set using a weighted average of prices from a basket of two wholesalers and up to three generic manufacturers. There was a minimum requirement that products in Category A were listed by either:
 - i. two wholesalers; or
 - ii. one wholesaler and two manufacturers.
 - b. **Category C:** This typically applied when a product was only available as a branded product or as a generic product from one or two sources. The price of a drug within Category C was based on a list price for a particular proprietary product, manufacturer or supplier.
 - c. **Category M:** This typically applied to commonly used generics that were available from several sources. A drug was eligible for inclusion in Category M if it was a generic drug which was readily available in the given presentation (ie made by more than one Scheme M manufacturer) and met one of the following conditions:

²³⁷ Document 00869, NHS BSA's supplementary response to the CMA's section 26 notice dated 28 June 2016.

²³⁸ For the purposes of the CMA's assessment, the NHS Reimbursement Price also includes the PPRS list price of Hydrocortone, prior to generic Hydrocortisone Tablets falling under the Drug Tariff.

²³⁹ Pharmacies can buy some medicines cheaper than the Drug Tariff price. As such, the NHS applies a discount to pharmacies' payments. This discount is often referred to as 'clawback' and was designed to share with the NHS the profits pharmacies can make by purchasing medicines at below the price at which they are reimbursed.

²⁴⁰ On 21 April 2008, Auden introduced a generic version of hydrocortisone tablets and discontinued the Hydrocortone brand. Document 00618, responses to questions 2 and 3, DHSC's response to the CMA's section 26 notice dated 6 July 2016.

²⁴¹ See DHSC, Guidance Notes with regards to the Drug Tariff.

- i. its annual net ingredient cost was at least £1,000,000 and its annual (dispensed) volume was at least 50,000 items; or
 - ii. its annual dispensed volume was at least 200,000 prescription items.²⁴²
- 3.178. The price of a drug within Category M was set using a weighted average from retrospective sales values (net of customer-specific discounts) and volume data supplied to the DHSC by manufacturers (during the Infringements, under Scheme M (see further below)). These prices were then adjusted by a formula to ensure that pharmacy contractors retained the profit margin agreed as part of the funding of the community pharmacy contractual framework. With respect to hydrocortisone tablets, the reimbursement price of Category M drugs was calculated by the DHSC and during the Infringements was based on a weighted average of data provided by Scheme M members.
- 3.179. Until June 2014, 10mg hydrocortisone tablets fell under Category A of the Drug Tariff. The Drug Tariff price for 10mg tablets was therefore determined by AM Pharma's, AAH and Alliance's list prices.
- 3.180. From July 2014, 10mg hydrocortisone tablets moved to Category M. AM Pharma was not a Scheme M member.²⁴³ The Drug Tariff price was set using data supplied by Scheme M members.²⁴⁴ Accord-UK – which took over sales of hydrocortisone tablets from AM Pharma from 1 September 2015 onwards – was a Scheme M member since its inception, effective from April 2005.²⁴⁵ Accordingly, from October 2015 Actavis's sales entered the Drug Tariff calculations for 10mg hydrocortisone tablets.²⁴⁶ Although competing suppliers began to enter from October 2015 onwards, during the Infringements their sales were only included in the Drug Tariff calculations for 10mg hydrocortisone tablets if they were Scheme M members:
- a. Although independent entry with 10mg tablets first occurred with Alissa in October 2015, followed by Bristol Laboratories and Resolution Chemicals in March 2016, it was only when AMCo (a Scheme M member) entered in May 2016 that another supplier's prices were included in the Category M price calculations. Until February 2017, only

²⁴² Document 01987.B, slide 5, DHSC's response to the CMA's section 26 notice dated 19 September 2017.

²⁴³ Document 00733, paragraph 2.2, AM Pharma/Accord-UK's response to the CMA's section 26 notice dated 18 October 2016.

²⁴⁴ Document 02195, data provided by the DHSC: 'Scheme M&W data for CMA case 50277-1'.

²⁴⁵ Document 00733, paragraph 2.1, AM Pharma/Accord-UK's response to the CMA's section 26 notice dated 18 October 2016.

²⁴⁶ Document 02664.E, response to question 1, DHSC's response to the CMA's section 26 notice dated 16 January 2018.

Actavis's and AMCo's prices were included in the Category M price calculations.

- b. In February 2017, Teva (also a Scheme M member) started selling 10mg tablets and its prices were also included in the Category M price calculations.
- c. In November 2017, Genesis Pharmaceuticals (also a Scheme M member) started selling 10mg tablets and its prices were included in the Category M price calculations.

3.181. As a result, in December 2017, the Category M Drug Tariff price was based on the sales of 10mg hydrocortisone tablets by the following Scheme M members: Actavis, AMCo,²⁴⁷ Teva and Genesis Pharmaceuticals Limited.²⁴⁸ The sales of other competitors were not included in the Drug Tariff price calculations for 10mg hydrocortisone tablets because they were not Scheme M members.

3.182. 20mg hydrocortisone tablets were in Category A of the Drug Tariff from the time they were de-branded by Auden in April 2008 and throughout the Infringements. The Drug Tariff for 20mg hydrocortisone tablets was until June 2019 based on the list prices of AAH, Alliance, and Actavis, with AAH and Alliance given a double weight. Since the Category A reimbursement price was based on list prices, it did not take into account customer-specific discounts such as rebates (in contrast to Category M).²⁴⁹ The Drug Tariff price for 20mg hydrocortisone tablets therefore was determined ultimately by Auden's, and later Actavis's, list price.

3.183. In June 2019, after the Infringements ended, 20mg hydrocortisone tablets were moved to Category M of the Drug Tariff. Following the termination of Scheme M on 30 June 2019 (see the following section), all suppliers' prices are now taken into account in the Category M price calculations.

c. Scheme M

3.184. During the Infringements, Scheme M was a voluntary scheme between the Secretary of State for Health and Social Care and the BGMA, as the representative body for the generics industry. It applied to those

²⁴⁷ With both Aesica and Focus products.

²⁴⁸ Mylan, which supplied Resolution Chemicals' Hydrocortisone Tablets (see Document 02836.B, response to question 3, Mylan's response to the CMA's section 26 notice dated 19 February 2018), was excluded from the average price calculations for Category M Drug Tariff: Document 02664.E, response to question 1, DHSC's response to the CMA's section 26 notice dated 16 January 2018.

²⁴⁹ List prices are the starting point for price negotiations and may not represent the actual price paid by customers.

manufacturers and suppliers of generic medicines for use in the NHS who chose to join it.²⁵⁰

- 3.185. As explained above, the DHSC used the retrospective sales and volume data supplied to it by Scheme M members to set the reimbursement prices for drugs in Category M, taking into account the agreed retained margin for community pharmacists.
- 3.186. Scheme M allowed its members to alter the price at which a medicine was sold to wholesalers or dispensing contractors without any requirement to discuss such changes with the DHSC in advance. The intention was that competition would restrain suppliers' pricing, consistently with the DHSC's policy that competition is the most effective 'regulator' of generic drug prices.²⁵¹
- 3.187. The Scheme M arrangements did, however, include a paragraph which stated that the DHSC '*may intervene to ensure that the NHS pays a reasonable price for the medicine(s) concerned*' if it identified '*any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure*'.²⁵² They also provided that a Scheme M member may be required to provide on reasonable request information regarding costs and/or profit margins.²⁵³ In the DHSC's examination of the reasonableness of the member's costs and prices, Scheme M also provided that the DHSC would have regard to a number of relevant factors which were listed in the arrangements.²⁵⁴
- 3.188. Since Scheme M was voluntary, a Scheme M member was free to withdraw from the Scheme M arrangements at any time.²⁵⁵
- 3.189. In June 2018, the DHSC gave notice of its intention to end Scheme M and replace it with new information regulations.²⁵⁶ Scheme M expired on 30 June

²⁵⁰ Sections 261(2) and 266(6) NHS Act 2006; and DHSC publication: '*Revised long-term arrangements for reimbursement of generic medicines*' (March 2010), paragraph 4.

²⁵¹ See report '*The Community Pharmacy Contractual Framework and the retained medicine margin*' dated 30 March 2010, paragraph 12.

²⁵² DHSC – Revised long-term arrangements for reimbursement of generic medicines. Scheme M. March 2010, paragraph 30.

²⁵³ DHSC – Revised long-term arrangements for reimbursement of generic medicines. Scheme M. March 2010, paragraph 31.

²⁵⁴ DHSC – Revised long-term arrangements for reimbursement of generic medicines. Scheme M. March 2010, paragraph 32. These included trends in the member's and other companies' prices for the product; any special features of the member's operation; any ratios inferred from the member's non-generics business; each member's reported costs and profit margins and the average of other similar companies; and information from external sources relating to the generics industry.

²⁵⁵ DHSC – Revised long-term arrangements for reimbursement of generic medicines. Scheme M. March 2010, paragraph 44. It would do so by withdrawing consent for the voluntary Scheme to be treated as applying to it.

²⁵⁶ See DHSC, '*Legal requirements to provide information about health service products: consultation response*', June 2018, paragraphs 1.1 to 1.5 (available at:

2019 and pricing information is now collected from all suppliers under the Health Service Products (Provision and Disclosure of Information) Regulations 2018, which also provide for quarterly submissions of information to the DHSC.

d. The Secretary of State's powers to intervene in prices

- 3.190. The Secretary of State also has certain powers to monitor and intervene in drug pricing in specific circumstances. These powers are set out in sections 261 to 266 of the NHS Act 2006 (as amended) (the '**NHS Act**'). The Secretary of State's role is discharged through the DHSC, and so this section will refer to the DHSC.
- 3.191. Section 261 of the NHS Act grants the DHSC the power to enter into voluntary schemes with industry members (such as the PPRS) for the purpose of controlling the cost of pharmaceutical medicines.
- 3.192. In addition, sections 262 and 263 of the NHS Act grant the Secretary of State the power – after consulting the relevant industry body – to:
- a. limit the price charged by a manufacturer or supplier for the supply of a health service medicine (section 262(1)) (the '**Reserve Power**'); and
 - b. introduce an industry-wide statutory scheme to control the price of medicines not covered by a voluntary scheme (section 263(1)) (the '**Statutory Scheme**').
- 3.193. The Statutory Scheme that was in force during the Infringements only applied to branded medicines.²⁵⁷ As hydrocortisone tablets have been de-branded since April 2008, the Statutory Scheme is not relevant.
- 3.194. Many generic medicines were supplied by licence holders who were also members of a voluntary scheme (for example, during the Infringements, the PPRS). Until 7 August 2017, these medicines were exempt from statutory price controls under section 262 of the NHS Act.²⁵⁸ Until that date, only if the

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/714355/Information_regulations_consultation_response.pdf

²⁵⁷ The Statutory Scheme consisted of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No. 2) Regulations 2008 and the Health Service Medicines (Information Relating to Sales of Branded Medicines etc) Regulations 2007, as amended (together the '**Health Service Medicines Regulations**'). The Health Service Medicines Regulations imposed price controls on and reporting obligations relating to 'presentations', defined as particular forms of medicines that are both prescription-only and traded under a specific name. They were superseded on 1 April 2018 by the Branded Health Service Medicines (Costs) Regulations 2018.

²⁵⁸ Section 262(2) NHS Act provided that the Reserve Power was '*not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies*'.

licence holder was not a member of any voluntary scheme could the generic medicines it sold potentially be subject to the Reserve Power.

3.195. This regulatory framework meant that:

- a. The Reserve Power was available to the DHSC in relation to Auden's hydrocortisone tablets until 31 August 2015. AM Pharma was not a member of any voluntary scheme.
- b. From 1 September 2015 until 6 August 2017, Actavis's hydrocortisone tablets were exempt from the Reserve Power as Accord-UK was a member of the PPRS.

3.196. The regulatory framework was amended from 7 August 2017.

3.197. On 7 August 2017, the Health Service Medical Suppliers (Costs) Act 2017 (the '**Costs Act**') entered into force.²⁵⁹

3.198. The Costs Act changed the UK's pharmaceutical price regulation framework in several respects. These included:

- a. making drugs outside a voluntary scheme subject to the potential for intervention under the Reserve Power, even if the licence holder is a member of a voluntary scheme;²⁶⁰ and
- b. allowing for regulations requiring licence holders to provide cost and other financial information to the DHSC upon request.²⁶¹

3.199. During the passage through Parliament of the Costs Act, the Secretary of State for Health stated that the key reasons for introducing it were to:

- a. remedy the fact that the Government's existing powers did not allow it to place price controls on unbranded generic medicines where a company was a member of the PPRS; and
- b. prevent such firms from being able to exploit such freedom of pricing for unbranded generic medicines where there is no competition in the market.²⁶²

²⁵⁹ By virtue of the Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017.

²⁶⁰ Section 4 of the Costs Act amended section 262(2) to state that '*If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier as regards that medicine*' (emphasis added).

²⁶¹ Section 8 of the Act inserted a new section 264A into the NHS Act, allowing for such regulations for purposes including '*the exercise by the Secretary of State of any powers under section 260 to 264 and 265*'.

²⁶² See [Health Service Medical Supplies \(Costs\) Bill - Monday 24 October 2016 - Hansard - UK Parliament](#)

- 3.200. The Secretary of State also set out that another element of the Costs Act was to strengthen the Government's powers to gather information for determining value for money and controlling prices by enabling:

'the Government to put the current voluntary arrangements for data provision with manufacturers and wholesalers of unbranded generic medicines and manufactured specials on a statutory footing. As the arrangements are currently voluntary, they do not cover all products and companies, which limits the robustness of the reimbursement price setting mechanism'.²⁶³

- 3.201. As a result of the Costs Act, the Reserve Power was from 7 August 2017 available once more to the DHSC in relation to Actavis's hydrocortisone tablets.²⁶⁴

- 3.202. Further regulations came into force in 2018, giving the DHSC supporting powers.²⁶⁵

II. The supply chain for hydrocortisone tablets in the UK

a. Suppliers of hydrocortisone tablets

- 3.203. As explained in section 3.D.II above, generally, to market and sell a pharmaceutical product, a company must obtain an MA.
- 3.204. Tables 3.4 and 3.5 below list the companies that have been granted or have acquired MAs to supply 10mg and 20mg hydrocortisone tablets in the UK, when they obtained their MAs and when they started supplying in the UK.

²⁶³ See [Health Service Medical Supplies \(Costs\) Bill - Monday 24 October 2016 - Hansard - UK Parliament](#)

²⁶⁴ On 7 August 2017, the Health Act 1999 (Commencement No 17) Order 2017 also brought into force an additional power, under section 261(8) NHS Act. This allows for the Secretary of State to prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price charged by him for the supply of any health service medicine covered by the scheme.

²⁶⁵ On 11 April 2018, under Regulation 2 and the Schedule to the Health Service Medicines (Price Control Penalties and Price Control Appeals Amendment) Regulations 2018, the DHSC was given the power to impose daily financial penalties (up to £10,000 per day) for non-compliance with its directions to limit prices. On 1 July 2018, under the Health Service Products (Provision and Disclosure of Information) Regulations 2018 and the new section 264A of the NHS Act, the DHSC was given supporting information-gathering powers, allowing it to require producers to provide information on manufacturing, supply and distribution costs (Regulations 25 and 26); and impose daily financial penalties for non-compliance with these requirements (Regulation 32).

Table 3.4: Companies that have been granted 10mg MAs to supply hydrocortisone tablets in the UK and dates they started supply²⁶⁶

Name of company	Type of tablet	Date MAs granted	Date supply started
Auden/Actavis	Full	23 February 1989	April 2008
Alissa Healthcare	Skinny	25 November 2014	October 2015
Bristol Laboratories	Skinny	12 January 2016	March 2016
Resolution Chemicals	Skinny	1 March 2016	March 2016
AMCo (Aesica)	Skinny	27 September 2012	May 2016
Teva	Skinny	29 November 2016	February 2017
AMCo (Focus)	Skinny	10 October 2016	October 2017
Genesis Pharmaceuticals	Skinny	1 June 2017	November 2017
Renata	Skinny	14 August 2017	February 2019

Table 3.5: Companies that have been granted 20mg MAs to supply hydrocortisone tablets in the UK and dates they started supply²⁶⁷

Name of company	Type of tablet	Date MAs granted	Date supply started
Auden/Actavis	Full	23 February 1989	April 2008
Waymade	Full	11 May 1987	July 2015
Bristol Laboratories	Skinny	12 January 2016	March 2016
Resolution Chemicals	Skinny	1 March 2016	March 2016
Teva	Skinny	29 November 2016	February 2017
AMCo (Focus)	Skinny	10 October 2016	August 2017
Genesis Pharmaceuticals	Skinny	1 June 2017	November 2017
Renata	Skinny	14 August 2017	February 2019

²⁶⁶ See Document 00623, Document 01625, Document 01626 and Document 02703.E, lists of hydrocortisone manufacturers, suppliers and distributors provided by the MHRA on 22 February 2016, 25 August 2016, 1 June 2017 and 22 February 2018. See also Document 00639, Auden's response to the CMA's section 26 notice dated 18 March 2016; Document 01646, Teva's response to the CMA's section 26 notice dated 1 June 2017; Document 03893, Renata's response to the CMA's section 26 notice dated 25 June 2019; Document 00618, DHSC's response to the CMA's section 26 notice dated 6 July 2016; Document 02249, Genesis Pharmaceutical's response to the CMA's section 26 notice dated 15 January 2018 and Document 206657, Focus and Amdipharm's Hydrocortisone Tablet Sales data.

²⁶⁷ See Document 00623, Document 01625, Document 01626 and Document 02703.E, lists of hydrocortisone manufacturers, suppliers and distributors provided by the MHRA on 22 February 2016, 25 August 2016, 1 June 2017 and 22 February 2018. See also Document 00639, Auden's response to the CMA's section 26 notice dated 18 March 2016; Document 01646, Teva's response to the CMA's section 26 notice dated 1 June 2017;

- 3.205. A company which holds an MA may either manufacture the pharmaceutical product itself or contract with a third-party contract manufacturing organisation ('**CMO**') to manufacture the pharmaceutical product on its behalf. The company which holds an MA is primarily responsible for ensuring the drug complies with its licence and other applicable legislation, rather than a third-party manufacturer. However, a third-party manufacturer may, for example, have contractual liabilities to the holder of an MA.
- 3.206. In the case of hydrocortisone tablets, Aesica was both Waymade's and AMCo's CMO while Tiofarma was Auden's CMO. They explained their role as follows:
- a. Aesica explained that as a CMO it serves '*pharmaceutical firms with active pharmaceutical ingredient ("API") and finished dose formulation development and manufacturing services*'. It further explained that '*[p]harmaceutical firms outsource their requirements to Aesica; Aesica does not act like an originator firm with its own research and development programmes, launching new products on to the marketplace, nor like a generic firm seeking to market patent-expired originator products and/or challenging the validity of existing originator patent products*' (such as Auden, AMCo or Waymade). Also, as a CMO, Aesica '*does not actively seek new customers for individual products, including Hydrocortisone Tablets. Instead Aesica markets itself to pharmaceutical firms as competent in developing and manufacturing API and finished dosages in general*'.²⁶⁸
 - b. Tiofarma explained that as a CMO, it '*can manufacture Hydrocortisone Tablets for holders of Marketing Authorization ("MA") for Hydrocortisone Tablets. [...] Tiofarma's business model is simple: it offers formulation and manufacturing services to the holders of MAs. It manufactures their products in a manner that is consistent with their MA (Product License)*' and is required to '*hold a GMP [Good Manufacturing Practice] license*' for such purposes. Tiofarma emphasised that it '*can only contract manufacture for MA holders. Tiofarma can only start supplying commercial batches of Hydrocortisone tablets to an MA holder if Tiofarma is named as a CMO in that particular MA*'. In relation to supplying Auden, Tiofarma

Document 03893, Renata's response to the CMA's section 26 notice dated 25 June 2019; Document 00618, DHSC's response to the CMA's section 26 notice dated 6 July 2016; Document 02249, Genesis Pharmaceutical's response to the CMA's section 26 notice dated 15 January 2018 and Document 206657, Focus and Amdipharm's Hydrocortisone Tablet Sales data.

²⁶⁸ Document 200292, Consort Medical's (Aesica) response to the CMA's section 26 notice dated 15 June 2016, replies to questions 1 and 2.

explained that it *'manufactures Hydrocortisone Tablets using the formulation in Auden McKenzie's dossier (and its underlying IP and exclusive data). Tiofarma does not have the right to develop a new formulation of Hydrocortisone Tablets for the UK market that is based on the formulation owned by Auden Mckenzie'*.²⁶⁹ The manufacturing agreement between Auden and Tiofarma set out that Tiofarma's role under the agreement was that of '[X]'.²⁷⁰

b. Distribution of pharmaceutical products: the different routes to market

3.207. There are different routes through which pharmaceuticals from manufacturers (or MA holders) reach downstream customers and patients. For example, a manufacturer (or MA holder) can sell its products directly to pharmacies, sometimes using a third-party logistics provider, or can sell to a wholesaler which contracts with pharmacies directly. In the UK, most pharmaceutical products are distributed through wholesalers to pharmacies.²⁷¹

3.208. Depending on the route to market, different types of intermediaries may be involved:²⁷²

- a. Pre-wholesalers: These offer logistical services to pharmaceutical manufacturers (mainly storage and transportation of pharmaceutical products from the manufacturer to wholesalers, hospitals and, in some instances, to pharmacies). Pre-wholesaling services differ from wholesaling in that they are services provided to the manufacturers and do not concern the purchase and sale of pharmaceuticals.²⁷³ Examples of pre-wholesalers are Alloga or Unidrug (UDG):²⁷⁴ both companies provided pre-wholesaling services to AMCo (as did Waymade for 10mg hydrocortisone tablets, up until 31 October 2014) (Waymade also

²⁶⁹ Document 00452, Tiofarma's response to the CMA's section 26 notice dated 4 April 2016, replies to questions 1, 3, 4, 12a and 14.

²⁷⁰ Document 00416, Manufacturing Agreement between Tiofarma and Auden signed on 14 November 2014. See clause 20.

²⁷¹ *A report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business*, 29 July 2016, paragraph 13. See [A report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business \(publishing.service.gov.uk\)](#).

²⁷² *Completed acquisition by AAH Pharmaceuticals Limited of Medical Advisory Services for Travellers Abroad Limited and Sangers (Northern Ireland) Limited*, 29 June 2016, paragraph 27. See [Full text of the decision - AAH/Sangers \(publishing.service.gov.uk\)](#).

²⁷³ See also Document 300236, *European Pharmaceutical Distribution: Key Players, Challenges and Future Strategies* by Scrip Reports. Page 12: 'Prewholesaling is logistics outsourcing, encompassing activities undertaken after the main manufacturing processes before the company sells the stock. At its most basic it covers the provision of product storage, in place of a manufacturer's own finished goods store, and distribution services to wholesalers' warehouses'.

²⁷⁴ See Document 300236, 'European Pharmaceutical Distribution: Key Players, Challenges and Future Strategies' by Scrip Reports. Page 33. See also Document 00656, Auden's response to the CMA's section 26 notice dated 23 May 2016, paragraph 13.3. Auden defined pre-wholesalers as logistics providers and gave DHL as an example.

provided pre-wholesaling services to AMCo for 10mg hydrocortisone tablets, until 31 October 2014).²⁷⁵

- b. Pharmaceutical wholesalers, which include:
 - i. full-line wholesalers: these offer a full range of pharmaceutical product lines (over 12,000 product lines) and offer twice daily delivery to the majority of customers for products that are not typically kept in stock by pharmacies. Examples of full-line wholesalers are AAH, Alliance and Phoenix, who are vertically integrated with their own multiple pharmacy chain (Lloyds, Boots and Well Pharmacy, respectively); and
 - ii. short-line wholesalers: these offer a smaller range of pharmaceutical product lines (around 3,000 lines) and typically operate on a next-day courier delivery basis. Typically, these are fast moving product lines and generics that sell in large quantities that do not necessarily require frequent deliveries to pharmacies. Examples of short-line wholesalers are DE Pharmaceuticals ('**DE Pharma**'), Mawdsley-Brooks ('**Mawdsleys**') and Sigma Pharmaceuticals ('**Sigma**').
- c. Parallel importers: this involves the purchase of pharmaceuticals (typically, branded) from abroad which may need re-packaging for sale in the UK because of language differences.
- d. Direct supply from manufacturers (or MA holders): this involves the direct distribution of pharmaceutical products by manufacturers to pharmacies (with delivery typically through an agency agreement).

3.209. AMCo, Auden and Waymade, in their capacity as MA holders, explained their business models and routes to market as follows:

- a. AMCo explained to the CMA in April 2016 that it had '*a streamlined distribution model in the UK in which products are shipped from the relevant contract manufacturer directly to a pre-wholesale distributor. The products are then ordered from this prewholesale distributor by a number of chosen wholesalers.*²⁷⁶ Similarly, AMCo explained that its subsidiary, Focus, '*has an asset light business with outsourced product development and manufacturing (much like many UK generics companies, as well as Concordia itself). Focus therefore identifies*

²⁷⁵ See Document 00444, AMCo's response to the CMA's section 26 notice dated 8 March 2016, reply to question 8.

²⁷⁶ Document 00444, AMCo's response to the CMA's section 26 notice dated 8 March 2016, reply to question 7.

*products of interest and, after research and negotiation, partners with third parties who assist Focus with product development and manufacturing’.*²⁷⁷

- b. Auden explained that, generally, *‘[t]he product is made according to a particular formulation described in the marketing authorisation and must be made at sites approved in the marketing authorisation. These sites could be the site of the marketing authorisation holder or a manufacturer. If the latter, i.e. the manufacturer is not the marketing authorisation holder (as is the case for Hydrocortisone Tablets with Tiofarma being the manufacturer), [...] the product is shipped from the manufacturer’s site to the marketing authorisation holder’s depot/warehouse or a nominated depot/warehouse (e.g. the pre-wholesale storage site). Accordingly, Auden Mckenzie obtains Hydrocortisone Tablets (in packaged form) from its contract manufacturer, Tiofarma and the tablets are delivered by Tiofarma to Auden Mckenzie’s nominated warehouses’.* In terms of road to market, Auden explained that *‘[g]eneric manufacturers/distributors receive orders from customers, who are typically wholesalers (including both full-line and short-line wholesalers) but will also include certain larger pharmacies and hospitals. Logistics suppliers (or pre-wholesalers) are then used to supply the product to the customer (whether wholesaler, pharmacy or hospital). Auden uses a pre-wholesaler (such as DHL or another logistics provider) to deliver the product to the wholesaler’s depots or direct to the pharmacy/hospital. Wholesalers then fulfil orders from their customers, which may include vertically integrated pharmacies/retail chains, hospitals, dispensing doctors or independent pharmacies’.*²⁷⁸
- c. Waymade’s business model was somewhat different from AMCo and Auden’s insofar it operated as both an MA holder and a short-line wholesaler up until 1 January 2015, when it disposed of its distribution and parallel import business. Waymade explained that *‘during the period from 1 January 2010 to 1 January 2015’* its primary function *‘was carrying on a parallel imports business and acting as what is known as a “short-line” wholesaler in supplying pharmaceutical products. It would acquire pharmaceutical products from manufacturers and sell them to a customer base of several thousand entities, most of which were retail pharmacists. Waymade also held MAs to various drugs as part of its Sovereign Generics business’* which included *‘the manufacture,*

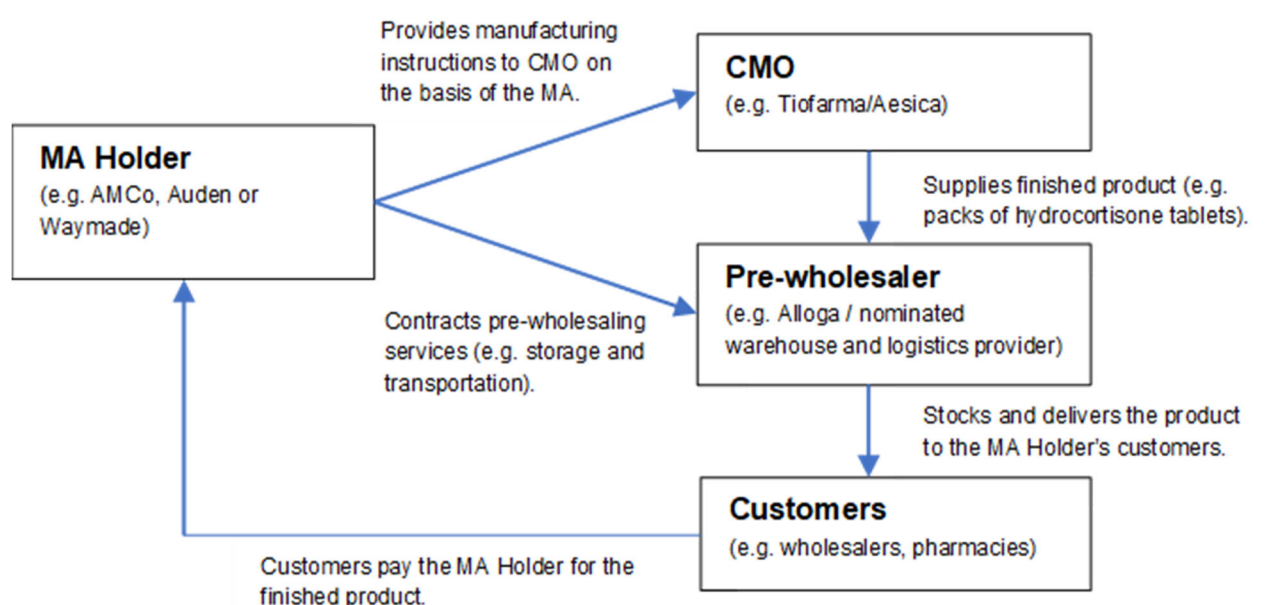
²⁷⁷ Document 02662, AMCo’s response to the CMA’s section 26 notice dated 25 January 2018, reply to question 5.b.

²⁷⁸ Document 00656, Auden’s response to the CMA’s section 26 dated 23 May 2016, reply to question 13.

marketing and distribution internationally of a substantial portfolio of off-patent, branded, pharmaceuticals. Waymade specified that, in its position as a MA holder, it *'supplies its own 20mg hydrocortisone tablets in the UK to wholesalers'* through its Sovereign Generics business and that *'[t]he tablets are produced by Aesica for Waymade'*.²⁷⁹

3.210. Figure 3.6 summarises AMCo, Auden and Waymade's road-to-market in their position as MA holders for hydrocortisone tablets:

Figure 3.6: AMCo, Auden and Waymade's road to market as MA holders for hydrocortisone tablets



3.211. In essence, with respect to hydrocortisone tablets, AMCo, Auden and Waymade's business model consisted of outsourcing the main elements of the supply chain (ie the manufacture, distribution and commercialisation of their hydrocortisone tablets) and setting the price of their product for sale to final customers; a business model which is described as 'virtual' by both Auden and Cinven.²⁸⁰

²⁷⁹ Document 200003, Waymade's response to the CMA's section 26 notice of 5 May 2016, paragraphs 8, 16 and 3.2.

²⁸⁰ Auden's 'business model is relatively straightforward and "virtual" with manufacturing and distribution outsourced and sales channels through large distributors'. Like Auden, AMCo was described by Cinven as having 'a purely virtual business model', with no in-house manufacturing or distribution. See Document 00681, Project Apple due diligence report dated 11 December 2014, pages 7, 10 and 19; and Document LIO6492.6, AMCo Q3 Portfolio Review Committee paper dated September 2013, page 4.

c. Customers

- 3.212. At the end of the supply chain are retail pharmacies, dispensing doctors and hospitals which source hydrocortisone tablets either directly from a supplier or through a wholesaler.²⁸¹ Retail pharmacies make up the largest customer group.²⁸²
- 3.213. The purchase price paid by a pharmacy for hydrocortisone tablets is determined following negotiation between the pharmacy and the relevant supplier or wholesaler. Pharmacies then receive a payment for the prescriptions they fulfil from CCGs. As explained in section 3.E.I.b above, the amount that pharmacies receive is specified in the Drug Tariff.²⁸³
- 3.214. In 2016/2017 there were 11,699 community pharmacies, of which 4,434 were independent, in the UK.²⁸⁴ The largest pharmacy groups were: Boots (a subsidiary of Alliance), Lloyds (a subsidiary of AAH) , Rowlands, Superdrug and Well Pharmacy (a subsidiary of Bestway). In 2015, these pharmacy groups together held around 44% of the retail pharmacy market.²⁸⁵ Boots was the largest single chain, with the highest market share.²⁸⁶

III. Prescribing and dispensing of hydrocortisone tablets

- 3.215. Hydrocortisone tablets are not available for purchase over the counter. They need to be prescribed to patients by a GP or other qualified healthcare professional, once they have first been assessed by a specialist.
- 3.216. Prescription-only medicines such as hydrocortisone tablets are characterised by certain features that impact upon the prescribing and dispensing decisions of healthcare professionals and pharmacies:

²⁸¹ European Commission decision in Case M.7818 - MCKESSON / UDG HEALTHCARE (Pharmaceutical Wholesale and Associated Businesses) of 3 March 2016, paragraph 15.

²⁸² See Document 300236, *European Pharmaceutical Distribution: Key Players, Challenges and Future Strategies* by Scrip Reports. Page 16. Community pharmacies accounted for 82% of all sales of medicines in the UK in 2006. See also the European Healthcare Distribution Association's annual report for 2016/17, slide 10. Access: [girp annual report 2016-2017.pdf](#).

²⁸³ The NHS Reimbursement Price is produced on a monthly basis by NHS Prescription Services. See [NHS Prescription Services | NHSBSA](#). These prices relate to England. NHS Reimbursement Price data is not available on a monthly basis for the whole of the UK.

²⁸⁴ Data for England only. General Pharmaceutical Services in England 2007/2008 to 2016/2017. [General Pharmaceutical Services in England 2007/2008 to 2016/2017 - NHS Digital](#). Community pharmacies were known as chemists in the past. They are pharmacies that deal directly with people in their local area. Community pharmacy contractors who own five or less pharmacies are known as 'independents'.

²⁸⁵ Based on number of pharmacy licences – see *A report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business*, 29 July 2016, paragraph 2.8.

²⁸⁶ *A report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business*, 29 July 2016, paragraph 2.8. See [A report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business \(publishing.service.gov.uk\)](#). In 2013, Auden's market share estimates were: Boots (20%), Lloyds (13%), Coop (Well Pharmacy) (7%), Drs (7%), Rowlands (4%), Tesco (2%), other multiple groups (8%) and independents (39%). See Document 00036, Auden's 'Independent Seven scheme' attached to Document 00035, email from [Auden Senior Employee 2] to [X] dated 27 August 2013.

- a. Healthcare professionals select the most therapeutically appropriate and effective medicine to prescribe to a patient. Neither the patient nor the healthcare professional is particularly price-sensitive since they do not pay for the product. The NHS typically pays for the medicine.
- b. Once a patient is established on a particular treatment, there are often significant medical reasons why it is disadvantageous to alter their medication. There is, for example, an increased likelihood of adverse metabolic side effects for patients who are established on hydrocortisone tablets who then transfer to another drug, such as prednisolone.²⁸⁷ There may be additional costs associated with altering a patient's medication, including further healthcare professionals' (usually a specialist's) time in effecting a switch, associated patient confusion and/or unwillingness to change, as well as potential increased costs for the NHS if therapeutic failure occurs. Accordingly, a decision to switch a patient with adrenal insufficiency away from hydrocortisone tablets (or commence treatment with a medicine other than hydrocortisone tablets) would need to be made by an endocrinologist and would only be done in rare instances when a patient is not able to tolerate hydrocortisone tablets.²⁸⁸
- c. The ability of the dispenser (typically a pharmacy) to decide which medicine to dispense is limited by the prescriber's decision (see paragraphs 3.63 to 3.64 above). Within the parameters of the prescription, the dispenser would typically be expected to choose the cheapest version of the medicine since it pays for the drug and will be reimbursed by the NHS at a fixed level. This means dispensing the cheapest version of the drug maximises the pharmacy's profit margin (see paragraphs 3.69 to 3.70 above).

a. Prescribing

- 3.217. The overwhelming majority of prescriptions for hydrocortisone tablets are open, specifying only the generic name and strength²⁸⁹ without reference to supplier or manufacturer. The particular condition of the patient is also

²⁸⁷ Document 00603, response to question 9, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

²⁸⁸ Document 02046.B, note of call between CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 7.b, page 5.

²⁸⁹ Although some prescriptions may contain the total daily dosage instead of tablet strength as a direction, the number of prescriptions written this way was very small, accounting for 1-5% of all prescriptions and mainly limited to handwritten hospital prescriptions; see Document 00601, Document 00542, Document 00522 and Document 00612, responses to questions 3 and 4, Sainsbury's Pharmacy's, Day Lewis', Boots' and Well Pharmacy's responses to the CMA's section 26 notice dated 16 June 2016).

typically not specified on the prescription.²⁹⁰ Prescription Cost Analysis ('PCA') data for England shows that only around 1% of the number of packs of hydrocortisone tablets dispensed between 2014 and 2015 were prescribed by reference to a supplier or the former brand name 'Hydrocortone'.²⁹¹ Entry by other suppliers of hydrocortisone tablets from late 2015 and early 2016 did not have any material effect on the proportion of open prescription hydrocortisone tablets.²⁹²

3.218. GPs typically use prescribing software to inform their prescribing decisions. This software provides GPs with national and locally authored patient safety information messages, recommendations and other prescribing information.²⁹³ To facilitate generic prescribing, GP prescribing software is usually able to identify if a generic name is available so that where a prescriber types in a brand name, they can use a function key to prompt them with the generic name. With respect to hydrocortisone tablets, GP software does not 'flag' that a particular supplier or manufacturer must be used.²⁹⁴

3.219. Moreover, most software allows prescribers to specify the brand name or the manufacturer or marketing authorisation holder on the prescription by clicking on the proper selection in the software's interface or by using the appropriate search criteria.²⁹⁵ Instead, some GP prescribing software does not enable the prescriber to specify the manufacturer or marketing authorisation holder on the prescription, meaning that only open prescriptions for hydrocortisone tablets are generated as a result.²⁹⁶

²⁹⁰ Document 00608, Document 00601, Document 00552, Document 00542, Document 00597, Document 00522, Document 00548, Document 00606 and Document 00612, responses to question 3, Tesco Pharmacy's, Sainsbury's Pharmacy's, Morrisons Pharmacy's, Day Lewis', Rowlands Pharmacy's, Boots', Lloyds Pharmacy's, Superdrug's and Well Pharmacy's responses to the CMA's section 26 notice dated 16 June 2016). See also Document 00603, response to question 11, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

²⁹¹ Comprehensive data not available before 2014. Using data over a longer period, ie from January 2014 to April 2017, does not materially change the results.

²⁹² CMA analysis based on NHS BSA data for England (Document 00588, response to question 3 to the CMA's section 26 notice dated 28 June 2016; and Document 01804, response to question 2 of the CMA's section 26 notice dated 21 June 2017) combined with PCA data for England.

²⁹³ BMA (2003), Prescribing in General Practice.

²⁹⁴ Document 00544, Document 00610, Document 00550 and Document 00537, responses to questions 5 and 6, Emis Health's, TPP's, Microtest's and CSC's responses to the CMA's section 26 notice dated 29 June 2016; Document 00546, response to question 6, INPS's response to the CMA's section 26 notice dated 30 June 2016; Document 01755, Document 01747, Document 01745, and Document 01782, response to question 1, Emis Health's, TPP's, Microtest's and INPS's responses to the CMA's section 26 notice dated 20 June 2017.

²⁹⁵ Document 00550, Microtest Limited's response to the CMA's section 26 notice of 29 June 2016; Document 00546, In Practice System's response to the CMA's section 26 response of 30 June 2016; EMIS Health's response to the CMA's section 26 response of 29 June 2016; and The Phoenix Partnership's response to the CMA's section 26 notice of 29 June 2016.

²⁹⁶ Document 00537, CSC Computer Sciences Limited's response to the CMA's section 26 notice of 29 June 2016.

3.220. The MHRA explained to the CMA that in cases where products are not interchangeable from a patient safety perspective, the MHRA would generally require them to have a brand name (even if they are a generic product) so that products can be more easily distinguished. These brand names would be reflected in GP prescribing software in order to help GPs to prescribe the right product and close a prescription. For hydrocortisone tablets, the MHRA did not request that a brand name (eg 'Hydrocortone') be used to distinguish full from skinny label tablets as it was not concerned about patients switching from full to skinny label tablets (see section 3.E.III.c.ii below).²⁹⁷

b. Dispensing

- 3.221. As the overwhelming majority of prescriptions for hydrocortisone tablets are open, the choice of which drug to dispense against a prescription for hydrocortisone tablets in most cases falls to the pharmacist.
- 3.222. Pharmacy dispensing is a specialised and regulated profession. In England and Wales, the activities of pharmacies are governed by various regulations, particularly the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations.²⁹⁸ Similar regulations apply in Scotland and Northern Ireland.
- 3.223. The ability of a pharmacist to decide which medicine to dispense can be limited by the prescriber's decision. This essentially concerns whether a prescription is open or closed, and, if open, to what degree.
- 3.224. Where the prescription is closed (ie where the prescriber specifies the brand name or a particular supplier of a drug that should be dispensed), pharmacists are required to dispense that particular medicine.²⁹⁹
- 3.225. By contrast, where a prescription is open (ie where it specifies only the generic name of a drug (as in the case of hydrocortisone tablets)), pharmacists are able to dispense any version of the relevant drug that has been authorised to be sold in the UK (ie that has been granted an MA), subject to any relevant guidance.³⁰⁰

²⁹⁷ Document 206640, note of call between the MHRA and the CMA of 31 March 2021, paragraph 4.4.

²⁹⁸ For instance, SI 2013/349 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 (applicable in 2013).

²⁹⁹ SI 2013/349 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, Schedule 4, paragraph 5(2), provides that where a person presents to a pharmacist 'an order for drugs', the pharmacist must 'provide the drugs so ordered'.

³⁰⁰ The NHSEI explained to the CMA that '[c]ommunity pharmacists are required by law to dispense exactly what is written on a prescription. Where a prescription is open, pharmacists will meet their legal obligations by dispensing any licensed product that matches that description'. See Document 206557, note of call between the NHSEI and the CMA of 22 March 2021, paragraph 5.5.

c. 'Off-label' use of skinny label hydrocortisone tablets

3.226. Healthcare professionals may prescribe and/or dispense drugs to treat a condition that is not included in the therapeutic indications listed in the SmPC of the supplier's MA. Situations where a licensed medicine is used outside the terms of its licensed indications are referred to as '**off-label**' use of medicines.³⁰¹

i. Regulatory framework applicable to off-label use of medicines

3.227. During the Infringements, there were no regulations or guidance specifically on prescribing or dispensing skinny label hydrocortisone tablets for off-label use.

3.228. Off-label use of medicines in the UK was not regulated by EU or UK law. Instead, some general **non-binding guidance** from professional bodies existed at the time,³⁰² notably from the General Medical Council ('**GMC**') and the Medicines and Healthcare products Regulatory Agency ('**MHRA**').³⁰³

³⁰¹ In Annex I to its Guideline on good pharmacovigilance practices, the European Medicines Agency (EMA) specifies that off-label use '*relates to situations where the medicinal product is intentionally used for a medical purpose not in accordance with the authorised product information*' (page 13, EMA/876333/2011 Rev. 1 of 12 December 2012). The term '*unlicensed use of medicines*' is used variously in professional guidance either (i) to cover **any** use of a medicine outside of its licensed indications (including both the off-label use of medicines with an MA outside of their licensed indications **and** the use of medicines with no MA) **or** (ii) specifically to denote the use of a medicine with no MA (as opposed to a licensed medicine used off-label). This second type of unlicensed use does not apply to hydrocortisone tablets and is subject to stronger regulation and guidance (for example, the legal and regulatory framework which applies to the use of 'specials'). This is because medicines with no MA have not generally demonstrated their clinical safety and efficacy to the same standard as those with an MA.

³⁰² The non-binding nature of guidance on the off-label use of medicines was highlighted by the High Court in [2018] EWHC 2465 *Bayer v NHS Darlington CCG*, paragraphs 56, 151 and 153. This position was endorsed by the Court of Appeal in [2020] EWCA Civ 449 *Bayer v NHS Darlington CCG*, paragraphs 186 to 192. In the same case, the High Court confirmed that the off-label use of medicines was neither subject to nor regulated by EU law ([2018] EWHC 2465 *Bayer v NHS Darlington CCG*, paragraphs 153 and 215). In T-452/14 *Laboratoires CTRS v Commission*, the European Court of Justice also confirmed that '*off-label prescribing is not prohibited, or even regulated, by EU law*', and that '*There is no provision which prevents doctors from prescribing a medicinal product for therapeutic indications other than those for which a marketing authorisation has been granted*' (paragraph 79). On the legal and regulatory framework for the off-label use of medicines, see the European Commission's *Study on off-label use of medicinal products in the EU* (2017), pages 8 to 9 (available at: https://ec.europa.eu/health/sites/health/files/files/documents/2017_02_28_final_study_report_on_off-label_use_.pdf).

³⁰³ The Royal Pharmaceutical Society of Great Britain ('**RPSGB**') also issued the '*RPSGB Legal and Ethical Advisory Service Fact Sheet 5: The Use of Unlicensed Medicines in Pharmacy*' in 2007 which it referred to as '*common sense guidance*' which was not '*intended to interpret the law, the Code of ethics or Council policy*' (Document 00215, Royal Pharmaceutical Society of Great Britain, Legal and Ethical Advisory Service, '*Fact Sheet Five: The use of unlicensed medicines in pharmacy*' (September 2007)). On off-label use of medicines the factsheet advises that dispensing pharmacists should take '*reasonable steps*' to ensure the prescriber understands that the product they have prescribed will be used off-label and the '*possible consequences of this*'. It also noted that in case of an adverse reaction from off-label use '*the supplying pharmacist may assume some liability with the doctor who prescribed it*'. In 2010, the RPSGB was split into the Royal Pharmaceutical Society ('**RPS**'), which maintained the professional leadership role, and the General Pharmaceutical Council ('**GPhC**'), which received the regulatory powers of the society. No equivalent advice about dispensing off-label was issued by the RPS or GPhC. However, in 2014 the RPS issued the '*Professional Standards for Hospital Pharmacy Services*' in which it recommended that, wherever possible, medicines are dispensed in accordance with their MAs. The RPS advised that '*[s]election between different licensed options for individual patients is guided by*

- 3.229. While the guidance at the time generally recommended that licensed medicines be prescribed and dispensed in accordance with the terms of their licence wherever possible, healthcare professionals had discretion to prescribe and dispense medicines as they saw appropriate and in accordance with their professional judgement. For instance:
- a. The GMC issued non-binding guidance in 2013 (*'Good practice in prescribing medicines and managing devices'*) which recommended that healthcare professionals *'should usually'* prescribe medicines in accordance with the terms of their licence but acknowledged that healthcare professionals could prescribe and dispense medicines for off-label use (or even prescribe and dispense unlicensed medicines) *'where, on the basis of assessment of the individual patient, you conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient'*.³⁰⁴ The GMC's guidance recognised that *'[s]ome medicines are routinely used outside the terms of their license'* and where prescribing medicines for off-label use *'is supported by authoritative clinical guidance, it may be sufficient to describe in general terms why the medicine is not licensed for the proposed use or patient population'*.³⁰⁵
 - b. The MHRA issued updated non-binding guidance in 2014 (*'Off-label or unlicensed use of medicines: prescribers' responsibilities'*) which also recognised that *'there are clinical situations when the use of unlicensed medicines or use of medicines outside the terms of the licence (ie, 'off-label') may be judged by the prescriber to be in the best interest of the patient on the basis of the available evidence'*. The MHRA drew attention to the fact that *'[t]he responsibility that falls on healthcare professionals when prescribing an unlicensed medicine or a medicine off-label may be greater than when prescribing a licensed medicine within the terms of its licence. Prescribers should pay particular attention to the risks associated with using unlicensed medicines or using a licensed medicine off-label.'* While the examples were non-exhaustive, the MHRA noted that the *'risks may include: adverse reactions; product quality; or discrepant product information or labelling'*.³⁰⁶

considerations of safe use, effectiveness, tolerability and value'. See [Royal Pharmaceutical Society Professional standards for hospital pharmacy services \(July 2014\)](#), page 13.

³⁰⁴ GMC, *Good practice in prescribing and managing medicines and devices* (2013), paragraph 68. Available at: https://www.gmc-uk.org/-/media/documents/prescribing-guidance_pdf-59055247.pdf.

³⁰⁵ GMC, *Good practice in prescribing and managing medicines and devices* (2013), paragraph 72.

³⁰⁶ MHRA, *Off-label or unlicensed use of medicines: prescribers' responsibilities*, published December 2014 (available at [Off-label or unlicensed use of medicines: prescribers' responsibilities - GOV.UK \(www.gov.uk\)](#)).

*the guidance, on its face, admits of exceptions’.*³¹¹ The Court of Appeal endorsed the High Court’s assessment that the GMC’s guidance in the round *‘positively requires treating clinicians to take cost into account as an element of good medical practice. That obligation does not stop simply because an unlicensed drug is under consideration’.*³¹²

3.233. The GMC issued a statement in line with the High Court’s judgment: *‘[w]e expect doctors to make good use of the resources available to them and sympathise with the concerns of healthcare professionals making decisions between using a cheaper product outside the terms of its license or a more expensive licensed alternative’*, stating that *‘where doctors are working in partnership with patients, following clinical guidance and making prescribing decisions in good faith on the basis of evidence and experience’* such use *‘would not cause us any concerns’.*³¹³

3.234. In a section of this statement the GMC recognised that its prescribing guidance:

*‘states that doctors should usually prescribe licensed medicines in accordance with the terms of their licence. The use of the words “should” and “usually” are significant and indicate that we expect doctors to use their judgment to apply the principles in the guidance to the specific situations they face. We say that when prescribing an unlicensed medicine or using a product “off-label” (beyond the terms of its license) doctors must be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy. We are also clear that doctors “must give patients (or their parents or carers) sufficient information about the medicines you propose to prescribe to allow them to make an informed decision”’.*³¹⁴

ii. Impact of the regulatory framework on prescribing and dispensing of skinny label tablets for off-label use

3.235. As explained above, the professional guidance did not specifically address instances where a bioequivalent drug (of proven safety and efficacy) was used off-label to treat ‘carved out’ indications covered by an orphan designation. As such, the decision whether to prescribe and dispense skinny

³¹¹ [2018] EWHC 2465 *Bayer v NHS Darlington CCG*, paragraph 151.

³¹² [2020] EWCA Civ 449 *Bayer v NHS Darlington CCG*, paragraphs 186 to 192.

³¹³ See: [GMC responds to new NICE guidance - GMC \(gmc-uk.org\)](#). This statement is discussed in [2018] EWHC 2465 *Bayer v NHS Darlington CCG*, paragraphs 61 to 63 and 151 to 152.

³¹⁴ See: [GMC responds to new NICE guidance - GMC \(gmc-uk.org\)](#).

label tablets for off-label use would fall within the remit of the healthcare professional's discretion.

- 3.236. As explained in section 3.D.III.c above, it is purely a result of regulatory circumstance that skinny label hydrocortisone tablets could not include the indication '*adrenal insufficiency in adults*' on their MAs. Save for an accident of timing (whether the licences were obtained before or after MAs were granted for Plenadren), no supplier's MA would have excluded the treatment of '*adrenal insufficiency in adults*' given all hydrocortisone tablets were bioequivalent: they were all equally safe and effective for treating the same conditions from a clinical perspective.³¹⁵ As such, many healthcare professionals could have reasonably taken the view that there were no or negligible additional risks to patient safety from using skinny rather than full label hydrocortisone tablets.
- 3.237. During the Infringements, prescribers overwhelmingly issued open prescriptions which did not distinguish between on-label and off-label use of hydrocortisone tablets.³¹⁶ This prescribing behaviour did not change after skinny label tablets entered: prescribers still overwhelmingly issued open prescriptions for hydrocortisone tablets (see section 3.D.III.a above).
- 3.238. Since the overwhelming majority of prescriptions for hydrocortisone tablets were open and typically did not specify the condition of the patient, pharmacies were able to dispense any licensed hydrocortisone tablets that were available. Pharmacies could either dispense full label tablets or skinny label tablets when filling a prescription for 'hydrocortisone tablets', as both types of tablets were licensed medicines.³¹⁷
- 3.239. As explained in paragraphs 3.69 to 3.70 above, a pharmacy is paid the same amount irrespective of the price that it pays for the drug or which drug it dispenses (as long as the drug dispensed falls within the parameters of the prescription). For hydrocortisone tablets, this meant that a pharmacy was paid the same amount regardless of whether a full or a skinny label product was dispensed. Given that skinny label tablets were generally cheaper than full label tablets, pharmacies had an incentive to dispense a skinny label

³¹⁵ For example, in the case of Auden's 10mg and 20mg tablets, and Waymade's 10mg tablets, bioequivalence was established to 20mg hydrocortisone tablets manufactured by Merck Sharp & Dohme. Auden established bioequivalence to the branded Hydrocortone tablet, then still licensed in the UK. Waymade established bioequivalence with a Portuguese MSD tablet according to the same guidelines. See: PL17507/0054-5, [Public assessment report](#) for Auden/Actavis's 10mg and 20mg hydrocortisone tablets (2007), and PL 20072/0238, [Public assessment report](#) for Waymade's 10mg hydrocortisone tablets (2012).

³¹⁶ Compare Document 00656, Auden/Actavis's response to the CMA's section 26 notice dated 23 May 2016, paragraph 12.4: '*a prescription written as "Hydrocortisone Tablets" would not be regarded as an off-label prescription.*'

³¹⁷ Document 206557, note of call between the CMA and NHSEI of 22 March 2021, paragraph 5.3.

tablet to fill an open prescription as that would have allowed them to maximise the profit they made.

- 3.240. Contemporaneously, and before skinny label tablets were launched, the MHRA and the Chief Pharmaceutical Officers for NHS England, NHS Scotland and NHS Wales did not consider that the off-label use of skinny label hydrocortisone tablets created any risks to patient safety that would justify taking any action to limit or prevent off-label use.
- 3.241. The MHRA's lack of concern for off-label use of skinny label tablets from the perspective of patient safety is evidenced by its contemporaneous correspondence with Auden and the actions (or lack of action) it took as a result. For instance:
- a. Further to receiving correspondence from Auden concerning the difference in indications between full and skinny label tablets, the MHRA replied in December 2014 and April 2015 that *'[f]rom the public health perspective, there are no material differences between the available generic immediate release hydrocortisone tablets; these are all bioequivalent to the brand leader'*. The MHRA disagreed with Auden that there was any need for the MHRA to formally require skinny label tablet suppliers to alter their labelling and packaging to further differentiate their products from Auden's full label tablets.³¹⁸
 - b. Instead, the MHRA explored with MA holders of skinny label tablets whether they might voluntarily include some text that reflected the CMDh's guidance on usage patents³¹⁹ which explicitly acknowledges that the product can be used for other indications than those listed on the SmPC.³²⁰
 - c. The MHRA also suggested that MA holders of skinny label tablets write to the MA holder of Plenadren *'to explore whether consent can be obtained for marketing [...] for the orphan protected indication'*,

³¹⁸ Document 00288, letter from [X] to [X] dated 19 December 2014 and Document 00628, letter from [X] to [X] dated 21 April 2015.

³¹⁹ CMDh stands for 'Co-ordination Group for Mutual Recognition and Decentralised Procedures – Human'. The CMDh's guidance can be found at [CMDh_279_2012_Rev_1_05_2019_clean - Q A on Usage patents.pdf \(hma.eu\)](https://www.hma.eu/CMDh_279_2012_Rev_1_05_2019_clean_-_Q_A_on_Usage_patents.pdf).

³²⁰ The MHRA explained to Auden: *'[o]n the inadvertent prescribing or dispensing of a hydrocortisone tablet product that excluded the orphan-protected indication a parallel can be drawn with 'usage patents' where some parts of the SmPC of the reference product are under patent protection. In that case, a generic medicinal product can still be authorised if the product information (SmPC, package leaflet and labelling) exclude the indications still covered by patent law. CMDh guidance is available and provides agreed standard text for the package leaflet in this situation that explains why some therapeutic indication(s) or dosage form(s) may be missing.: '(Active substance) which is contained in (product) (may also be/is also)* authorised to treat other conditions which are not mentioned in this leaflet. Ask your doctor or pharmacist if you have further questions'*. See Document 00288, letter from [X] to [X] dated 19 December 2014.

recognising that, had it not been for the orphan designation, skinny label products could have been licensed for adrenal insufficiency in adults.³²¹

- d. The MHRA decided not to issue any guidance on dispensing hydrocortisone tablets as there were no public health concerns. The MHRA explained to the CMA that it would only have intervened in dispensing decisions where there was a public health concern, which was not the case for hydrocortisone since skinny and full label tablets were bioequivalent.³²²
 - e. The MHRA decided not to require Auden to reintroduce the brand name '*Hydrocortone*' to allow GPs and pharmacists to distinguish full label from skinny label tablets as it was not concerned about patients switching.³²³
 - f. The MHRA advised [Chief Pharmaceutical Officer for NHS England], that there was no patient safety issue arising from skinny label hydrocortisone tablets dispensed off-label (ie to treat adult adrenal insufficiency) because they were bioequivalent to full label tablets.³²⁴ This communication arose as a result of Auden contacting NHS England in addition to [Chief Pharmaceutical Officer for NHS England].
- 3.242. In parallel, and further to receiving the advice from the MHRA, [Chief Pharmaceutical Officer for NHS England] relayed to Auden that '*there are no material differences between the available generic immediate release hydrocortisone tablets and they are all bioequivalent to the brand leader*' and that '*[b]ased on the advice I have received so far, I do not see that there are any risks to patient safety that would warrant any communication to senior pharmacists*' (as Auden had requested).³²⁵ NHSEI explained to the CMA that it did not consider it necessary to issue any guidance as '*pharmacists would have understood that Auden McKenzie's full label hydrocortisone tablets are bioequivalent to skinny label hydrocortisone tablets, meaning that they are*

³²¹ Document 202786, letter from [redacted] to AMCo dated 21 April 2015 and Document 00700, letter from [redacted] to [redacted] (Medfiles) dated 21 April 2015.

³²² Document 206640, note of call between the CMA and the MHRA of 31 March 2021, paragraphs 4.1 and 4.3.

³²³ Document 206640, note of call between the CMA and the MHRA of 31 March 2021, paragraph 4.4.

³²⁴ Document 206640, note of call between the CMA and the MHRA of 31 March 2021, paragraph 3.1.

³²⁵ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden's External Consultant], [redacted] and [Auden Senior Employee 4] dated 20 May 2014 and received by Auden on 22 May 2014. This view was shared by the MHRA, which advised [Chief Pharmaceutical Officer for NHS England] and assisted him in responding to Auden's correspondence; see Document 206640, note of call between the CMA and the MHRA on 31 March 2021, paragraph 2.1 and Document 206557, note of call between the CMA and NHS England and NHS Improvement on 22 March 2021, paragraph 2.1.

pharmaceutically equivalent and therefore dispensing them did not present any threat to patient safety'.³²⁶

3.243. The Chief Pharmaceutical Officers for NHS Scotland and NHS Wales took a similar position – that they would also '*not take action*' in relation to off-label use of skinny label hydrocortisone tablets.³²⁷

3.244. Similarly, medical practitioners and pharmacists contacted by the CMA also agreed that there was no risk to patient safety associated with dispensing skinny label tablets for adult patients with adrenal insufficiency. For instance:

- a. [Professor of Endocrinology] explained that he was not familiar with the distinction between 'full' and 'skinny' label tablets, and did not see the rationale for making such a distinction if both drugs were bioequivalent. In his view, as long as the products are bioequivalent there would be no risk associated with prescribing skinny label tablets. He also noted that prescribers write open prescriptions for 'hydrocortisone tablets', so as long as hydrocortisone tablets are dispensed (regardless of full or skinny label), this would be '*perfectly safe*'.³²⁸
- b. Day Lewis' [X] explained that in his view as a pharmacist, the fact that full and skinny label hydrocortisone tablets were bioequivalent meant that Day Lewis pharmacists had a level of discretion as to which hydrocortisone tablets they dispensed. He also explained that pharmacies would have understood that skinny and full label hydrocortisone tablets were bioequivalent in any case and the difference in indications was the result of a licensing quirk caused by the orphan status.³²⁹
- c. Sigma's [X] explained that in his experience as a pharmacist, hydrocortisone tablet prescriptions were open which meant that pharmacists are at liberty to dispense a skinny or full label product against the prescriptions for hydrocortisone tablets. In his view, as long

³²⁶ Document 206557, note of call between the NHSEI and the CMA of 22 March 2021, paragraphs 4.2 and 5.6.

³²⁷ Document 00158, email from [Auden's External Consultant] to [Auden Senior Employee 4] and [X] dated 9 June 2014.

³²⁸ Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 3, page 3.

³²⁹ Document 206418, note of call between Day Lewis and the CMA of 8 February 2021. Paragraphs 2.3 and 2.11 [X] also explained that he understood the rigour involved in proving bioequivalence. The processes and tests that skinny label tablet suppliers had to go through (including the assay, release and dissolution requirements) meant that there was no pharmaceutically differentiating features between full and skinny label tablets and that the products were not pharmaceutically distinguishable. He was very confident that there would have been no risk of patient harm from using skinny label tablets. He considered it to be a matter of licensing and regulation, not a patient safety issue. See Document 206416, note of call between Day Lewis and the CMA of 16 March 2021. Paragraph 3.1.

as the pharmacist fills the prescription with hydrocortisone tablets '*it is fine*'.³³⁰

3.245. Ultimately, and as explained in section 3.E.V.b.v below, after skinny label hydrocortisone tablets were launched in October 2015, they accounted for just over 50% of all hydrocortisone tablets dispensed in 2017, an amount exceeding the proportion of the market not covered by the orphan designation. The CMA is not aware of any cases of a patient suffering an adverse reaction as a result of off-label use of skinny label tablets or of any cases where a dispenser has been found to have breached its professional responsibilities as a result.

IV. Demand for hydrocortisone tablets

3.246. This section describes demand for hydrocortisone tablets prior to and after skinny label tablets were first launched in October 2015.

3.247. In summary:

- a. Before being launched in October 2015, there was uncertainty over how much demand there would be for skinny label hydrocortisone tablets. However, the clear expectation of the incumbent (Auden) and potential entrants was that customers would buy skinny label tablets and entrants would be able sell their skinny label tablets in part because they anticipated that skinny label tablets would be prescribed and dispensed for off-label use. The only uncertainty that existed was what the scale of demand would be. It would have come as no surprise to market participants that skinny label tablet suppliers would enter and go on to take sales from full label tablets.
- b. From October 2015 onwards, skinny label tablets suppliers entered the market and took significant market share from Auden/Actavis's sales of full label tablets. Alissa was the first skinny label supplier to come to market with 10mg hydrocortisone tablets and its market experience confirmed previously held expectation: there was demand for skinny label tablets. Bristol Laboratories' and Resolution Chemicals' market entry with their own skinny label tablets in March 2016 increased competition in the market, which caused prices to fall. The fact that AMCo was finding it '*a little tougher to sell*' the fixed allocation of Actavis's full label tablets at high prices coupled with the progressive loss of value of AMCo's stockholding of its own skinny label tablets due to declining prices led to AMCo entering the market with its own skinny

³³⁰ Document 206582, note of call between Sigma and the CMA of 4 March 2021. Paragraph 2.4.

label tablets in May 2016. Skinny label tablets accounted for approximately 50% of total market demand within two years of the first entry in October 2015 with off-label dispensing of skinny label tablets becoming widespread.

a. Expectations of demand prior to market entry of skinny label tablets

3.248. Between October 2008 and October 2015 10mg hydrocortisone tablet prices increased from £22.28 to £67.74, with a rate of annual growth in monthly packs dispensed of around 4%. Auden's price increases and the resulting profits to be made from supplying 10mg hydrocortisone tablets in the UK sparked the interest of a number of other suppliers, who decided to initiate their own development of hydrocortisone tablets with a view to launching. For example:

- a. Alissa, which started its development in 2011, explained that it had *'witnessed a situation where the market was being massaged, as there was insufficient supply into the market, which was the reason why the price over a period of time was increasing'*.³³¹
- b. Bristol Laboratories, which started its development in 2011, explained that it was interested in developing a low volume / high value product and that hydrocortisone tablets fitted that profile.³³²
- c. Resolution Chemicals, which started its development in August 2012, explained that it saw a gap in the hydrocortisone tablets market because there was only one generic present (supplied by Auden) and no reference product. Resolution wanted to be second to market and saw this as a good business opportunity.³³³
- d. Genesis Pharmaceuticals, which started its development in October 2012, gave the fact that hydrocortisone tablets *'were being sold at an extremely high price'* as one of the reasons for developing its own product.³³⁴
- e. Teva, which started its development in March 2014, referred to the size of the market (in both revenue and volume terms) as one of the reasons for developing its own skinny label tablets.³³⁵ A

³³¹ Document 00699, [Alissa Senior Employee]'s witness statement dated 30 September 2016.

³³² Document 00527, Bristol Laboratories' response to the CMA's section 26 notice dated 1 April 2016, answer to question 2.

³³³ Document 206344, Note of call between the CMA and [REDACTED] (Resolution Chemicals) dated 4 March 2021.

³³⁴ Document 02249, Genesis Pharmaceuticals' response to the CMA's section 26 notice dated 15 January 2018, response to question 3.

³³⁵ Document 01646, Teva's response to the CMA's section 26 notice dated 1 June 2017.

contemporaneous internal presentation prepared for Teva also shows that it saw upside potential for hydrocortisone tablets as '*low competition environment allows higher prices*'.³³⁶

- 3.249. Despite the limitations in the labelling of the hydrocortisone tablets MAs they would be able to obtain as a result of the orphan designation, each of the suppliers listed above pursued its development of 10mg hydrocortisone tablets and commercialising its tablets in the UK. Each worked towards launching under a skinny label MA and did eventually launch, taking market share.
- 3.250. In itself, the fact that these suppliers decided to continue investing resources in these developments and commercialising their products shows that they expected that there would be demand for skinny label tablets in the market.
- 3.251. Waymade and AMCo also worked towards developing and commercialising skinny label hydrocortisone tablets. Their efforts and investments in themselves also demonstrate that they expected that there would be demand for skinny label tablets in the market.
- 3.252. Waymade was the first company to obtain a skinny label MA: on 27 September 2012 it was granted a 10mg MA without the indication for adult adrenal insufficiency. That MA was acquired by AMCo on 31 October 2012. AMCo eventually entered with its own 10mg skinny label tablets in May 2016.
- 3.253. In this Decision, the CMA has found that first Waymade, and then (after the 10mg MA was transferred) AMCo, agreed not to enter independently with their own skinny label 10mg hydrocortisone tablets in exchange for payments from Auden/Actavis.
- 3.254. A significant body of evidence demonstrates that, throughout the period from March 2012 (when Waymade was informed by the MHRA that its 10mg MA would be skinny label) to October 2015 (when the first skinny label supplier entered the market) inclusive, it was understood by each of Waymade, AMCo and Auden/Actavis that there would be demand for skinny label tablets and that off-label dispensing could occur if they were launched. Contemporaneous documentary evidence demonstrates that each of Waymade, AMCo and Auden/Actavis consistently believed that skinny label hydrocortisone tablets would not only successfully enter the market but

³³⁶ Document 01657, Teva - Hydrocortisone Tablets presentation dated 1 April 2014.

achieve a material level of sales. This belief is reflected in their commercial behaviour.

3.255. The parties' contemporaneous estimates of the extent of demand pre-entry must be placed in context. They fall into five key periods:

- a. March to October 2012.
- b. October 2013 to January 2014.
- c. April to June 2014.
- d. September 2014 to January 2015.
- e. March to October 2015.

3.256. **Between March and October 2012**, Waymade was informed that its 10mg MA would be skinny label³³⁷ and negotiated the sale of its Amdipharm group to Cinven. That sale included the 10mg skinny label MA Waymade obtained on 27 September 2012. During the negotiations both Waymade and Cinven prepared estimates of the market share skinny label 10mg tablets could win from Auden's full label tablets.³³⁸ These ranged between 17% of total volumes (Waymade) and 6% of total volumes (Cinven). Cinven's greater caution did not reflect a lack of belief in demand for skinny label tablets, but a concern that other companies would also enter and take market share.³³⁹ In October 2012 Waymade also entered into an agreement with Auden, under which Auden supplied Waymade with heavily discounted 10mg hydrocortisone tablets which Waymade was able to sell for a significant profit. The individuals who negotiated that supply agreement on both sides stated that it was agreed in order to preserve the volumes Auden obtained

³³⁷ Document 300223, email from [X] to [Waymade Employee] dated 15 March 2012. Document 300227, MHRA RFI dated 5 April 2012. Document 300274, email from [X] to [Waymade Employee] dated 13 July 2012. Document 300271, emails between [Waymade Employee] and [Waymade Senior Employee 1] dated 13 July 2012. Document 300267, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 13 July 2012. Document 300274, email from [Waymade Employee] to [Waymade Senior Employee 1] copied to [Amdipharm Senior Employee] dated 13 July 2012.

³³⁸ Document 202512, slide pack entitled '*PROJECT AMPULE Information memorandum*' dated 6 July 2012, slides 39 and 82. Document 202511, external review of Amdipharm key products dated 25 July 2012, slide 10. Document 300290, spreadsheet titled 'Hydrocortisone 10mg tablets sales data Jul12' attached to an email from [Amdipharm Senior Employee] to [Waymade Senior Employee 1] dated 25 September 2012 (document 300289). Document 202320, spreadsheet titled 'Ampule – UK products' attached to an email from [AMCo Senior Employee 4] to [AMCo Senior Employee 1] dated 9 October 2012 (document 202319). Document 202506, final due diligence report prepared for Cinven dated 23 October 2012, slides 9 and 32.

³³⁹ Document 202506, final due diligence report prepared for Cinven dated 23 July 2012, slides 12 and 32.

from its CMO Tiofarma:³⁴⁰ demonstrating that skinny label tablets were considered to form a real threat to Auden's position as sole supplier.

- 3.257. Waymade sold the Amdipharm group, and with it the 10mg MA and supply agreement with Auden, to Cinven on 31 October 2012. AMCo received monthly supplies of heavily discounted full label 10mg hydrocortisone tablets from Auden which it was able to sell for a significant profit. [Auden Senior Employee 1] explained in interview that Auden supplied AMCo on these terms in order to preserve its CMO volumes:³⁴¹ demonstrating once again that skinny label tablets were considered to form a real threat to Auden's position as sole supplier.
- 3.258. **Between November 2013 and February 2014**, AMCo attempted to negotiate a new, forward-looking supply arrangement for heavily discounted full label 10mg hydrocortisone tablets with Auden. AMCo initially predicted that it could sell around 18,000 packs per month of its own skinny label tablets (equating to 24% of total volumes)³⁴² and sought to obtain the same volume from Auden.³⁴³
- 3.259. During the same period, AMCo negotiated the potential acquisition of Auden's hydrocortisone tablets business. However, AMCo ultimately decided that this acquisition was not worth pursuing given the risk to Auden's position from skinny label entry.³⁴⁴

³⁴⁰ [Auden Senior Employee 1] stated that 'as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable' (Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68). [Amdipharm Senior Employee] of Waymade stated: 'maybe the inference from me is that, you know, he [[Auden Senior Employee 1]] can supply me or I'll get someone else to supply me, and if he wants to retain the manufacturing volumes, then he might agree to supply me' (Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, pages 14-15).

³⁴¹ [Auden Senior Employee 1] explained that after the transition from Waymade, Auden continued to supply AMCo on these terms in order to preserve its CMO volumes: 'after the move from Waymade to Amdipharm ... In 2012, we supplied Amdipharm at a price of £1 per pack'. This was because AMCo ceased to be a 'pure wholesaler' when it acquired the 10mg MA from Waymade; and '[w]e [Auden] wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]'. Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.

³⁴² Document 202660, spreadsheet titled 'model (2)' attached to document 202659, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 4] dated 23 May 2014. See 'Product X' figures in the 'assume generics launched' and 'Sheet 1' tabs. Although the spreadsheet was attached to an email in May 2014, it is likely that it was prepared in late 2013: it modelled all potential scenarios, including competitive entry, from January 2014 onwards and assumed (subject 'to check') an Auden ASP of £40 (Auden's ASP in May 2014 reached £53.65). The 'Proposed' tab shows that AMCo proposed to increase its supply volumes from Auden to 17,000 packs per month in January 2014. The information in the 'current' tab matches the numbers AMCo used for its internal forecasts in December 2013 – see for instance, Document 202597, email from [AMCo Employee] to [AMCo Senior Employee 1] and [AMCo Senior Employee 4] dated 20 December 2013. The number of packs, ASP and total sales in the email are identical to those listed in the 'current' tab of the spreadsheet (Document 202660).

³⁴³ Document 202552, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 15 November 2013. Document 202553, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden Mckenzie (Pharma Division) Limited and Amdipharm Limited, page 20, Schedule A. See also Document 202557, email from [Amdipharm Senior Employee] to [X] dated 15 November 2013.

³⁴⁴ Document 200031, email from [AMCo Senior Employee 2] to AMCo staff dated 2 December 2013. Document 200163, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 2 January 2014. Document

- 3.260. Auden resisted AMCo's demands to increase its volumes and from December 2013 onwards took a robust position in the negotiations, arguing that the orphan designation meant AMCo's skinny label 10mg tablets could only gain a lower market share.³⁴⁵ In January 2014, it appeared that AMCo's supply arrangement with Auden was at risk of breaking down. Each of the parties took precautionary measures:
- a. AMCo prioritised its 10mg product development and estimated that there would be significant demand for its skinny label tablets.³⁴⁶ In particular, it estimated that it could sell around 12,000 packs per month of its own skinny label tablets (equating to 16% of total volumes).³⁴⁷
 - b. Auden launched 'Project Guardian', an initiative designed to influence healthcare professionals and stakeholders against off-label dispensing, in anticipation of AMCo's launch (demonstrating that it perceived a real risk to its position from skinny label entry).³⁴⁸
- 3.261. During the same period AMCo negotiated the potential acquisition of Waymade's full label 20mg MA. However, AMCo again reached the view that this acquisition was not worth pursuing given the risk from skinny label entry.³⁴⁹
- 3.262. Project Guardian received a lukewarm reception from stakeholders.³⁵⁰ It became clear to Auden that skinny label tablets would win a significant market share from full label tablets if they were launched. Auden offered to continue supplying AMCo with its full label tablets, and the parties returned

200071, email from [AMCo Senior Employee 8] to AMCo staff dated 7 January 2014. Document 202629, AMCo strategic development monthly report for January 2014, page 3.

³⁴⁵ Document 202596, email from [Auden Senior Employee 1] to [Amdipharm Senior Employee] dated 18 December 2013 and email from [Auden Senior Employee 1] to [Amdipharm Senior Employee] dated 19 December 2013. Document 200160, minutes of Mercury Pharma Group Limited management meeting on 19 December 2013.

³⁴⁶ Document 202597, email from [AMCo Senior Employee 4] to [AMCo Employee], [AMCo Senior Employee 1] and [AMCo Senior Employee 6] dated 20 December 2013. Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 8] dated 2 January 2014. Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.

³⁴⁷ Document 200090, PPRM slides on 10mg hydrocortisone tablets dated 22 January 2014, slide 10. Document 202613, email from [AMCo Senior Employee 4] to AMCo staff dated 22 January 2014. Document 200103, January 2014 BD & L Report EPRM approvals, page 3. Document 200498, minutes of AMCo board meeting dated 29 January 2014. Document 203632, email from [AMCo Employee] to [X] dated 17 February 2014.

³⁴⁸ Document 200085, email from [AMCo Senior Employee 2] to AMCo management dated 14 January 2014. Document 00062F, Professional Advice (Hydrocortisone) Proposal Prepared for Auden McKenzie (Pharma Division) Ltd by [Auden's External Consultant] dated 6 February 2014, 2 Client Requirements. Document 00135, Project Guardian presentation dated February 2014, pages 9, 11, 16 and 33. See also Document 00064, untitled report containing analysis on hydrocortisone attached to Document 00063, email from [X] (H2 Pharma) to [Auden Senior Employee 4] dated 18 February 2014. Document 00139, Project Guardian communications proposal dated 16 April 2014, slide 3. See further section 3.F.III.h below.

³⁴⁹ Document 200109, email from [AMCo Senior Employee 2] to AMCo staff dated 11 April 2014. Document 200116, email from [AMCo Senior Employee 2] to [X] dated 2 May 2014. Document 200116 email from [AMCo Senior Employee 2] to [X] dated 15 May 2014.

³⁵⁰ See, for example, Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden Senior Employee 1], [Auden Senior Employee 4] and [Auden's External Consultant] dated 20 May 2014.

to negotiations from April 2014 onwards.³⁵¹ During the period **from April to June 2014**:

- a. AMCo consistently projected that it could sell 10,000 packs per month of its skinny label 10mg tablets (equating to 13% of total volumes) if it launched;³⁵²
- b. AMCo informed Auden that it was projecting selling 12,000 packs per month of its skinny label 10mg tablets;³⁵³ and
- c. AMCo ultimately succeeded in convincing Auden to double its supply volumes to 12,000 packs per month on the basis that if Auden did not, AMCo would launch.³⁵⁴ On the same day as the parties renewed their supply deal, AMCo suspended the development of its skinny label tablets, noting that it had otherwise been planning to launch.³⁵⁵

3.263. **Between September 2014 and January 2015**, Allergan negotiated the acquisition of AM Pharma. In response to the grant of a skinny label MA to Orion/Alissa (which prompted Auden to revisit Project Guardian, noting the risk of off-label use of Alissa's product³⁵⁶), Allergan predicted widespread off-label dispensing of skinny label hydrocortisone tablets, leading to a loss of 60% of Auden's volume market share within three years.³⁵⁷ Allergan was sufficiently concerned about the risk to Auden's position as sole supplier from skinny label hydrocortisone tablets that it reduced the price it was willing to pay for AM Pharma by £220 million in order to 'de-risk' the position.³⁵⁸

³⁵¹ Document 200108, AMCo Monthly Management Pack, March 2014, page 6. The pack was likely drafted in April and the reference to Auden's offer to continue to supply AMCo may have been inserted on the basis of [Auden Senior Employee 1] approaching [AMCo Senior Employee 1] in April 2014.

³⁵² Document 200106, email from [AMCo Senior Employee 4] to [AMCo Senior Employee 1] dated 22 April 2014. Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014. See also Document 200108, AMCo Monthly Management Pack for March 2014, page 54, and Document 202645, email from [AMCo Senior Employee 4] to [REDACTED] dated 17 April 2014; Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 23 April 2014.

³⁵³ Document 00149, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 28 May 2014. See also Document 202666, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 2] dated 27 May 2014 and document 202667, presentation titled 'Strategic Projects – Cinven 27.05.14', page 2.

³⁵⁴ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014.

³⁵⁵ Document 200126, email from [AMCo Senior Employee 1] to AMCo staff dated 28 June 2014.

³⁵⁶ Document 00235, email from [REDACTED] (Auden McKenzie) to [REDACTED] (MHRA) dated 28 November 2014. Document 00239, letter from [REDACTED] to [REDACTED], dated 1 December 2014. See also Document 00243, letter from [REDACTED] to [REDACTED], dated 1 December 2014. Document 00282, email from [REDACTED] (Auden McKenzie) to [REDACTED] (MHRA) dated 4 December 2014. Document 00254, email from [Auden's External Consultant] to [Auden Senior Employee 4] dated 9 January 2015. However, the MHRA again rebuffed Auden: Document 00288, letter from [REDACTED] to [REDACTED] dated 19 December 2014.

³⁵⁷ Document 00706, Project Apple Presentation January 2015, Hydrocortisone Background.

³⁵⁸ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

- 3.264. **Between March 2015 and October 2015**, AMCo observed the increasing likelihood of Alissa entering the market with its skinny label tablets.³⁵⁹ AMCo believed that this entry would be successful and was concerned that it would lead to price falls.³⁶⁰ The expectation of successful skinny label entry prompted AMCo to re-engage with its Aesica product and order further raw material, predicting that it would sell 12,000 packs a month of its skinny label tablets if they were launched.³⁶¹ In the meantime, AMCo also considered selling skinny label tablets under the MA it expected to obtain through its newly acquired subsidiary Focus Pharmaceuticals.³⁶² AMCo also considered that this launch, if pursued, would be successful: in August 2015 AMCo projected selling 10,000 packs per month of the Focus product, the same level as its prediction for its own product in mid-2014.³⁶³ AMCo separately considered selling skinny label hydrocortisone tablets through its development with the German CMO MIBE – an historic project begun by the Mercury Pharma group prior to Cinven’s acquisition of Amdipharm. In June 2015 and September 2015 AMCo estimated that it would achieve 20% market share if it launched its MIBE product in 2016.³⁶⁴
- 3.265. In summary, the parties’ assessments of the extent of likely demand for skinny label hydrocortisone tablets varied over time. However, there was never any doubt that there would be some demand. Indeed, the parties were sufficiently concerned that skinny label tablets would be very successful in taking market share from full label that they walked away from two negotiations to acquire full label MAs (in the case of AMCo) and very significantly reduced the price they were prepared to pay for full label MAs (in the case of Allergan).
- 3.266. Table 3.7 below records the projections the parties made of the expected level of 10mg skinny label sales at various points during these periods. These projections are drawn from contemporaneous internal documents.

³⁵⁹ AMCo became aware that Alissa’s product would be skinny label on 2 December 2014. See document 202952, email from [X] to [AMCo Senior Employee 2], [AMCo Senior Employee 5] and [AMCo Senior Employee 7] dated 2 December 2014.

³⁶⁰ Document 202792, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 17 March 2015. Document 202780, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 6] dated 18 March 2015. Document 202826, email from [AMCo Employee] to [AMCo Senior Employee 3] dated 19 October 2015.

³⁶¹ Document 201070, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Senior Employee 2], [AMCo Senior Employee 7] and [AMCo Senior Employee 5] dated 18 February 2015.

³⁶² Document 202954, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 3] and [AMCo Senior Employee 6] dated 20 May 2015. AMCo acquired Focus Pharmaceuticals Ltd, a speciality pharmaceuticals business, on 1 October 2014.

³⁶³ Document 200144, email from [Focus Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 5 August 2015; and document 200145, Hydrocortisone 10mg and 20mg tablet proposal.

³⁶⁴ Document 202932, spreadsheet titled ‘Hydrocortisone TABLETS 10MG X 30 – JANILA’, see ‘NPV#10 June15’ and ‘Sept-2015’ tabs.

Table 3.7: parties' contemporaneous estimates of demand for 10mg skinny label hydrocortisone tablets

Date	Party	Document	Volume estimate (packs)	Volume estimate as % of total market*	Value estimate (annual) (£)**
July 2012	Waymade	202512	9,745 per month	13%	£3.7m
		202511	11,002 per month	14%	£4.2m
300290		10,295 to 24,022 per month	15% to 35%	Profit between £4.2m and £10.1m	
202320		40,000 in 2013 following launch in July (6,667 per month)	9%	£2.7m	
		120,000 in 2014 (10,000 per month)	13%	£5.4m	
		160,000 by 2015 (13,333 per month)	17%	£8.5m	
October 2012	Waymade	202506	160,000 by 2015 (13,333 per month)	17%	£5.6m
	Cinven		28,000 in 2013 following launch in July (4,667 per month)	6%	£1.9m
			84,000 in 2014	9%	£3.8m

Date	Party	Document	Volume estimate (packs)	Volume estimate as % of total market*	Value estimate (annual) (£)**
			(7,000 per month)		
			112,000 in 2015 (9,333 per month)	12%	£3.9m
November/December 2013	AMCo	202660	18,000 per month	24%	£7.4m
December 2013		202597	13,877 per month	17%	£6m
January 2014		200090	12,000 per month	16%	£6.5m
		200103	11,425 per month	15%	£6.2m
February 2014		203632	12,000 per month	16%	£6.5m
April 2014		200106	10,000 per month	13%	£5.4m

Date	Party	Document	Volume estimate (packs)	Volume estimate as % of total market*	Value estimate (annual) (£)**
June 2014		200120	10,000 per month	13%	£5.4m
January 2015	Allergan	00706		60% over three years (all skinny label entrants)	
February 2015		201070	12,000 per month	15%	£7.6m
June 2015		202932	17,808 per month (MIBE product)	20%	£1.34m (in 2016)
August 2015	AMCo	200145	10,000 per month (Focus product)	13%	Profit of £3.3m
September 2015		202932	17,934 per month (MIBE product)	20%	£1.41m (in 2016)

* Where a party gave an estimate, this has been used. Where it did not, a volume estimate as % of total market has been calculated based on NHS BSA data for volumes for the relevant year (see table 3.1 above).

** Where a party gave an estimate, this has been used. Where it did not, a value estimate has been calculated based on total market size data (using CMA calculations based on data submitted by relevant parties) and the relevant volume share estimates for the relevant year that the forecast relates to (where known, otherwise based on the date of the document).

b. Demand after skinny label entry

3.267. As explained in section 3.E.III above:

- a. There was no specific guidance on off-label dispensing during the period under investigation in this case.
- b. The overwhelming majority of prescriptions for hydrocortisone tablets are open, meaning they specify only '*hydrocortisone tablets*' and potentially a strength and not the indication or condition of the patient. The MHRA does not require the use of a brand name, as it generally does in cases where products are not interchangeable from a patient safety perspective.³⁶⁵
- c. This means that pharmacies are able to dispense any hydrocortisone tablets (whether full or skinny label) to fulfil a prescription. They are incentivised to dispense the cheapest product available since they will be reimbursed the same amount under the Drug Tariff and maximise their profit margin.

3.268. As explained in sections 3.D.III and 3.E.III above:

- a. Off-label dispensing is not illegal or in breach of regulations. It is left to pharmacies' discretion subject to general, non-binding guidance.
- b. Full and skinny label tablets are bioequivalent: equally safe and effective for treating the same conditions from a clinical perspective. The difference between the indications on their MAs is an accident of timing (reflecting whether the MAs were obtained before or after Plenadren's MA in 2011).
- c. During the period under investigation in this case, both the Chief Pharmaceutical Officer for NHS England and the MHRA informed Auden that they did not consider off-label use of skinny label hydrocortisone tablets to create any risks to patient safety that would justify taking any action to prevent it. When contacted by the CMA during this investigation they confirmed that off-label dispensing '*did not present any threat to patient safety*'³⁶⁶ and that '*there were no public health issues*'³⁶⁷ as a result.

³⁶⁵ Document 206640, note of call between the MHRA and the CMA of 31 March 2021, paragraph 4.4.

³⁶⁶ Document 206557, note of call between the NHSEI and the CMA of 22 March 2021, paragraph 5.6.

³⁶⁷ Document 206640, note of call between the MHRA and the CMA of 31 March 2021, paragraph 4.1.

- d. Medical practitioners and some pharmacists contacted by the CMA during this investigation took the same view. In particular, [Professor of Endocrinology] considered off-label dispensing of hydrocortisone tablets '*perfectly safe*'.³⁶⁸
- e. Notwithstanding the orphan designation, GP prescribing software does not generally prompt prescribers to specify a particular supplier or manufacturer, as it would in cases where the MHRA insists on use of a brand name to distinguish products that are not interchangeable from a patient safety perspective.
- f. The CMA is not aware of any cases of a patient suffering an adverse reaction as a result of off-label use of skinny label tablets, or of any cases where a dispenser has been found to have breached its professional responsibilities as a result.

3.269. As explained in section 3.E.V.b.i below, skinny label hydrocortisone tablets were first launched in October 2015 (by Alissa with 10mg tablets). The paragraphs below describe the impact that the entry of skinny label tablets had on the market and the purchasing and dispensing decisions of pharmacies and wholesalers. The reaction of customers and suppliers to the availability of skinny label tablets confirmed what had been expected – that customers would switch to using skinny label tablets (as explained in section 3.E.IV.a above). In particular:

- a. The first skinny label tablet entrant (Alissa) quickly won sales (in the same month that it entered (October 2015) and saw its sales increase each month (see section 3.E.V.b.v below).
- b. The switch to skinny label tablets continued following entry by more skinny label tablet suppliers, including Bristol Laboratories and Resolution Chemicals (both entering in March 2016) and AMCo (entering in May 2016) (see section 3.E.V.b.v below).
- c. A significant proportion of pharmacies, accounting for just over 50% of all hydrocortisone tablets dispensed switched to using skinny label tablets. The majority of those who switched were independent pharmacies, who tended to be the most price-sensitive customers (see section 3.E.IV.c.i below).
- d. There were, however, also a significant proportion of pharmacies, accounting for just under 50% of all hydrocortisone tablets dispensed

³⁶⁸ Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 3, page 3.

who continued to use full label tablets. The majority of those pharmacies were larger retail chains, who formed an assured base of customers for Auden/Actavis (see section 3.E.IV.c.i below).

i. Competitor entry with skinny label tablets

- 3.270. In early October 2015, Alissa was preparing for the launch of its skinny label tablets: *'We have 79,500 packs in stock. Target 10k packs per month, although initially it would be good to see 15k into the market in October'*.³⁶⁹³⁷⁰
- 3.271. On 20 October 2015, Alissa announced the official launch of its skinny label tablets to select wholesalers and pharmacies and explained that *'[w]e will only sell 10,000 packs a month into the market'* and offered to *'ring fence a quantity each month'* for its customers, suggesting that customers list Alissa's tablets as *'Hydrocortisone 10mg tablets (Alissa)'*.³⁷¹ Alissa provided a promotional flyer it was said to *'have sent to 16,320 pharmacy addressees in the UK'*.³⁷²
- 3.272. Alissa's launch, offering its skinny label tablets at a small discount over the full label product's price, was successful.³⁷³ By 31 October 2015, just 11 days after launch, Alissa had already processed sales orders for a total of 5,530 packs.³⁷⁴ Alissa obtained sales orders amounting to 7,310 packs³⁷⁵ and 12,150³⁷⁶ packs in November and December 2015, respectively. This growing trend continued through early 2016, with sales amounting to 13,060 packs in January and 18,615 packs in February 2016.
- 3.273. On 8 and 9 March 2016 respectively, Bristol Laboratories and Resolution Chemicals launched their own skinny label tablets.³⁷⁷ Bristol Laboratories and Resolution Chemicals' sales of their skinny label tablets for March 2016 were 11,690 and 3,270 packs,³⁷⁸ respectively, with skinny label tablets

³⁶⁹ Document 206116, email from [Alissa Senior Employee] to [X] dated 9 October 2015.

³⁷⁰ [X] explained to the CMA that Alissa would generally target 10-20% of the market with any new launches given Alissa's relatively small size. See document 206413, note of call between the CMA and [X].

³⁷¹ Document 206108, email from [Alissa Senior Employee] to [X] ([wholesaler]) dated 20 October 2015. See also document 03412, email from [Alissa Senior Employee] to [X] ([wholesaler]) dated 20 October 2015.

³⁷² Document 03412, email from [Alissa Senior Employee] to [X] ([wholesaler]) dated 20 October 2015. See also document 206109, flyer sent to [X] ([wholesaler]) on 21 October 2015.

³⁷³ See, for instance, document 206108, email from [Alissa Senior Employee] to [X] ([wholesaler]) dated 20 October 2015.

³⁷⁴ Document 206017, Alissa's sales data for skinny 10mg hydrocortisone tablets from October 2015 to April 2016. Alissa secured sales from short-line wholesalers [X].

³⁷⁵ Alissa secured new orders from [wholesalers and pharmacies] [X].

³⁷⁶ Alissa secured new orders from [wholesalers] [X].

³⁷⁷ Document 00527, Bristol Laboratories' response to the CMA's section 26 notice dated 17 March 2016, and document 00592, Resolution Chemical's response to the CMA's section 26 notice dated 28 June 2016.

³⁷⁸ Document 00529, Bristol Laboratories' sales data for March 2016, and document 00593, Resolution Chemical's sales data for March 2016.

achieving total sales for that month of 31,162 packs (a 17% share of all 10mg tablet sales in March 2016).³⁷⁹

- 3.274. The speed at which skinny label tablets generated sales confirmed the expectation that there would be demand for skinny label tablets once they were made available to the market (see section 3.E.IV.b.v below).
- 3.275. AMCo closely monitored these market entries and decided to enter in May 2016 with its own skinny label tablets as a result of the declining prices for hydrocortisone tablets that came as a result of competition:
- a. On 8 March 2016 [AMCo Employee] told [AMCo Senior Employee 3] that given further independent entry, *'buyers are likely to be buying hand to mouth from now on'* and asked for help ensuring that AMCo's allocation of stock from Auden was released promptly so as to be available for sale: *'With the market as fluid as it is at the moment I would like to avoid any unnecessary delay in placing our stock'*. [AMCo Employee] followed up on the following day, noting that two of AMCo's customers *'have both declined to buy any stock from me this month as they are very nervous about the price dropping quickly'*. [AMCo Senior Employee 3] forwarded her email to [AMCo Senior Employee 1], stating: *'Further power to the bow of launching in my view. I am thinking we go ahead and launch Asicca [sic] (or however you spell it) product asap'*.³⁸⁰
 - b. AMCo entered the market in May 2016 via an active sale to short-line wholesaler DE Pharma³⁸¹ given that it was finding it *'a little tougher to sell'* Actavis's full label product³⁸² This entry came following a meeting between DE Pharma and AMCo in which DE Pharma reported *'on the increasing level of sales of skinny tablets (at the expense of full label counterparts)'* which was *'as a result of an increase in the number of suppliers which had reduced prices and also increased the supply/availability of skinny label tablets'*.³⁸³³⁸⁴

³⁷⁹ Total 10mg hydrocortisone tablet sales in March 2016 were 87,218 packs.

³⁸⁰ Document 202857, emails between [AMCo Employee], [AMCo Senior Employee 3] and [AMCo Senior Employee 1] dated 8-10 March 2016.

³⁸¹ Document 202892, email from [AMCo Employee] to [§] dated 22 April 2016. On the basis of the contemporaneous evidence on the CMA's case file, this was the first time that AMCo actively approached a short-line wholesaler with regards to skinny label hydrocortisone tablets. As a result of the meeting, AMCo managed to secure sales of its skinny label tablets. Sales were made in May 2016 – see Document 201045, Sales by Customer – Aesica Queenborough Ltd livery tab.

³⁸² Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.

³⁸³ Document 206580, note of call between the CMA and DE Pharma of 17 March 2021.

³⁸⁴ DE Pharma explained to the CMA that at this moment in time there was a risk to suppliers as *'they could lose a lot of potential margin because prices were falling quickly and significantly. As a result, all skinny label tablet*

- c. On 17 May 2016, [AMCo Employee] reported how part of the market had switched to purchasing skinny label tablets: *'I am struggling to sell the allocation of Auden stock now that our mainline wholesaler customers are tied into retro schemes. The shortliners have switched their demand to the skinny products [...] The market for the full fat product is now limited to national retail chains'*.³⁸⁵

ii. Customers' initial reactions to skinny label entry

3.276. Once skinny label tablets were made available in the market, it was mainly short-line wholesalers that purchased the product in the first instance, consistent with [AMCo Employee]'s reports on market experience as explained at paragraph 3.275.a above. Contemporaneous documents and the explanations provided by suppliers and short-line wholesalers point to two reasons for this:

- a. Independent pharmacies, which are short-line wholesalers' main customer base and make up a substantial amount of the marketplace (circa 40% of the market – see section 3.E.II.c above), are the most price conscious. Since skinny label tablets were offered at a discount to full-label tablets, independent pharmacies showed a willingness to switch to skinny label tablets, albeit dispensing most of this stock for off-label use.³⁸⁶
- b. A portion of short-line wholesale was excluded from direct supply of full-label tablets from Auden or was offered unfavourable terms as compared to retail pharmacy, affecting its ability to compete on a level-playing field with other wholesalers in the market.³⁸⁷

3.277. In contrast, suppliers of skinny label tablets explained that, initially, there was a degree of reticence from full-line wholesalers to stock and list skinny label

suppliers were very keen to sell their product as quickly as possible before prices (and the margins they could achieve) fell further because of competition'. See Document 206580, note of call between the CMA and DE Pharma of 17 March 2021.

³⁸⁵ Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016.

³⁸⁶ See, for instance, Document 206579, note of call between the CMA and DE Pharma of 23 February 2021; Document 206612, note of call between the CMA and Mawdsleys of 3 March 2021 and Document 206344, note of call between the CMA and Sigma of 4 March 2021.

³⁸⁷ Document 206124, note of call between the CMA and [Alissa Senior Employee] of 23 December 2020. Alissa explained to the CMA that *'[m]ost wholesalers do purchase as they have not had access to supply prior to our launch in 2015. The introduction of Alissa product provided an opportunity that had previously not been available to wholesalers'*. See document 01553, Alissa's response to the CMA's section 26 notice dated 4 May 2017. Contemporaneous Auden email correspondence confirms this. See for instance, Document 00156, email from [Auden Senior Employee 4] to [Auden Senior Employee 2] and other Auden staff dated 2 June 2014; Document 00179, email from [X] to DE Pharma staff dated 8 July 2014; Document 00189, email from [Auden Senior Employee 3] to [X] dated 11 September 2014; Document 00190, email from [X] to [X] (Durbin) dated 22 September 2014; Document 00198, email from [Auden Senior Employee 4] to [Auden Senior Employee 2] and other Auden staff dated 13 October 2014; and Document 00249, email from [Auden Senior Employee 4] to [Auden Senior Employee 2] and other Auden staff dated 12 December 2014.

tablets and that they refused to purchase skinny label tablets for their own multiple retail pharmacy chains (eg Boots and Lloyds), given the decision by their pharmacy chains' Superintendent Pharmacist not to stock the skinny label product.³⁸⁸

- 3.278. Illustrative of this dichotomy are Alliance and Boots's internal conversations on the matter in December 2015: *'There has been a new entrant to the Hydrocortisone Tabs market, but due to the orphan status of the drug no new entrants will ever be able to have all of the indications. This has meant that there is now a two tier market for the product, pharmacists that are not concerned by this are using the new product, others (usually with a PSO) are not'*.³⁸⁹
- 3.279. Section 3.E.IV.c below describes in detail the decisions taken by pharmacies and wholesalers towards purchasing and dispensing full and skinny-label hydrocortisone tablets since these were made available in the market.

³⁸⁸ Document 00512, Alissa's response to the CMA's section 26 notice dated 15 June 2016; Document 206413, note of call between the CMA and [REDACTED] (Alissa) dated 22 February 2021; Document 01553, Alissa's email to the CMA dated 15 May 2017; Document 206124, note of call between the CMA and [Alissa Senior Employee] of 23 December 2020; Document 00527, Bristol Laboratories' response to the CMA's section 26 notice dated 17 March 2016; Document 01566, Bristol Laboratories' response to the CMA's section 26 notice dated 4 May 2017; and Document 01648, email from Resolution Chemicals to the CMA dated 13 June 2017.

³⁸⁹ Document 03528, email from [REDACTED] (Alliance) to [REDACTED] (Boots) dated 10 December 2015.

c. Pharmacy and wholesaler purchasing and dispensing decisions after skinny label entry

i. Pharmacy purchasing and dispensing decisions

3.280. As explained in section 3.E.III.a above, the overwhelming majority of prescriptions for hydrocortisone tablets were (and continue to be) open prescriptions. Full and skinny label hydrocortisone tablets are also bioequivalent (see section 3.D.III.c above). Consequently, pharmacies had a discretion as to whether to dispense full or skinny label tablets regardless of what condition they had been prescribed for, which has led to widespread off-label use of skinny label tablets.

3.281. The evidence collected from the ten largest pharmacy chains³⁹⁰ shows that the proportion of skinny label hydrocortisone tablets purchased, and therefore dispensed, varied across customers, as set out in table 3.8 below.

³⁹⁰ The ten largest pharmacies account for around 57% of the UK pharmacy market (see Table 2 of [the CMA's report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business](#)).

Table 3.8: Pharmacies' purchases of skinny label hydrocortisone tablets (March 2016 to November 2017)

	Hydrocortisone tablet purchase volumes (packs)		Skinny label purchases (packs)		Skinny label purchases as a proportion of all hydrocortisone tablet purchases	
	2016	2017	2016	2017	2016	2017
Asda	24,956	18,409	2,453	1,852	9.8%	10.1%
Boots	151,092	161,853	1,182	2,057	0.8%	1.3%
Day Lewis	25,086	29,407	20,591	26,597	82.1%	90.4%
Lloyds	138,947	153,767	584	6,247	0.4%	4.1%
Morrisons	6,505	7,342	767	877	11.8%	11.9%
Rowlands	36,340	40,360	205	295	0.6%	0.7%
Sainsbury's	3,478	-	-	-	0%	0%
Superdrug	5,596	6,474	896	150	16%	2.3%
Tesco	16,718	18,677	14,895	18,289	89.1%	97.9%
Well	44,126	50,549	-	50	0%	0.1%
Other (independent)	271,654	265,529	233,290	288,071	85.9%	108.5%

Source: CMA analysis of pharmacy responses to section 26 notices and data submitted by relevant parties.

Notes: (1) purchase volumes include packs of both 10mg and 20mgs tablets. (2) 'Other (independent)' volumes are calculated as: total sales volumes of hydrocortisone tablets in the UK – total volumes sold by AAH, Alliance, DE and Sigma – total volumes purchased by Day Lewis, Rowlands, Tesco and Well. (3) Day Lewis has informed the CMA that it has a wholesale function as well as purchasing hydrocortisone tablets for its own pharmacy dispensing.³⁹¹ This means that Day Lewis's purchase volumes shown in this table are higher than the volumes it dispensed as a pharmacy, and 'Other (independent)' pharmacy volumes are slightly understated. These discrepancies are not material to the CMA's conclusions.

3.282. Despite skinny label tablets being bioequivalent to full label tablets, readily dispensed off-label by many pharmacies and sold at significantly lower prices than Auden/Actavis's full label tablets, there were some pharmacies that determined that they could not or should not dispense skinny label hydrocortisone tablets because of their assessment of a potential regulatory risk from dispensing off-label. In those instances, only full label tablets were able to meet these pharmacies' needs. Given that only Auden/Actavis was able to sell 10mg full label hydrocortisone tablets (with 10mg accounting for 96% of all hydrocortisone tablets dispensed), these customers had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets. Accordingly, these pharmacies formed an assured base for Auden/Actavis and accounted for slightly less than 50% of total demand

³⁹¹ Document 206416, Note of call between the CMA and Day Lewis on 16 March 2021, paragraph 2.2.

for hydrocortisone tablets in 2017, as shown in table 3.2 above. The pharmacies that had no choice but to purchase Auden/Actavis's full label tablets were:

- a. Asda (approximately 10% of all purchases being skinny label tablets);
- b. Boots (around 1% of all purchases being skinny label tablets);
- c. Lloyds (approximately 4% of all purchases being skinny label tablets);
- d. Morrisons (approximately 12% of all purchases being skinny label tablets);
- e. Rowlands (less than 1% of all purchases being skinny label tablets);
- f. Sainsbury's (no purchases of skinny label tablets);
- g. Superdrug (approximately 2% of all purchases being skinny label tablets); and
- h. Well Pharmacy (virtually no purchases being skinny label tablets).

3.283. These pharmacies' reasons for their purchasing decisions demonstrate that they had no choice but to purchase full label hydrocortisone tablets, were unable to switch to cheaper skinny label tablets, and would purchase and use skinny label tablets only in certain specific scenarios:³⁹²

- a. Asda delegated the decision as to which of skinny or full label would be purchased to AAH or Alliance.³⁹³ Given AAH's and Alliance's approach to full and skinny label tablets at the time (see section 3.E.IV.c.ii below), this meant that Asda purchased and used mostly full label hydrocortisone tablets.
- b. Boots determined which product to purchase based on whether the product was fully indicated. Although price was a factor that Boots generally considered,³⁹⁴ for hydrocortisone tablets, '*price was not a factor because licensing indications determined which hydrocortisone tablets Boots needed to use*'³⁹⁵ and patient safety was '*the most*

³⁹² In particular, if a prescription specified a skinny label tablet or if a patient expressed a preference to receive a particular supplier's tablets.

³⁹³ Document 00519, responses to questions 1 and 2, Asda's response to the CMA's section 26 notice dated 16 June 2016.

³⁹⁴ Document 206577A, Note of call between Boots and the CMA dated 14 April 2021, paragraph 2.1.

³⁹⁵ Document 206577A, Note of call between Boots and the CMA dated 14 April 2021, paragraph 2.2. Boots pharmacists are '*expected to give a patient the product that is licensed for their condition*' (paragraph 2.2). Boots also '*considers the indications covered by the product before looking at price*', see paragraph 2.3. This was the

important factor'.³⁹⁶ Boots '*needed a product that was licensed for [adrenal insufficiency in adults], which was the fully-indicated product*'.³⁹⁷ Boots considered and discounted also using skinny label tablets because it was '*very important*' for Boots that '*the decision on which products to purchase is simple and easy for Boots pharmacists to administer*'.³⁹⁸ and the financial benefit from using skinny label tablets was '*small and would have been lost quickly*'.³⁹⁹ As a result, Boots continued to require full label tablets.⁴⁰⁰ Although Boots purchased some skinny label tablets, it would only dispense skinny label products '*to meet the specific requirements of the prescriber or to ensure patient suitability and safety*'.⁴⁰¹ or where a patient requested a specific suppliers' tablets.^{402,403}

- c. Lloyds Pharmacy's purchasing decision was determined by whether the product was fully indicated. It considered the '*use of a skinny label product outside of its therapeutic indications, and licence, when a licensed product is available ... contrary to the principles of the UK medicines licensing system*'.⁴⁰⁴ Similar to Boots, Lloyds would not use skinny label hydrocortisone tablets '*if the carved out indications are likely to involve a significant proportion of prescribed indications,*

case for 10mg hydrocortisone tablets. The situation was different for 20mg hydrocortisone tablets because '*two fully-indicated products were available. In that case, price was a relevant factor for Boots in deciding which hydrocortisone tablets to use*' (Document 206577A, note of call between Boots and the CMA dated 14 April 2021, paragraph 2.7).

³⁹⁶ Document 206577A, Note of call between Boots and the CMA dated 14 April 2021, paragraph 2.1. Although Boots previously expressed full label tablets as being its '*preferred product*' (Document 02175, responses to questions 1, 2 and 4(b), Boots' response to the CMA's section 26 notice dated 19 December 2017), its decision on which hydrocortisone tablets to purchase was not it expressing a 'preference' for full label tablets but rather it needing to purchase Auden's tablets because those were the only full label tablets available.

³⁹⁷ Document 206577A, Note of call between Boots and the CMA dated 14 April 2021, paragraph 2.4. Boots '*discounted alternative 10mg hydrocortisone tablets because they were not licensed for adrenal insufficiency in adults*' (paragraph 2.4). See also Document 02188, internal Boots email dated 11 January 2016: '*Full preferred product switch – not possible as alternative product does not have all licensed indications and would only be acceptable clinically and ethically for 5%*'.

³⁹⁸ Document 206577A, Note of call between Boots and the CMA dated 14 April 2021, paragraph 2.1.

³⁹⁹ Document 206577A, Note of call between Boots and the CMA dated 14 April 2021, paragraph 2.5.

⁴⁰⁰ Document 02175, responses to questions 1, 2 and 4(b), Boots' response to the CMA's section 26 notice dated 19 December 2017: '*the decision was made to keep the Almus product as the preferred product as it covered all indications (i.e. full label)*'; and Document 02188, internal Boots email dated 11 January 2016: '*Full preferred product switch – not possible as alternative product does not have all licensed indications and would only be acceptable clinically and ethically for 5%*'.

⁴⁰¹ Document 01787, responses to questions 1 and 5, Boots' response to the CMA's section 26 notice dated 19 June 2017 and Document 206577A, note of call between Boots and the CMA dated 14 April 2021, paragraph 3.3.

⁴⁰² Document 206577A, note of call between Boots and the CMA dated 14 April 2021, paragraph 3.3.

⁴⁰³ In an internal email chain of January 2016, Boots staff considered that Boots stores could not fully switch from dispensing full label tablets to skinny label tablets as it was '*not possible as alternative product does not have all licensed indications and would only be acceptable clinically and ethically for 5% (650/13000 packs) dispensing*'. See Document 02188, internal Boots email chain dated 11 January 2016.

⁴⁰⁴ Document 02198, response to question 4, Lloyds Pharmacy's response to the CMA's section 26 notice dated 17 January 2018.

involving many patients and that pharmacists will have difficulty defining the exact indication for which the medicine is to be used for'.⁴⁰⁵

- d. Morrisons' purchasing decision was driven by whether the product was fully indicated. Morrisons instructed its wholesaler (Alliance) to *'only supply full label Hydrocortisone tablets to avoid complexity in store (eg separation of skinny and full label products in the drawers) and the possibility of inadvertent errors (eg the supply of skinny versus a full label generic prescription)'.⁴⁰⁶* This position ensured that Morrisons' pharmacy teams could *'dispense without having to check/research which licensed indications are covered by the Skinny Label, thus making the dispensing process easier and safer for stores and customers'.⁴⁰⁷*
- e. Rowlands determined its purchasing decisions based on whether the product was fully indicated. Rowlands *'instructed'* its pharmacies to *'purchase the full label product to fulfil its Hydrocortisone 10mg & 20mg Tablets prescriptions'⁴⁰⁸* and used only full label tablets *'[b]ecause of the complexity and legal risk involved with dispensing products outside of their licensed indications'.⁴⁰⁹*
- f. Similar to Asda, Sainsbury's delegated the decision as to which of skinny or full label would be purchased to its wholesalers (AAH and Alliance).⁴¹⁰ Given AAH's and Alliance's approach to full and skinny label tablets at the time (see section 3.E.IV.c.ii below), this meant that Sainsbury's purchased and used mostly full label hydrocortisone tablets.

⁴⁰⁵ Document 01810, response to question 2(a), Lloyds Pharmacy's response to the CMA's section 26 notice dated 19 June 2017.

⁴⁰⁶ Document 01930, email from Morrisons to the CMA dated 20 July 2017. Initially (from December 2016 to March 2017), more than 50% of Morrisons's purchases were skinny label tablets when Morrisons was *'reliant on the wholesaler'* to fulfil Morrisons's *'generic order' 'in the most cost effective manner'*. Its position changed from April 2017 once its Superintendent Pharmacist *'was fully aware of the situation'*, (Document 01930, email from Morrisons to the CMA dated 24 July 2017).

⁴⁰⁷ Document 01930, email from Morrisons to the CMA dated 20 July 2017 and Document 02168, response to question 3, Morrisons' response to the CMA's section 26 notice dated 8 January 2018. See also document 02202, response to question 7, Alliance's response to the CMA's section 26 notice dated 19 December 2017: *'Our understanding of the request [to update Alliance's ordering system to ensure that Morrisons got its preferred version of a product] was that Morrison's wished to ensure compliance to dispensing a fully indicated product for prescriptions'*.

⁴⁰⁸ Document 01836, response to question 1, Rowlands' response to the CMA's section 26 notice dated 19 June 2017. Rowlands also explained that *'we have always advised Rowlands pharmacies to purchase the Actavis product as it can [be] used to treat patients of all ages. We do this by restricting our PMR systems to purchase the Actavis product when ordering Hydrocortisone 10mg & 20mg tablets'*, response to questions 1 and 6.

⁴⁰⁹ Document 00597, response to question 5, Rowlands' response to the CMA's section 26 notice dated 16 June 2016.

⁴¹⁰ Document 00601, response to question 2, Sainsbury's response to the CMA's section 26 notice dated 16 June 2016.

- g. Superdrug determined its purchasing decisions based on whether the product was fully indicated. Superdrug purchased full label products '*in preference to a Skinny label product in accordance with MHRA guidance relating to the use of licensed products*'.⁴¹¹ It would only purchase skinny label tablets in certain circumstances, namely if: full label tablets were out of stock; there was a specific patient request for a skinny label product; the pharmacist identified a patient need for a skinny label product; or a specific skinny label product was prescribed.⁴¹²
 - h. Well Pharmacy determined its purchasing decisions based on whether the product was fully indicated. Well Pharmacy purchased only full label tablets because '*the Auden product is the only product to carry all indications and therefore we can dispense this product against 100% of generic Hydrocortisone scripts*'⁴¹³ and to '*simplify the process for our teams*'.⁴¹⁴
- 3.284. In contrast, other pharmacies, accounting for just over 50% of total demand for hydrocortisone tablets, considered that they could dispense off-label and switch to cheaper skinny label tablets. The majority of those pharmacies were independent pharmacies, as shown in table 3.8 above, but also included Day Lewis (dispensed virtually only skinny label tablets)⁴¹⁵ and Tesco (virtually all purchases being skinny label tablets), with both of those pharmacies having switched almost entirely to using skinny label tablets.
- 3.285. DE Pharma, Mawdsleys and Sigma (short-line wholesalers) explained how and why their customers, predominantly independent pharmacies, switched to skinny label tablets:
- a. DE Pharma listed (ie offered for sale) both full and skinny label tablets because its customers wanted choice,⁴¹⁶ taking the decision to list

⁴¹¹ Document 01887, responses to questions 2 (a), Superdrug's response to the CMA's section 26 notice dated 19 June 2017.

⁴¹² Document 01887, responses to questions 1 and 2, Superdrug's response to the CMA's section 26 notice dated 19 June 2017.

⁴¹³ Document 00612, response to question 2, Well Pharmacy's response to the CMA's section 26 notice dated 16 June 2016. See also, Document 01813, response to question 6, Well Pharmacy's response to the CMA's section 26 notice dated 30 June 2017.

⁴¹⁴ Document 00612, response to question 5, Well Pharmacy's response to the CMA's section 26 notice dated 16 June 2016.

⁴¹⁵ Based on dispensing data (see Document 01885) because Day Lewis has a wholesale function as well as purchasing hydrocortisone tablets for its own pharmacy dispensing (see Document 206416, Note of call between the CMA and Day Lewis on 16 March 2021, paragraph 2.2), meaning that Day Lewis's purchase volumes are higher than the volumes it dispensed as a pharmacy.

⁴¹⁶ Document 01779, response to question 4, DE Pharma's responses to the CMA's section 26 notice dated 21 June 2017.

skinny label tablets from January 2016.⁴¹⁷ DE Pharma *'dual listed skinny and full label tablets and let its customers choose which to purchase'*.⁴¹⁸ Independent pharmacies, who are *'very price sensitive'*,⁴¹⁹ switched to skinny label tablets because *'the skinny label tablet was cheaper'*. Switching to skinny label tablets was *'facilitated by open prescriptions'*⁴²⁰ and increased over time as the price gap between full and skinny label tablets increased.⁴²¹

- b. Mawdsleys explained that it *'became aware that customers were interested in skinny label tablets'* from seeing sales increasing.⁴²² Independent pharmacies, *'who are more price sensitive'*,⁴²³ *'would purchase skinny label tablets if the price was lower than the price of full label tablets'*.⁴²⁴
- c. Sigma started selling skinny label tablets because its customers, independent pharmacies, who are *'very price-sensitive'*,⁴²⁵ demanded *'the cheapest product which is the Skinny label'*.⁴²⁶ Pharmacists were able to choose between full and skinny label tablets because prescriptions were open.⁴²⁷

⁴¹⁷ Document 01779, response to question 2, DE Pharma's responses to the CMA's section 26 notice dated 21 June 2017.

⁴¹⁸ Document 206579, Note of call between the CMA and DE Pharma dated 23 February 2021, paragraph 2.7.

⁴¹⁹ Document 206579, Note of call between the CMA and DE Pharma dated 23 February 2021, paragraph 2.2. See also paragraph 2.3: *'a price difference of only a few pence might be enough for an independent pharmacy to switch'*; and paragraph 5.1 *'Independent pharmacies' purchasing decisions are all about price and stock availability. A lot of wholesalers and pharmacies buy on the penny'*.

⁴²⁰ Document 206579, Note of call between the CMA and DE Pharma dated 23 February 2021, paragraph 2.9.

⁴²¹ Document 206579, Note of call between the CMA and DE Pharma dated 23 February 2021, paragraph 2.10.

⁴²² Document 206612, Note of call between the CMA and Mawdsleys dated 3 March 2021, paragraph 2.7.

⁴²³ Document 206612, note of call between the CMA and Mawdsleys dated 3 March 2021, paragraph 2.5.

⁴²⁴ Document 206612, Note of call between the CMA and Mawdsleys dated 3 March 2021, paragraph 2.5. See also paragraph 2.4: *'if skinny was below the price of the full labels, a lot of independents would by skinny'*.

⁴²⁵ Document 206582, note of call with Sigma dated 4 March 2021, paragraph 2.3. See also paragraph 2.5: independent pharmacies are *'sensitive to price'*, as a result of which the *'short-line wholesale segment of the market buys based on price'*. Independent multiple pharmacies (those with around 50 to 100 shops) are *'even more price sensitive'* than independent pharmacies, paragraph 2.5.

⁴²⁶ Document 01855, response to question 4.a, Sigma's response to the CMA's section 26 notice dated 21 June 2017. Sigma also *'has to compete with other wholesalers who offer both labels and therefore, we stock both labels'*, response to question 4.c.

⁴²⁷ Document 01855, response to question 4.b, Sigma's response to the CMA's section 26 notice dated 21 June 2017: *'The independent retail pharmacists in my opinion do not get a prescription specifically for Skinny or Full label product. The prescriptions are almost always generic not specifying the brand'*. See also Document 206582, note of call with Sigma dated 4 March 2021, paragraph 2.2: *'To fill such an open prescription, it does not matter if the product is full or skinny label, so long as the pharmacist fills the prescription with hydrocortisone tablets it is fine'*.

ii. Wholesaler purchasing decisions

- 3.286. Pharmacies either purchase hydrocortisone tablets directly from a supplier or through a wholesaler. Where they purchase through a wholesaler, pharmacy demand therefore determines wholesaler demand.⁴²⁸
- 3.287. The evidence collected from wholesalers shows that the proportion of skinny label hydrocortisone tablets purchased, and therefore sold, also varied across customers.
- 3.288. The principle difference in sales between full-line and short-line wholesalers was due to short-line wholesalers (eg DE Pharma, Mawdsleys and Sigma) selling predominantly to independent pharmacies, in contrast to full-line wholesalers (AAH and Alliance) selling predominantly to large pharmacy chains. As seen from table 3.9 below:
- a. The two largest full-line wholesalers (AAH and Alliance) mainly sold full label hydrocortisone tablets.⁴²⁹ This is consistent with many of their customers being large pharmacy chains who, as explained in section 3.E.IV.c.i above, had no choice but to purchase full label hydrocortisone tablets. However, their sales of skinny label tablets to customers other than their respective integrated pharmacy chains (Lloyds and Boots) increased substantially in 2017.
 - b. In contrast, DE Pharma and Sigma⁴³⁰ predominantly sold skinny label hydrocortisone tablets. This is consistent with their customers being predominantly independent pharmacies who, as explained in section 3.E.IV.c. above, were the primary customers who switched to skinny label hydrocortisone tablets.

⁴²⁸ Document 02197, responses to questions 6 and 7, AAH's response to the CMA's section 26 notice dated 19 December 2017; Document 02202, responses to questions 6 and 7, Alliance's responses to the CMA's section 26 notice dated 19 December 2017; Document 01779, response to question 4, DE Pharma's response to the CMA's section 26 notice dated 21 June 2017; Document 01855, response to question 4, Sigma's responses to the CMA's section 26 notice dated 21 June 2017; and Document 206612, note of call between the CMA and Mawdsleys dated 3 March 2021, paragraph 3.3.

⁴²⁹ Document 02202, response to question 6, Alliance's response to the CMA's section 26 notice dated 19 December 2017; and Document 02197, response to question 7, AAH's response to the CMA's section 26 notice dated 19 December 2017.

⁴³⁰ The CMA did not obtain sales data from Mawdsleys.

Table 3.9: Wholesalers' purchases of skinny label hydrocortisone tablets (March 2016 to November 2017)

	Hydrocortisone tablet purchase volumes (packs)		Skinny label purchase volumes (packs)		Skinny label purchases as a proportion of all hydrocortisone tablet purchases	
	2016	2017	2016	2017	2016	2017
AAH and Alliance	483,845	520,249	46,409	107,020	10%	21%
AAH	272,788	257,843	24,29	45,827	9%	18%
<i>AAH: to customers other than Lloyds</i>	<i>133,841</i>	<i>104,076</i>	<i>23,708</i>	<i>39,580</i>	<i>18%</i>	<i>38%</i>
Alliance	211,057	262,406	22,117	61,193	10%	23%
<i>Alliance: to customers other than Boots</i>	<i>61,308</i>	<i>98,416</i>	<i>21,264</i>	<i>59,359</i>	<i>35%</i>	<i>60%</i>
DE Pharma and Sigma	78,283	98,509	50,445	86,187	64%	87%
DE Pharma	49,411	62,869	30,025	52,827	61%	84%
Sigma	28,872	35,640	20,420	33,360	71%	94%

Source: CMA analysis of wholesaler responses to section 26 notices.

Note: purchase volumes include packs of both 10mg and 20mgs tablets.

- 3.289. The evidence indicates that short-line wholesalers' customers (predominantly independent pharmacies) are more price sensitive (and therefore more likely to buy skinny label hydrocortisone tablets) than full-line wholesalers. Full-line wholesalers made their decision on which hydrocortisone tablets to stock based on a broad range of factors, whereas short-line wholesalers prioritised price, leading them to sell more skinny label tablets.
- 3.290. The two largest full-line wholesalers AAH and Alliance explained that, when deciding which hydrocortisone tablets to stock, they considered factors including: customer demand; customer preferences; cost price and market selling price; product characteristics and suitability (including what indications the product was licensed for); product interchangeability; supplier service levels/reliability; and availability of product. Customer demand and preferences, and product characteristics and suitability were the most important factors considered by AAH and Alliance, followed by product

interchangeability and '*commercial*s' (including but not limited to purchase price) for AAH and pricing and service level considerations for Alliance.⁴³¹

3.291. AAH and Alliance explained that they offer both full and skinny label hydrocortisone tablets and the decision on which product to purchase is ultimately made by customers (ie pharmacies).^{432,433} Although customers can request Alliance to update its ordering system to ensure that a customer gets a particular product, only Boots⁴³⁴ and Morrisons⁴³⁵ expressly requested a full label product. AAH also confirmed that only Lloyds expressly requested a full label product.⁴³⁶

3.292. AAH identified '*product characteristics/customer preference*', '*licensed indications*' and '*product interchangeability*' as factors that limit or reduce AAH's ability or willingness to switch between different suppliers of hydrocortisone tablets.⁴³⁷

3.293. Alliance further explained that:

'only the Actavis UK Hydrocortisone Tablets had the indication for adrenal insufficiency in adults. Without the same indications it would not be appropriate for Alliance to switch to purchasing Hydrocortisone Tablets from other suppliers that did not have this indication, for supply to customers as a substitute for the Actavis UK Hydrocortisone tablets. In addition, information received from both Actavis, other manufacturers on the market and from Boots indicated that the skinny label product could not be used for 95% of prescriptions, therefore Actavis UK knew that Alliance were not able to switch the majority of its purchases to the Skinny label product [...] Alliance did list versions of the skinny label

⁴³¹ Document 01586 and Document 01581, response to question 5, AAH's and Alliance's responses to the CMA's section 26 notice dated 4 May 2017.

⁴³² Document 02197 and Document 02202, responses to questions 6 and 7, AAH's and Alliance's responses to the CMA's section 26 notice dated 19 December 2017.

⁴³³ However, some customers, such as Asda explained that '*the decision as to which of skinny or full label will be purchased from AAH and Alliance is taken by the wholesaler*', therefore delegating this to the wholesalers; see Document 00519, responses to questions 1 and 2, Asda's response to the CMA's section 26 notice dated 16 June 2016.

⁴³⁴ Document 01581, response to question 3, Alliance's response to the CMA's section 26 notice of 4 May 2017: '*it was indicated to Alliance Healthcare by Boots that they would not be able to utilise the new versions as they lacked this indication and so they would need to continue to purchase the Actavis version*'.

⁴³⁵ Document 02202, response to question 7, Alliance's response to the CMA's section 26 notice dated 19 December 2017.

⁴³⁶ Document 02197, response to question 7, AAH's response to the CMA's section 26 notice dated 19 December 2017.

⁴³⁷ Document 01586, response to question 5(c), AAH's response to the CMA's section 26 notice dated 4 May 2017.

product for customers that wished to purchase it however the majority of demand was still for the Full label version'.⁴³⁸

3.294. Short-line wholesalers DE Pharma and Sigma, on the other hand, sold almost entirely skinny label hydrocortisone tablets. They explained that this was driven by customer demand,⁴³⁹ which, in their case were independent pharmacies, who were price sensitive⁴⁴⁰ and did not dual stock.⁴⁴¹ Sigma further clarified that the *'drug tariff lists only one product and therefore the demand for our customers who are independent retail pharmacists is for the cheapest product which is Skinny label'.⁴⁴²*

V. Developments in the supply of hydrocortisone tablets

3.295. This section explains how prices (per pack)⁴⁴³ and volumes changed for 10mg and 20mg hydrocortisone tablets prior to, during and after the Infringements. This section includes a description of the independent entry that took place from 2015, and the effect of Auden/Actavis's price rises on NHS Reimbursement Prices.

3.296. In summary:

- a. Following the acquisition of the hydrocortisone tablets MAs, Auden started selling hydrocortisone tablets from April 2008 at a prices that were 549% (10mg) and 380% (20mg) higher⁴⁴⁴ than MSD and proceeded to consistently increase its prices over a prolonged period of time (from April 2008 to June 2015). Once Allergan acquired AM Pharma, Actavis continued to increase its prices for hydrocortisone tablets. Hydrocortisone tablet prices peaked at £72.14 in April 2016 (10mg tablets) and £72.19 in December 2015 (20mg tablets).
- b. Following independent entry by a number of competing suppliers, Actavis's prices started to fall. However, Actavis's price decreases were

⁴³⁸ Document 02202, response to question 3, Alliance's response to the CMA's section 26 notice dated 19 December 2017. See also Document 01581, response to question 3, Alliance's response to the CMA's section 26 notice dated 4 May 2017.

⁴³⁹ Document 01779 and Document 01855, response to question 4, DE Pharma's and Sigma's responses to the CMA's section 26 notice dated 21 June 2017.

⁴⁴⁰ Document 206579, Note of call between the CMA and DE Pharma dated 23 February 2021, paragraph 2.2 and 2.3 and Document 01855, response to question 4, Sigma's response to the CMA's section 26 notice dated 21 June 2017.

⁴⁴¹ Document 206580, Note of call between the CMA and DE Pharma dated 17 March 2021, paragraph 2.1.b.

⁴⁴² Document 01855, response to question 4, Sigma's response to the CMA's section 26 notice dated 21 June 2017.

⁴⁴³ In this section and throughout the Decision (unless where stated), prices are Average Selling Prices. Average selling price (ASP) is defined as the gross price per pack for each of 10mg and 20mg hydrocortisone tablets, net of rebates, and is usually presented monthly. Average prices have been computed by dividing sales values by the corresponding sales volumes.

⁴⁴⁴ A price of £4.54 per pack compared to MSD's price of £0.70 per pack (10mg) and a price of £5.14 per pack compared to MSD's price of [£1-£4] per pack (20mg).

steady over a prolonged period of time. In contrast, other suppliers' prices, including both skinny label 10mg and 20mg tablet prices and Waymade's 20mg full label tablet prices, fell quickly and significantly as competition intensified between those suppliers.

- c. Following independent entry, there were significant and persistent price differences between Actavis's prices and the prices charged by its competitors. The price difference narrowed more quickly for 20mg tablets due to the presence of a second full label tablet supplier (Waymade), with Actavis's prices and the prices charged by its competitors converging around early 2018. In contrast, the price difference between Actavis's prices and the prices charged by its competitors for 10mg tablets persisted [X].
- d. Until 2015 when independent entry occurred, that is, for nearly eight years, Auden/Actavis was the sole supplier of 10mg and 20mg hydrocortisone tablets, with a share of supply of 100% (by either value or volume).⁴⁴⁵ Following independent entry, competition eroded Auden/Actavis's share of supply to some degree, but shares then flattened out at around 50% by volumes (and higher in value terms), a feature which persisted throughout the Infringements.

a. Pre-entry period

i. Changes in Auden/Actavis's prices of hydrocortisone tablets

3.297. Auden/Actavis increased its prices⁴⁴⁶ significantly from the point at which it first commenced sales of hydrocortisone tablets in the UK, in April 2008, and

⁴⁴⁵ See section 4.C.II.c.i below on the relevance of Auden/Actavis's supply arrangements with Waymade and AMCo to its market shares.

⁴⁴⁶ For Auden/Actavis, the gross price is calculated by excluding the sales to AMCo, Waymade, and intercompany sales as these sales do not reflect prices to wholesalers or pharmacies and were distorted by the Agreements. Although the CMA sought to use data on prices net of rebates, this was not possible for Actavis prior to September 2015, and so rebates have been apportioned as follows:

AM Pharma's rebate policy was to link rebates to the overall revenue from the sale of products covered by a rebate agreement (Document 00670, paragraph 3.2(a), AM Pharma's response to the CMA's section 26 notice dated 23 June 2016). However, Accord-UK was unable to attribute the rebates balance to specific customers or products (including hydrocortisone tablets) prior to June 2015, when Allergan acquired AM Pharma (Document 00639, paragraph 1.2, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016). Given that revenue is likely to have been the key driver behind AM Pharma's rebates policy, the CMA considers that revenue is the most appropriate basis on which to allocate rebates to hydrocortisone tablets before June 2015 and that it should be presented as a percentage discount on gross prices. Accord-UK also submitted that it has '*significant concerns as to the accuracy of some of this [rebate] information for the period prior to 2012*' (Document 00649, email from King & Wood Mallesons to the CMA dated 19 May 2016). The CMA, therefore, considers that it cannot place reliance on any rebates figures before 2012 and subsequently has estimated the appropriate discount during this period by extrapolating the 2012 rebates discount backwards. (If 2011 rebate information were used, the discount would have amounted to 18% for hydrocortisone tablets. However, the CMA notes this is significantly larger than the average 5% rebate applied during 2012-2015, and is therefore not an appropriate basis to calculate rebates.) Accord-UK submitted AM Pharma's rebates data up to May 2015. This data was extrapolated forwards until September 2015, when the sales of hydrocortisone tablets were transferred

continued increasing prices until they reached their peak (of £72.14 in April 2016 (10mg tablets) and £72.19 in December 2015 (20mg tablets)). Overall, from 2008 to their peak, Auden/Actavis's prices increased by 1,489% (10mg) and 1,304% (20mg).⁴⁴⁷

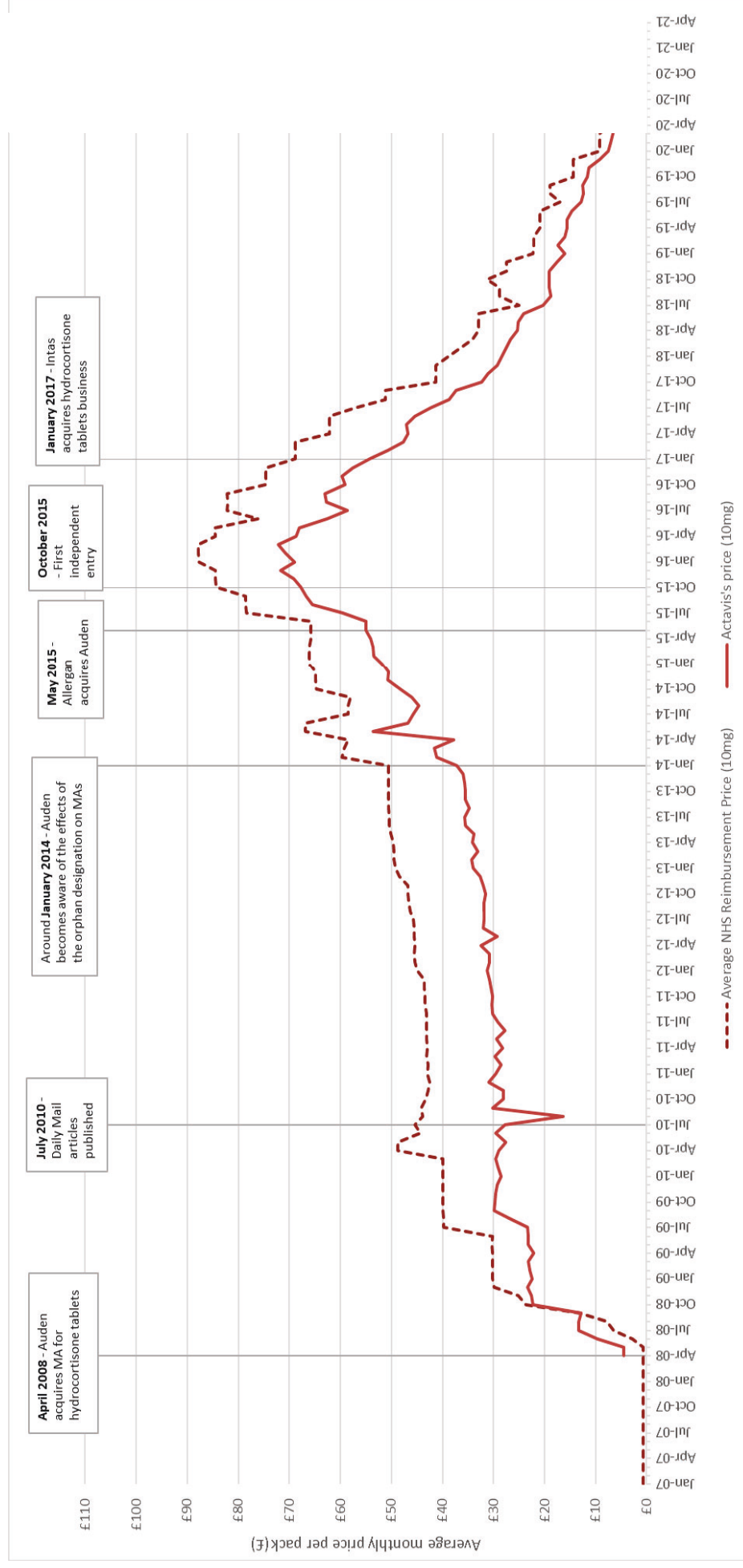
- 3.298. The evolution of Auden/Actavis's monthly prices, together with NHS Reimbursement prices, is shown in figures 3.10 and 3.11 below.

to Accord-UK. The CMA notes that there are some inconsistencies between the monthly revenue figures used to calculate Accord-UK's rebates and the monthly revenue figures submitted by Accord-UK. Accord-UK explained that this is due to the information on rebates coming from a different source than the original information on revenues submitted by Accord-UK. However, the CMA notes that the differences in revenues are very small (less than 1%) and therefore would not have a material impact on the calculation of Accord-UK's prices.

Given that Actavis UK is unable to identify the level of rebates which are attributable to individual customers, the total rebates balance (of which a portion is allocated to hydrocortisone tablets) includes rebates issued to AMCo and Waymade. This is a conservative approach as the rebates balances are likely to be overstated and therefore prices will be reduced below their actual levels.

⁴⁴⁷ An increase from £4.54 to £72.14 per pack (10mg) and from £5.14 to £72.19 per pack (20mg).

Figure 3.10: Auden/Actavis's average selling price and average NHS Reimbursement Price⁴⁴⁸ for 10mg hydrocortisone tablets

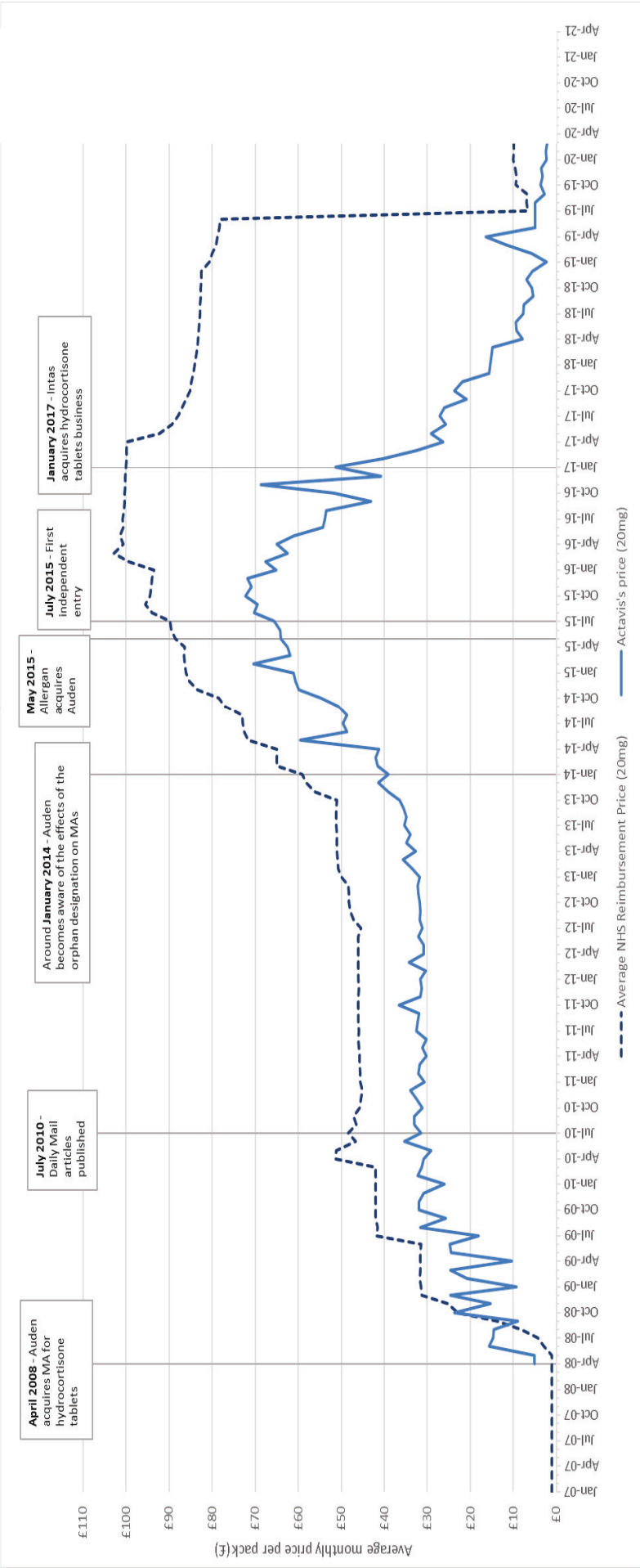


Source: CMA analysis based on the data submitted by Actavis and PCA data for England.

Notes: (1) NHS Reimbursement Price includes sales of branded Hydrocortone tablets during 2007. (2) Drug Tariff price is shown instead of NHS Reimbursement Price for January to April 2021 due to data availability.

⁴⁴⁸ Average NHS Reimbursement Price is the price the NHS pays for dispensing hydrocortisone tablets (see section 3.E.I above).

Figure 3.11: Auden/Actavis's average selling price and average NHS Reimbursement Price for 20mg hydrocortisone tablets



Source: CMA analysis based on the data submitted by Actavis and PCA data for England.

Notes: (1) NHS Reimbursement Price includes sales of branded Hydrocortone tablets during 2007. (2) Drug Tariff price is shown instead of NHS Reimbursement Price for January to April 2021 due to data availability.

- 3.299. Prices began to increase significantly soon after Auden launched its generic versions of hydrocortisone tablets (see paragraph 3.341) and by **June 2010** Auden's monthly prices had increased to:
- a. **£29.60** for 10mg hydrocortisone tablets, an increase of £25.06, representing a **552%** increase; and
 - b. **£35.34** for 20mg hydrocortisone tablets, an increase of £30.20, representing a **588%** increase.
- 3.300. On 18 July 2010, the Daily Mail published an article titled *"NHS doesn't care about cost of medicine": Drugs firms accused of profiteering by raising prices by ONE THOUSAND per cent*,⁴⁴⁹ which alleged that Auden was *'profiteering after imposing huge price rises for commonly prescribed drugs'*, including hydrocortisone tablets, in relation to which it was described as implementing *'huge unexplained price increase[s]'*.
- 3.301. Shortly afterwards, the Daily Mail published a follow-up article titled *'Drug firm slashes prices after MoS [Mail on Sunday] investigation – saving taxpayer £500k'*,⁴⁵⁰ which reported that Auden had *'slashed the price of its hydrocortisone tablets, used to treat kidney patients, by £7.40 – saving the NHS almost £500,000 on its monthly drugs bill'*.
- 3.302. This price drop was reflected in Auden's prices: in June 2010, its price for 10mg hydrocortisone tablets was £29.60 but this fell to £16.42 in August 2010. However, by September 2010, the price had again increased to £30.20.
- 3.303. Following publication of the Daily Mail articles, prices were relatively stable for a time. Auden's prices for both 10mg and 20mg hydrocortisone tablets remained around £30 throughout 2011. They then began to increase once more. Between June 2010 and December 2013, Auden's monthly price increased from:
- a. £29.60 to **£36.03** for 10mg hydrocortisone tablets, an increase of £6.43, representing a **22%** increase; and
 - b. £35.34 to **£41.39** for 20mg hydrocortisone tablets, an increase of £6.05, representing a **17%** increase.

⁴⁴⁹ ["NHS doesn't care about cost of medicine": Drugs firms accused of profiteering by raising prices by ONE THOUSAND per cent](#), *Daily Mail*, 18 July 2010.

⁴⁵⁰ ["Drug firm slashes prices after MoS investigation – saving taxpayer £500k"](#), *Daily Mail*, 25 July 2010.

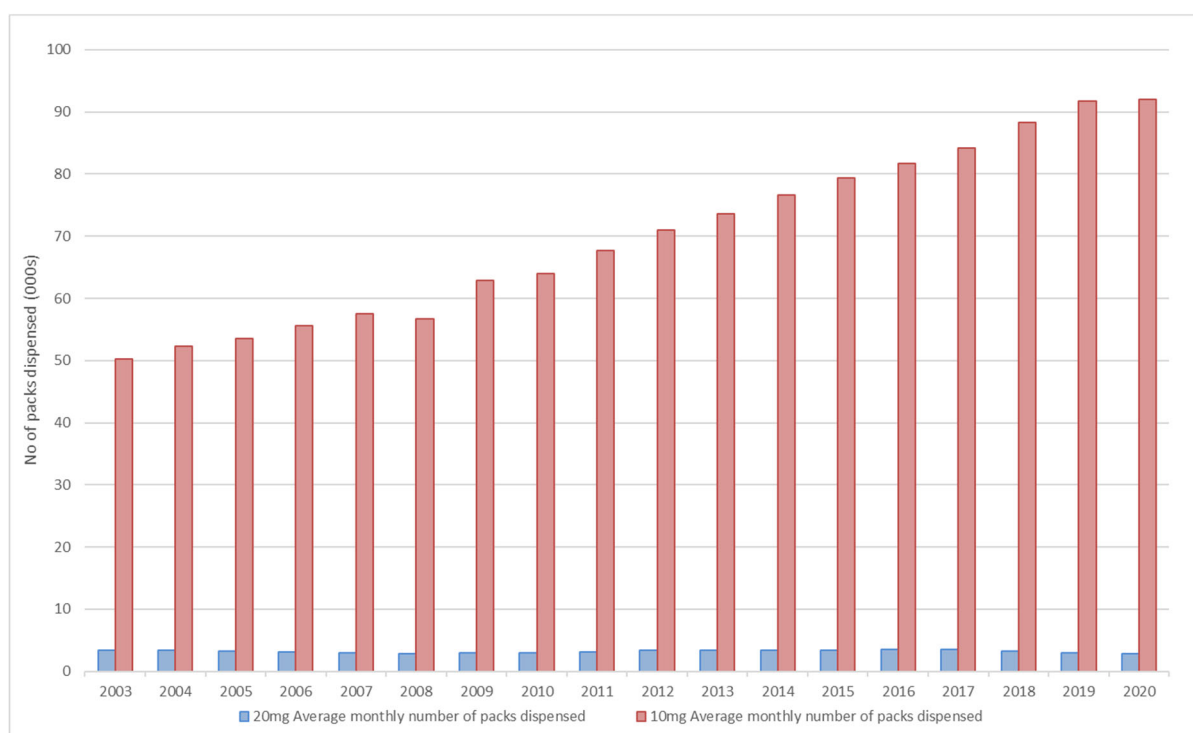
- 3.304. From December 2013 until Allergan's acquisition of AM Pharma in May 2015, Auden's monthly price increased at a quicker rate, from:
- a. £36.03 to **£54.99** for 10mg hydrocortisone tablets, an increase of £18.96, representing a **53%** increase; and
 - b. £41.39 to **£64.03** for 20mg hydrocortisone tablets, an increase of £22.64, representing a **55%** increase.
- 3.305. Prices continued to increase after Allergan acquired AM Pharma in May 2015 and transferred its business to Accord-UK from September 2015 onwards. Actavis's monthly prices reached a peak of:
- a. **£72.14** in March 2016 for 10mg hydrocortisone tablets, an increase of £17.15 relative to May 2015, representing a **31%** increase; and
 - b. **£72.19** in October 2015 for 20mg hydrocortisone tablets, an increase of £8.16 relative to May 2015, representing a **13%** increase.

ii. Volume and share of supply

- 3.306. From 2008 until 2015, that is for seven years during the pre-entry period, Auden was the sole supplier of hydrocortisone tablets in the UK with a share of supply of 100% (by both value and volume).⁴⁵¹
- 3.307. Figure 3.12 below shows volumes of hydrocortisone tablets dispensed in each year from 2003 to 2020. It illustrates that:
- a. Total volumes of 10mg tablets grew at a constant rate (of around 4% each year on average), consistent with 2% being new prescriptions each year (see paragraph 3.126).
 - b. Total volumes of 20mg tablets were broadly stable.

⁴⁵¹ See section 4.C.II.b.i below on the relevance of Auden/Actavis's supply arrangements with Waymade and AMCo to its market shares.

Figure 3.12: 10mg and 20mg hydrocortisone tablets total volumes, 2003-2020



Source: CMA analysis based on NHS BSA data

b. Post-entry period

i. Entry in UK supply of hydrocortisone tablets

3.308. 2015 marked the start of independent entry by suppliers of hydrocortisone tablets other than Auden/Actavis:

- a. In July 2015 Waymade was the first independent entrant for 20mg tablets, entering the market with full label 20mg hydrocortisone tablets manufactured by Aesica.⁴⁵²
- b. In October 2015, Alissa was the first independent entrant for 10mg tablets, entering the market with skinny label 10mg hydrocortisone tablets manufactured by Orion.⁴⁵³

3.309. Following those initial launches, further independent entry took place as follows:

⁴⁵² Document 200003, paragraph 1.3, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁴⁵³ Document 00512, paragraph 1, Alissa's response to the CMA's section 26 notice dated 15 June 2016.

- a. In March 2016, Resolution Chemicals entered the market with skinny label Hydrocortisone Tablets manufactured by Eirgen Pharma Limited.⁴⁵⁴
- b. Between March and April 2016, Bristol Laboratories entered the market with skinny label 10mg and 20mg hydrocortisone tablets, a product that it manufactured itself.⁴⁵⁵
- c. In May 2016, AMCo entered the market with skinny label 10mg hydrocortisone tablets manufactured by Aesica.⁴⁵⁶
- d. In February 2017, Teva entered the market with skinny label 10mg and 20mg hydrocortisone tablets, a product that it manufactured itself.⁴⁵⁷
- e. AMCo's subsidiary, Focus, commenced supplying 20mg and 10mg skinny label hydrocortisone tablets manufactured by Lamda in August and September 2017, respectively.⁴⁵⁸
- f. In November 2017, Genesis Pharmaceuticals entered with skinny label 10mg and 20mg hydrocortisone tablets [✂].⁴⁵⁹
- g. In February 2019, Renata UK Limited entered with skinny label 10mg and 20mg hydrocortisone tablets. Renata manufactures the product and distributes through its partnership with Flynn Pharma.⁴⁶⁰ As of May 2019 Renata has only sold 10mg hydrocortisone tablets in the UK market.

3.310. Entry dates and product supplied are shown in table 3.13 below.

⁴⁵⁴ Document 00592, paragraph 1, Resolution Chemicals' response to the CMA's section 26 notice dated 28 June 2016.

⁴⁵⁵ Document 00527, paragraph 5, Bristol Laboratories' response to the CMA's section 26 notice dated 17 March 2016.

⁴⁵⁶ Document 201353, Notes of oral hearing with Concordia dated 20 July 2017.

⁴⁵⁷ Document 01646, Teva's response to the CMA's section 26 notice dated 19 May 2017.

⁴⁵⁸ Document 02662, AMCo's response to question 1 of the CMA's section 26 notice dated 25 January 2018.

⁴⁵⁹ Document 02249, Genesis Pharmaceuticals' response to questions 7 – 8 of the CMA's section 26 notice dated 15 January 2018.

⁴⁶⁰ Document 03893, Renata's response to the CMA's section 26 notice dated 25 June 2019, response to question 1.

Table 3.13: Dates of independent entry by hydrocortisone tablet suppliers

Date of entry	Supplier	Full label	Skinny label	10mg	20mg
July 2015	Waymade	X			X
October 2015	Alissa		X	X	
March 2016	Resolution Chemicals ⁴⁶¹		X	X	X
March 2016	Bristol Laboratories		X	X	X
May 2016	AMCo (Aesica) ⁴⁶²		X	X	
February 2017	Teva		X	X	X
November 2017	Genesis Pharmaceuticals		X	X	X
February 2019	Renata		X	X	X

3.311. From table 3.13 above it is evident that:

- With the exception of Waymade's 20mg tablets, all entrants supplied skinny label hydrocortisone tablets, which means that for 10mg tablets Auden/Actavis was the only full label supplier, and for 20mg tablets Auden/Actavis was one of only two full label suppliers.
- While there was a delay of a few months between the first entrants and subsequent entrants for both 10mg and 20mg tablets, by March 2016, with the entry of Resolution Chemicals and Bristol Laboratories, there were three independent suppliers of both tablet strengths.

3.312. Since entry, some suppliers have subsequently exited the market or ceased supplying temporarily:

- Advanz stopped supplying from February 2021;⁴⁶³
- Alissa stopped supplying from around December 2020;⁴⁶⁴

⁴⁶¹ Mylan commenced distributing 10mg hydrocortisone tablets in June 2017 and 20mg tablets in July 2017, supplied by Resolution Chemicals (see Document 02836.B, response to questions 3 and 4, Mylan's response to the CMA's section 26 notice dated 19 February 2018). Mylan is therefore not separately considered in this section as its sales are captured within Resolution Chemicals' sales data.

⁴⁶² AMCo also started selling skinny label 10mg and 20mg hydrocortisone tablets through its subsidiary, Focus, in August 2017 (for 20mg tablets) and October 2017 (for 10mg tablets). See Document 206657, Focus and Amdipharm's Hydrocortisone Tablet Sales.

⁴⁶³ Document 206694, letter from Morgan Lewis to the CMA dated 15 June 2021.

⁴⁶⁴ Document 03850, email from Alissa to the CMA dated 26 June 2019; Document 205859, Alissa Healthcare Hydrocortisone UK sales Date in response to CMA s.26 on sales rolling data; and Document 205936, email from Alissa to the CMA dated 16 December 2020.

- c. Bristol Laboratories temporarily stopped supplying between May and November 2018;⁴⁶⁵
- d. Renata temporarily stopped supplying from February 2020;⁴⁶⁶ and
- e. [REDACTED].⁴⁶⁷

ii. Changes to Auden/Actavis's prices

- 3.313. Independent entry prompted Auden/Actavis's prices⁴⁶⁸ to fall, and prices fell steadily from the point of entry throughout the post-entry Infringement period and subsequently.
- 3.314. However, Auden/Actavis's prices fell more slowly than those of its competitors (see section 3.E.V.b.iv below).
- 3.315. Figures 3.14 and 3.15 below show how prices of 10mg and 20mg hydrocortisone tablets (both those of Auden/Actavis and competitors, and the Drug Tariff price) evolved following independent entry by a number of competing suppliers.

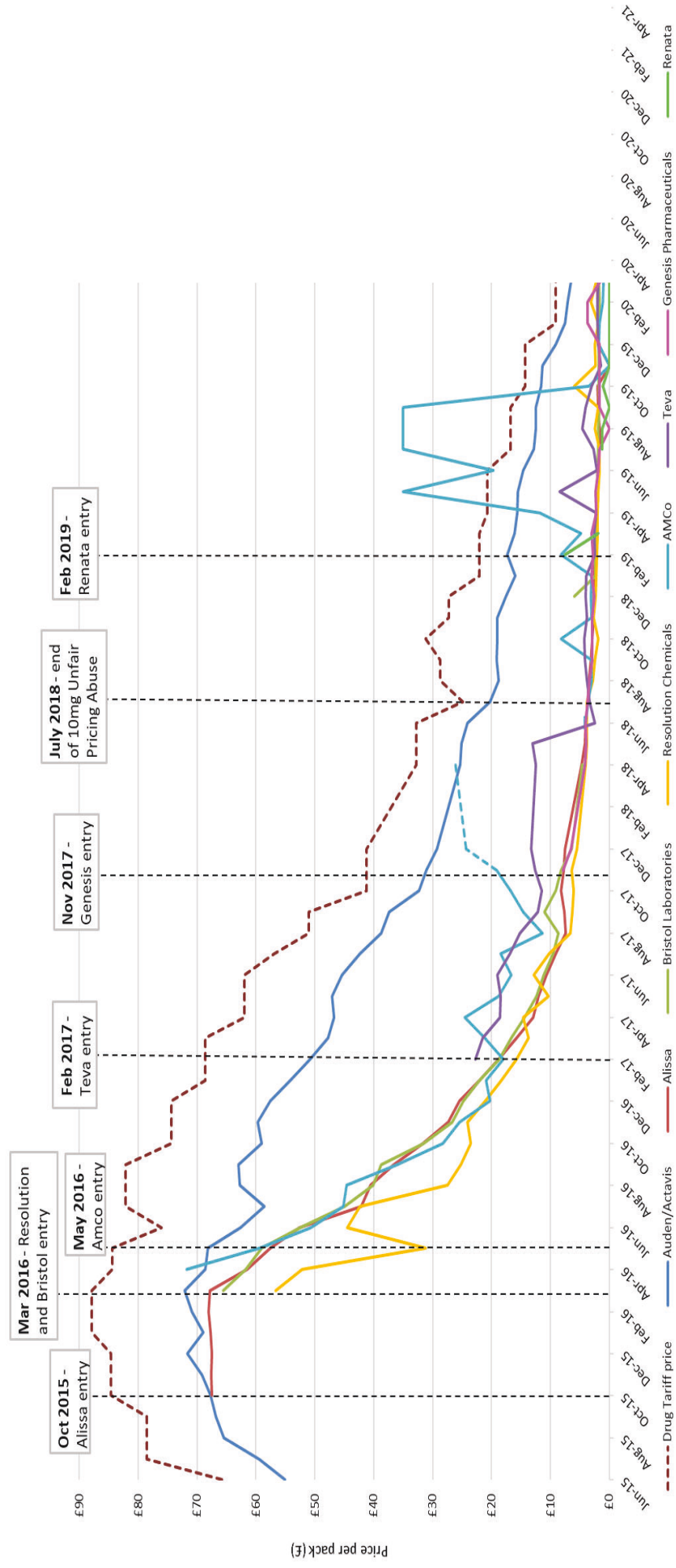
⁴⁶⁵ Document 03173, email from Bristol Laboratories to the CMA dated 5 June 2018. See also, Document 03774, Bristol's Laboratories in response to CMA s.26 on sales rolling data.

⁴⁶⁶ Document 205284, emails from Diamond Pharma Services (on behalf of Renata) to the CMA dated 10 and 12 August 2020. See also, Document 204964, Renata's response to the CMA's section 26 notice dated 25 June 2019.

⁴⁶⁷ Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

⁴⁶⁸ The issues with rebates data (described in footnote 446 above) were not present from September 2015 onwards: from September 2015 until 9 January 2017, Accord-UK provided monthly rebates data, for both 10mg and 20mg tablets. Since Intas' acquisition of Accord-UK on 9 January 2017 onwards, Accord-UK has provided average monthly sales price data, net of all discounts and rebates.

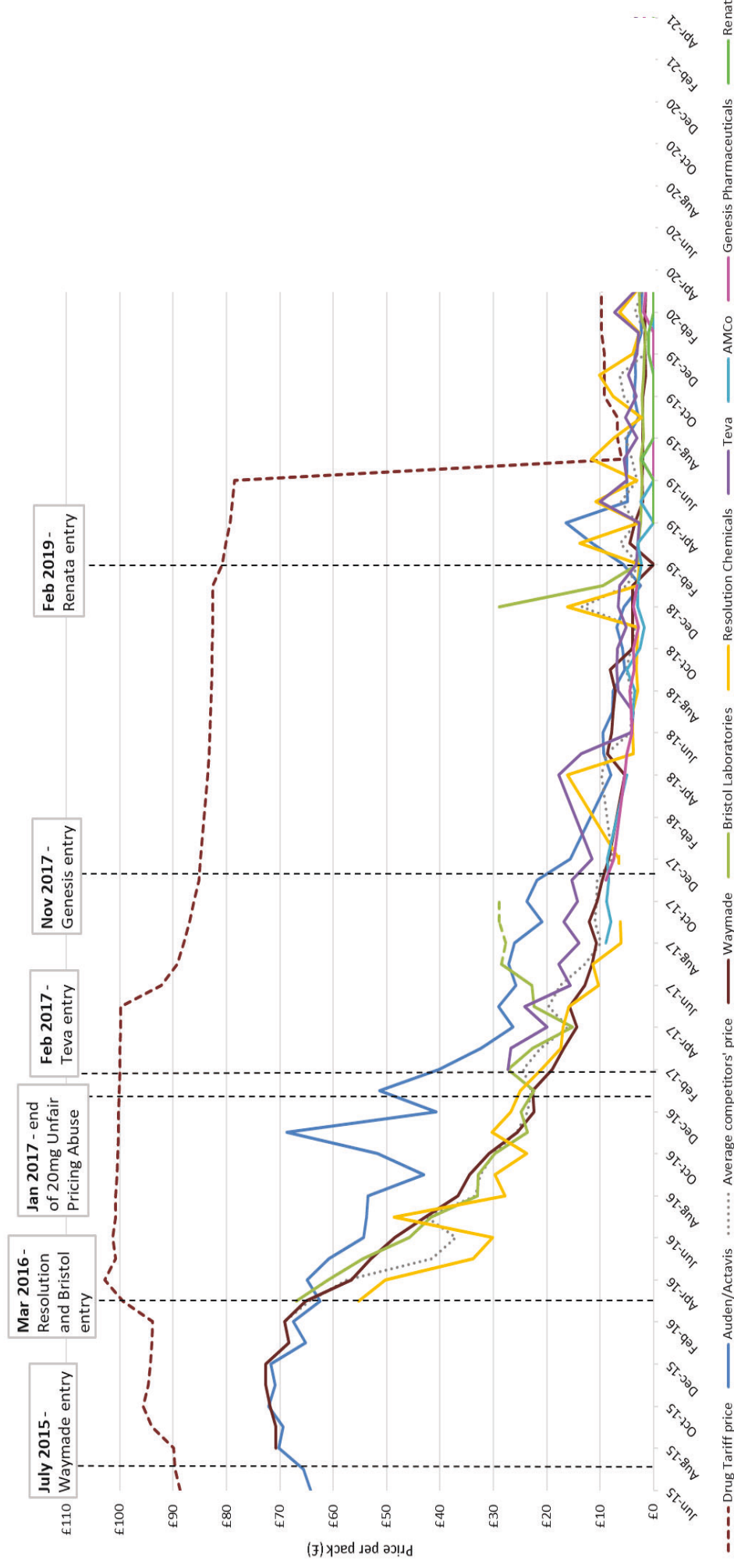
Figure 3.14: Average selling prices for 10mg hydrocortisone tablets following competitive entry



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

Notes: (1) The average competitors' price is weighted by volumes sold. (2) Although AMCo's prices are above those of the rest of the competing suppliers at certain points, these peaks relate to sales to NHS hospitals, which were made at (higher) prices agreed as part of competitive tenders (agreed in March 2017 and 2019). At these times, AMCo's non-NHS hospital sales were either zero or relatively small in comparison to its NHS hospital sales, hence leading to higher average selling prices than competitors who were either not selling to NHS hospitals under an awarded contract or selling smaller proportions to NHS hospitals relative to their non-NHS hospital sales.

Figure 3.15: Average selling prices for 20mg hydrocortisone tablets following competitive entry



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

Notes: (1) The average competitors' ASP is weighted by volumes sold. (2) Bristol Laboratories' average selling prices include sales to NHS hospitals, which were made at (higher) prices agreed as part of competitive tenders and which were agreed via competitive tender in March 2017. (2) The Drug Tariff price for 20mg fell significantly in July 2019 when it was moved from Category A to Category M.

- 3.316. From March 2016, prices began to decrease as new independent suppliers of hydrocortisone tablets entered the market. By December 2016, Actavis's monthly prices had decreased from:
- a. £72.14 to **£57.57** for 10mg hydrocortisone tablets, a decrease of £14.57, representing a 20% decrease; and
 - b. £62.43 to **£40.76** for 20mg hydrocortisone tablets, a decrease of £21.67, representing a 35% decrease.
- 3.317. Prices for 10mg tablets continued to decrease at a broadly consistent rate following Intas' acquisition of Accord-UK in January 2017. By the end of the 10mg Unfair Pricing Abuse, Actavis's monthly prices had decreased from **£57.57** to £20.23 in July 2018 for 10mg hydrocortisone tablets, a decrease of £37.34, representing a 65% decrease.
- 3.318. Since the end of the Infringements, prices have continued to fall further still though at a declining rate, and by April 2021, Actavis's monthly prices had decreased from:
- a. £20.23 in July 2018 to **[£1-£4]** for 10mg hydrocortisone tablets, [X]; and
 - b. £40.76 in December 2016⁴⁶⁹ to **[£1-£4]** for 20mg hydrocortisone tablets, [X].
- 3.319. Auden/Actavis's prices for 20mg fell more quickly than its 10mg prices. For example, by the end of 2017, around 18 months after independent entry began, 10mg prices had reached £29.33 whereas 20mg prices were £15.66 (price falls of 56% and 72% respectively from the pre-entry prices of £66.76 (in October 2015) and £55.06 (in June 2015) respectively). In mid-2018, when 20mg prices between Auden/Actavis and competitors' had converged (see paragraph 3.325 below), prices had reached £20.23 for 10mg tablets and £7.78 for 20mg tablets, further falls of 31% and 50% respectively.

iii. **Changes to competing prices**

- 3.320. As explained above, independent entry of hydrocortisone tablet suppliers commenced in 2015, and, with the exception of Waymade's 20mg hydrocortisone tablets, all entrants supplied a skinny label product.

⁴⁶⁹ The last full month before the end of the 20mg Unfair Pricing Abuse, and this month has been used on a cautious basis because prices increased in January 2017, so comparing to that month could overstate the extent of the price decrease.

3.321. The following trends are evident from figures 3.14 and 3.15:

- a. It was independent entry of competing suppliers that reversed the previous upwards trajectory in Auden/Actavis's prices and led to Auden/Actavis's prices falling.
- b. The prices of both 10mg and 20mg hydrocortisone tablets sold by competing suppliers fell following independent entry from early 2016. The rate of decline was rapid between 2016 and the end of 2017 (for example, 10mg prices fell by 89% and 20mg prices fell by 88% in that period), and then continued at a slower rate to present (10mg prices fell by [X]% and 20mg prices fell by [X]% during that period). Prices of 10mg tablets continue to decline to date (based on data up to April 2021), whereas 20mg tablet prices appear to be flattening. For example, between October 2020 and April 2021, [X].
- c. Prices of competing tablets have been fairly consistent with one another, whereas there has been a continual price difference Auden/Actavis's prices and those of between competing suppliers (see below).

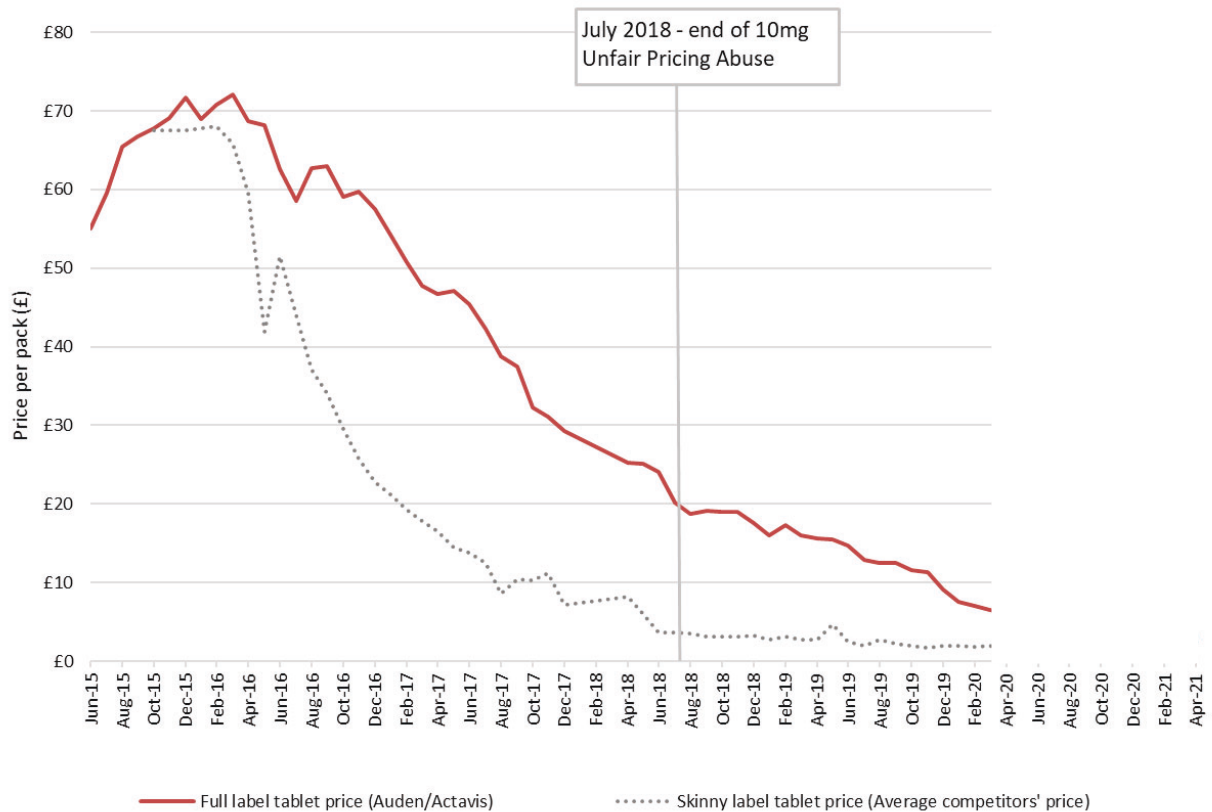
3.322. In relation to the impact on prices of independent entry by individual competitors:

- a. In the months immediately following entry by both Alissa (supplying 10mg skinny label tablets in October 2015) and Waymade (supplying 20mg full label tablets in July 2015), Actavis's and the entrant's prices tracked one another closely, and peaked or started to fall gradually.
- b. Bristol and Resolution entered in March 2016, followed by AMCo in May 2016. At this point competitors' prices began to fall more sharply, and to diverge from Actavis's prices.

iv. Changes to price differences (relative and absolute)

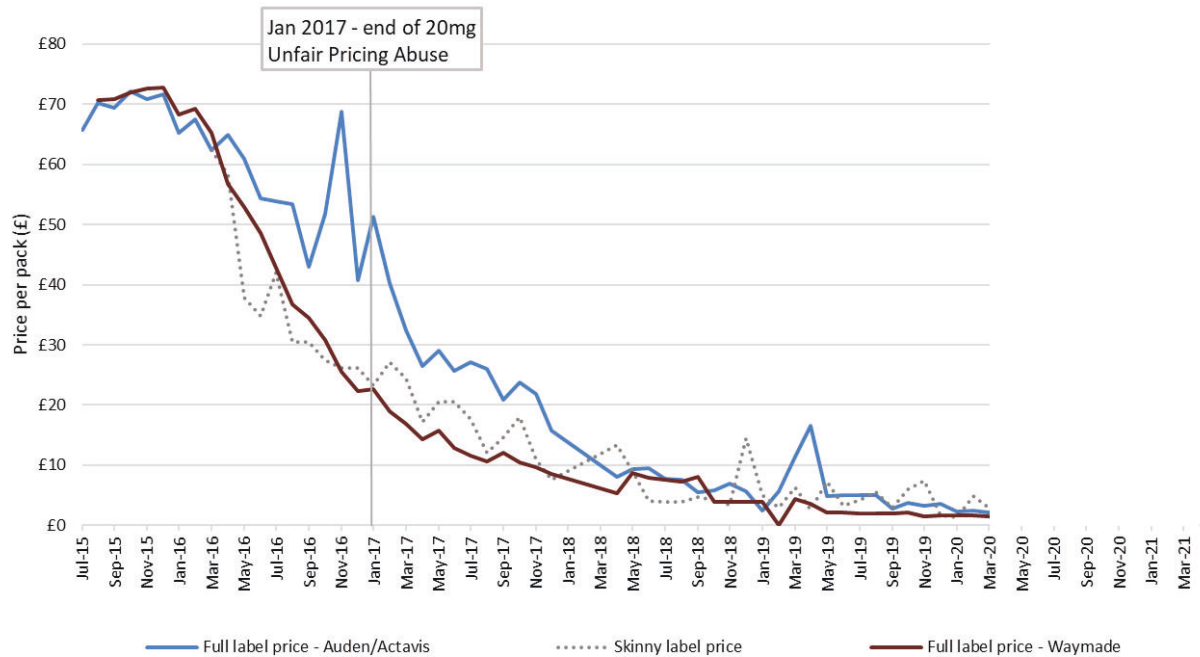
3.323. Figures 3.16 and 3.17 below show Auden/Actavis's full label prices, and those of competitors, that is, average skinny label prices and Waymade's full label prices (20mg only). Figures 3.18 and 3.19 below show the absolute and relative price differences between Auden/Actavis's prices and those of competitors.

Figure 3.16: 10mg full and skinny label tablet prices



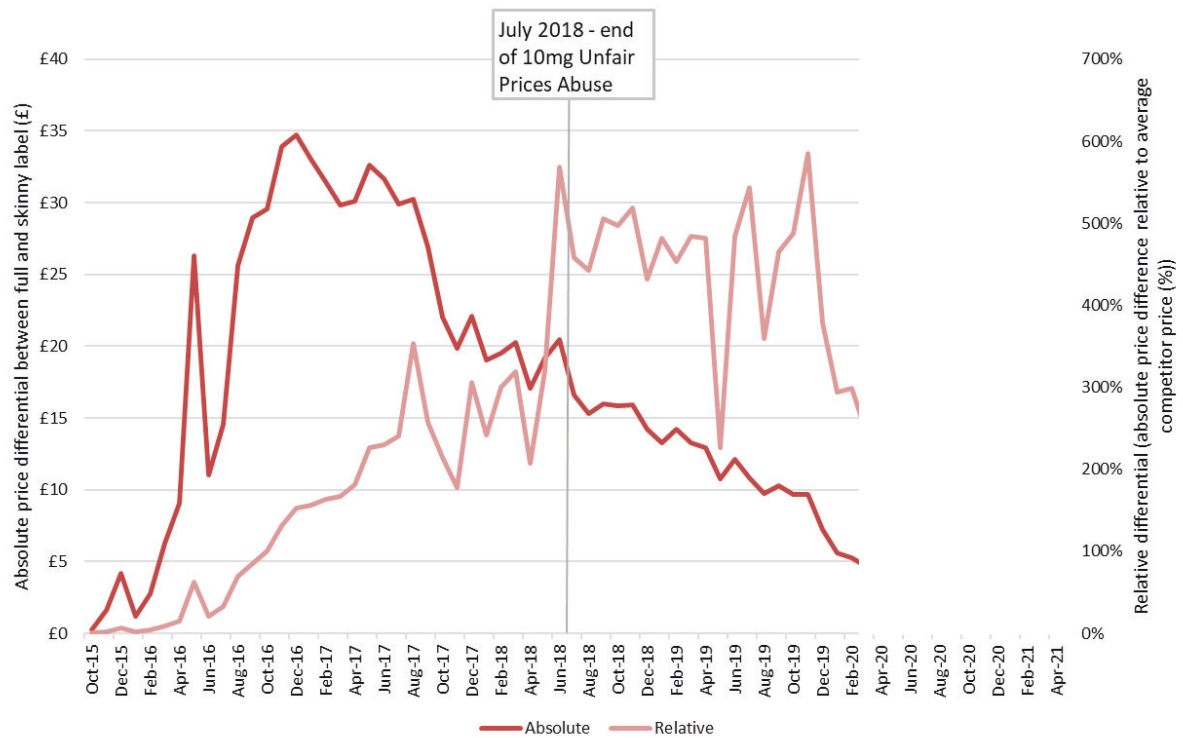
Source: CMA analysis based on data submitted by relevant parties.

Figure 3.17: 20mg full (Auden/Actavis and Waymade) and skinny label tablet prices



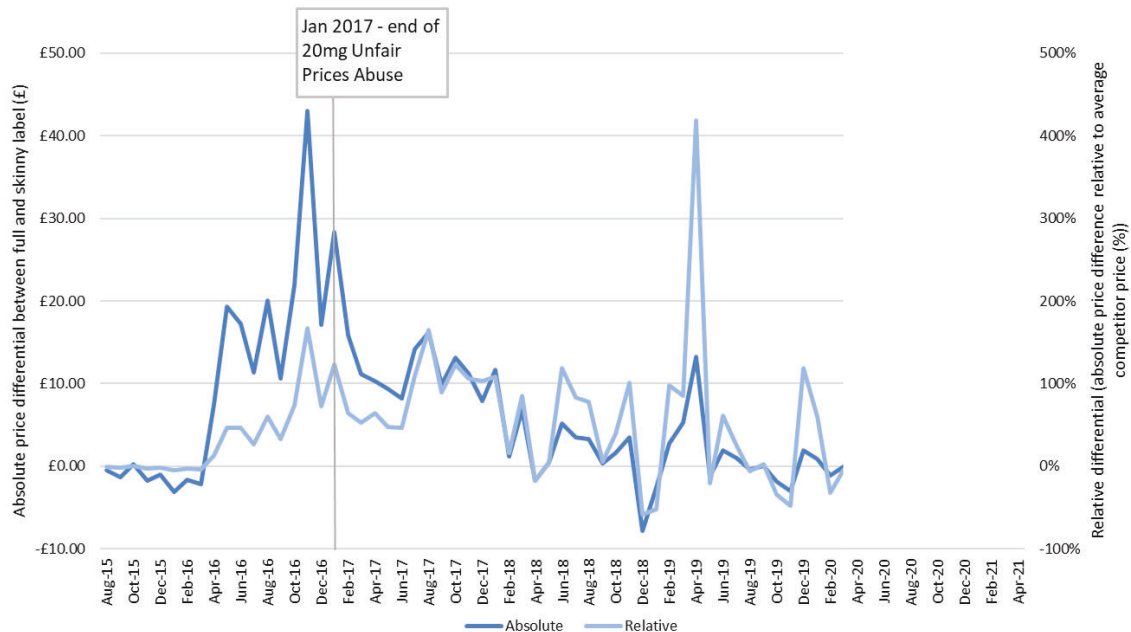
Source: CMA analysis based on data submitted by relevant parties.

Figure 3.18: 10mg absolute and relative price differences between full and skinny label tablet prices



Source: CMA analysis based on data submitted by relevant parties.

Figure 3.19: 20mg absolute and relative price differences between Auden/Actavis prices and competitors' tablet prices



Source: CMA analysis based on data submitted by relevant parties.

3.324. Following independent entry, Auden/Actavis was able to maintain a significant price differential as compared to its competitors' prices for both

10mg and 20mg tablets throughout the Infringements. Figures 3.16 to 3.19 show:

- a. There was a large gap (ie absolute price difference) between full and skinny label hydrocortisone tablet prices, that is between Auden/Actavis's prices and competitors' prices for 10mg tablets during the Infringement period (that is, until July 2018). While this gap has narrowed over time, [✂].
- b. There was a large gap between Auden/Actavis's prices and 20mg competitors' prices (that is both skinny label hydrocortisone tablets and Waymade's prices, which largely moved together) during the Infringement period (that is, until January 2017). Since the Infringement period ended however, prices have converged such that, since early 2018, full and skinny label hydrocortisone tablet prices (and Auden/Actavis's and competitors' prices) have been indistinguishable.
- c. The relative gap between Auden/Actavis's prices and its competitors' prices grew throughout the Infringement periods, such that at the end of the Infringement period Auden/Actavis's prices were five times higher than competitors' prices for 10mg tablets and twice competitors' prices for 20mg tablets. Since the end of those Infringement periods those relative price gaps have declined. However, whereas latest data (as of April 2021) shows [✂].

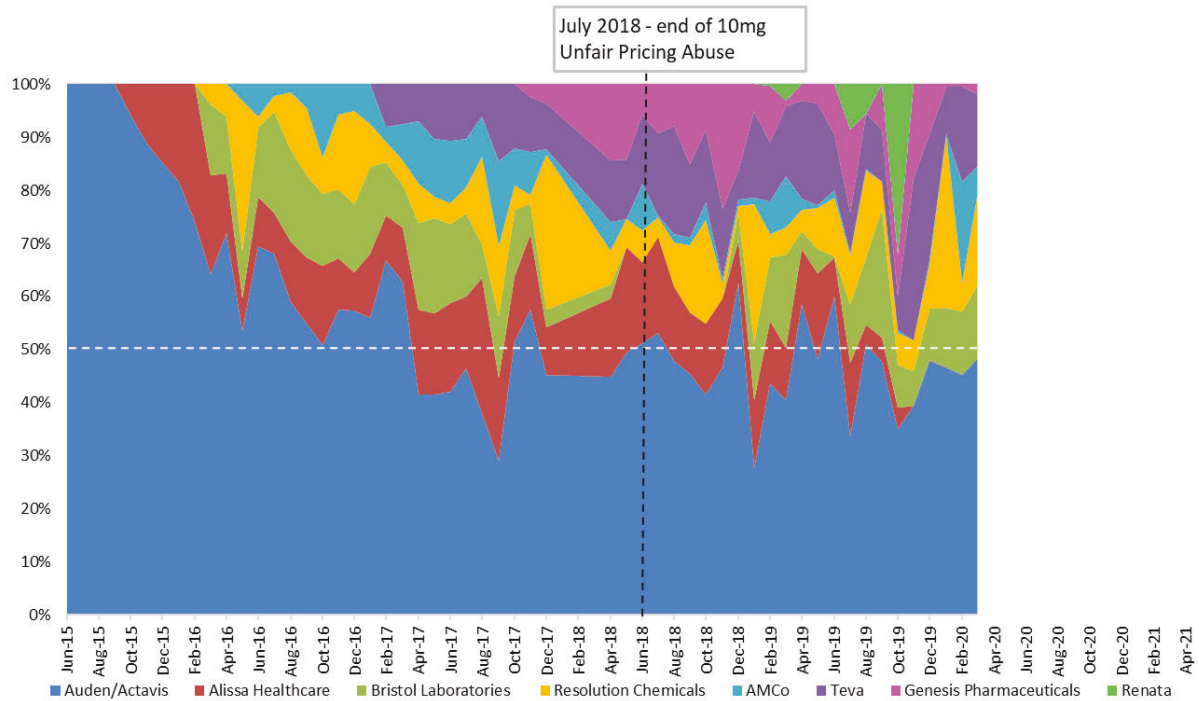
3.325. Figures 3.16 to 3.19 also illustrate differences between the evolution of prices for 10mg and 20mg hydrocortisone tablets, namely that Auden/Actavis's prices fell more quickly and then converged with the prices charged by competing suppliers more quickly for 20mg tablets. For 20mg tablets, prices had converged by around early 2018, whereas for 10mg tablets, although the absolute gap between Auden/Actavis's prices and competitors prices has been steadily narrowing, [✂].

3.326. While the number of entrants and entry dates are broadly similar between 10mg and 20mg tablets, a key difference is the presence of a second full label supplier of 20mg tablets, that is, Waymade. The price trends indicate that the presence of a competing full label supplier has resulted in a faster decrease in Auden/Actavis's prices and a faster convergence of prices between Auden/Actavis and its competitors' prices, when compared to the evolution of 10mg prices where there was no competing full label tablet supplier.

v. Changes to shares of supply

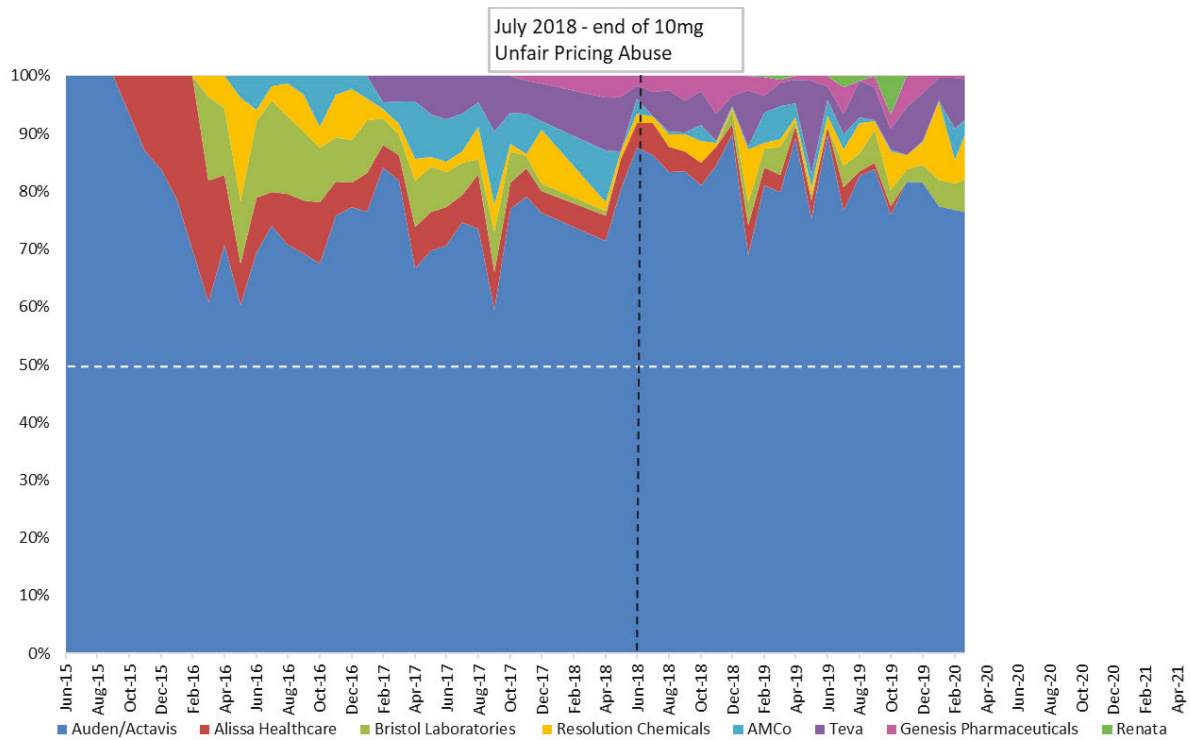
3.327. The shares of supply of 10mg and 20mg hydrocortisone tablets by value and volume are shown in figures 3.20 to 3.23 below.

Figure 3.20: 10mg hydrocortisone tablets shares of supply by volume



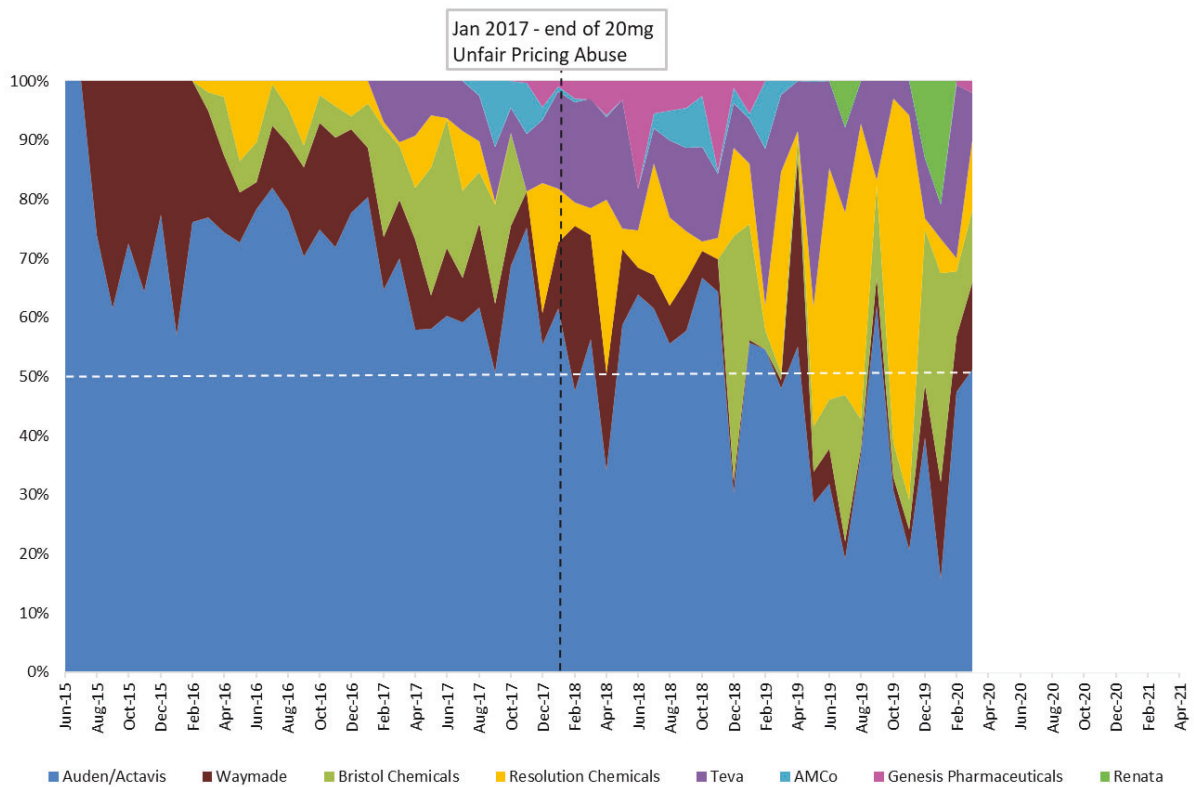
Source: CMA analysis based on data submitted by relevant parties.

Figure 3.21: 10mg hydrocortisone tablets shares of supply by value



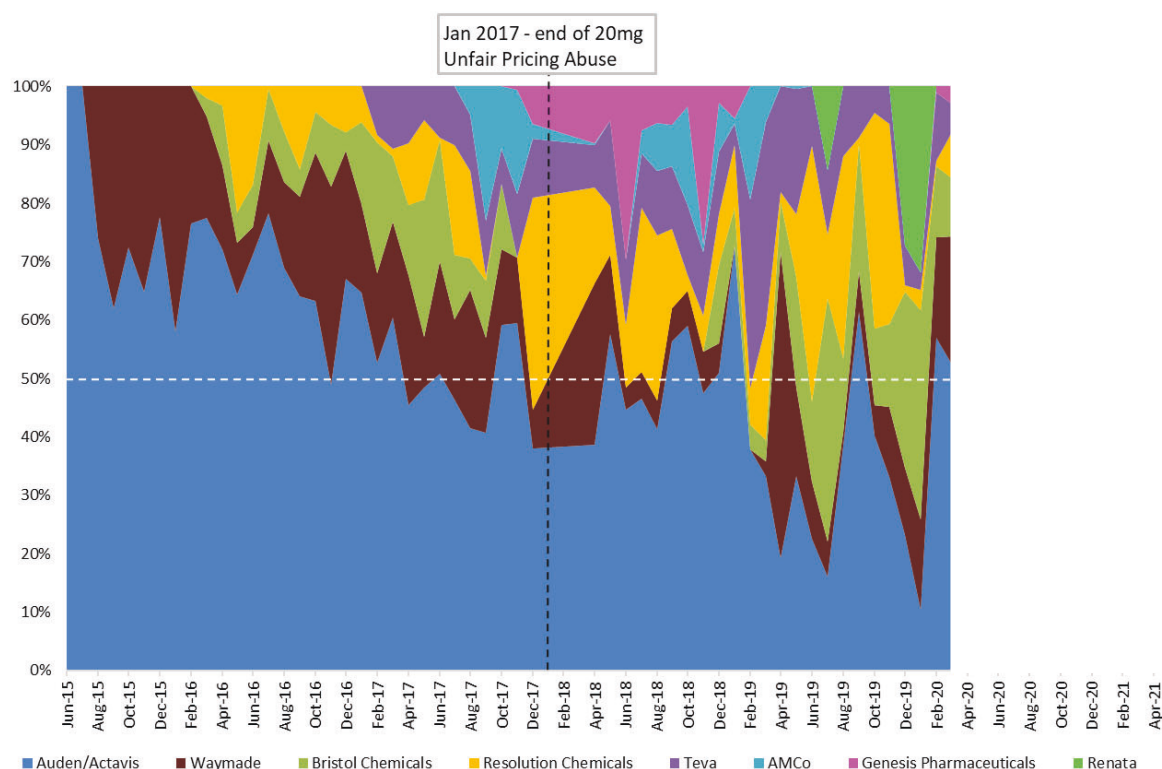
Source: CMA analysis based on data submitted by relevant parties.

Figure 3.22: 20mg hydrocortisone tablets shares of supply by volume



Source: CMA analysis based on data submitted by relevant parties.

Figure 3.23: 20mg hydrocortisone tablets shares of supply by value



Source: CMA analysis based on data submitted by relevant parties.

3.328. As illustrated in figures 3.20 to 3.23, following independent entry, Auden/Actavis lost share to competing suppliers, with changes as follows:

- a. Although competitors made sales immediately upon entry and won market share from Auden/Actavis, the overall uptake of skinny label tablets was gradual. For example, skinny label tablets represented 18% for 10mg and 35% for 20mg of all hydrocortisone tablets sold by three months after entry, 28% for 10mg and 23% for 20mg by six months after entry, and took 18 months for 10mg and 15 months for 20mg to reach a 50% share of supply by volume.
- b. During the Infringement period, competing suppliers' shares were usually between 10-20% (by either value or volume), and rarely exceeded this level.
- c. 10mg skinny label tablet volumes stabilised around 50%. For example, the average share for skinny label suppliers is 43% across the post-entry Infringement period, and [X]% during the post-Infringement period.
- d. Whereas Actavis's shares of supply by volume declined gradually and then stabilised around 50%, the shares of supply of competitors have

not been stable and instead have fluctuated with different suppliers winning larger shares at different times.

- e. Shares of supply by value follow a similar pattern to shares of supply by volume, though 10mg value shares, and 20mg value shares during the Infringement period, were higher than volume shares reflecting the fact that Auden/Actavis's prices of its full label tablets were higher than those of its competitors (that is, 10mg and 20mg skinny label tablets and Waymade's 20mg full label tablets). Since 2018, 20mg hydrocortisone tablet value and volume shares have been similar to one another, reflecting that Auden/Actavis and competitors have been charging, and continue to charge, similar prices.

3.329. These shares of supply trends are consistent with the price patterns explained above in that they show:

- a. The steepest and most significant falls in prices (both Auden/Actavis's and its competitors') occurred in the period immediately following independent entry of several suppliers, that is around March 2016 onwards, when there was switching from full to skinny label tablets.
- b. After the initial period of switching to skinny label tablets, the continued rivalry between competing suppliers (as seen through the volatile shares) has resulted in prices continuing to fall after the initial phase of entry and prices between those competing suppliers converging with one another over time. By contrast, the gap between Auden/Actavis's prices and its competitors' prices narrowed more slowly over time (and even increased in relative terms) during the Infringement period.

c. Changes in the NHS Reimbursement Prices for hydrocortisone tablets in the UK

3.330. Figures 3.10 and 3.11 above show Auden/Actavis's prices and the average NHS Reimbursement Price for 10mg and 20mg hydrocortisone tablets separately over the period January 2007 to April 2021.

3.331. Figures 3.10 and 3.11 above demonstrate that the monthly average NHS Reimbursement Prices for 10mg and 20mg hydrocortisone tablets largely followed the same trend as Auden/Actavis's hydrocortisone tablets prices, with the exception of 20mg tablets following entry when NHS Reimbursement prices were substantially higher than Auden/Actavis's prices (and also average selling prices) until the switch to category M:

- a. NHS reimbursement prices for 10mg and 20mg hydrocortisone tablets increased from **£0.70** and **[£1-£4]** in April 2008 when the medicine was sold as a branded product by MSD, to **£87.90** and **£102.75** in March 2016 as a result of Auden/Actavis's regular price increases over the period, representing price increases of **12,457%** and **9,503%**, respectively.⁴⁷⁰
- b. Following independent entry by competing suppliers of 10mg hydrocortisone tablets, the monthly NHS Reimbursement Prices fell broadly on the same trend as Auden/Actavis's prices, falling from £87.90 in March 2016 to [X].
- c. For 20mg tablets, there was little downward trend in NHS Reimbursement Prices (ie it did not follow 20mg prices) due to the calculation of the Reimbursement Price based on 20mg tablets being in category A (see section 3.E.I.b above). Belatedly, 20mg tablets switched to category M in June 2019, resulting in a significantly lower reimbursement price (falling by [X] from £102.75 in March 2016 to [X]).

d. The effects of Auden/Actavis' price increases on the NHS

- 3.332. During the Unfair Pricing Abuses NHS expenditure on hydrocortisone tablets rose dramatically and remained extremely high.
- 3.333. In 2007, the NHS's annual UK expenditure on hydrocortisone tablets was approximately **£500,000**. NHS expenditure increased significantly as a result of Auden/Actavis's price increases, reaching a peak of almost **£84 million** in 2016 (that is, 161 times higher than in 2007).⁴⁷¹
- 3.334. The effects of Auden/Actavis's price increases persisted for years following entry. This is illustrated in table 3.24 and figure 3.25 below. The total NHS expenditure on hydrocortisone tablets during the Unfair Pricing Abuses was £465m on 10mg hydrocortisone tablets⁴⁷² and £19.6m on 20mg hydrocortisone tablets.⁴⁷³

⁴⁷⁰ NHS Reimbursement Price for Hydrocortisone Tablets peaked in March 2016. The absolute price increase over this period for 10mg and 20mg tablets was £87.20 and £101.68, respectively.

⁴⁷¹ CMA calculations using the number of hydrocortisone tablets (including 'Hydrocortone' tablets) dispensed and the NHS Reimbursement Price data contained within the PCA data for England, Wales, Scotland and Northern Ireland.

⁴⁷² CMA calculations, from 1 October 2008 to 31 July 2018.

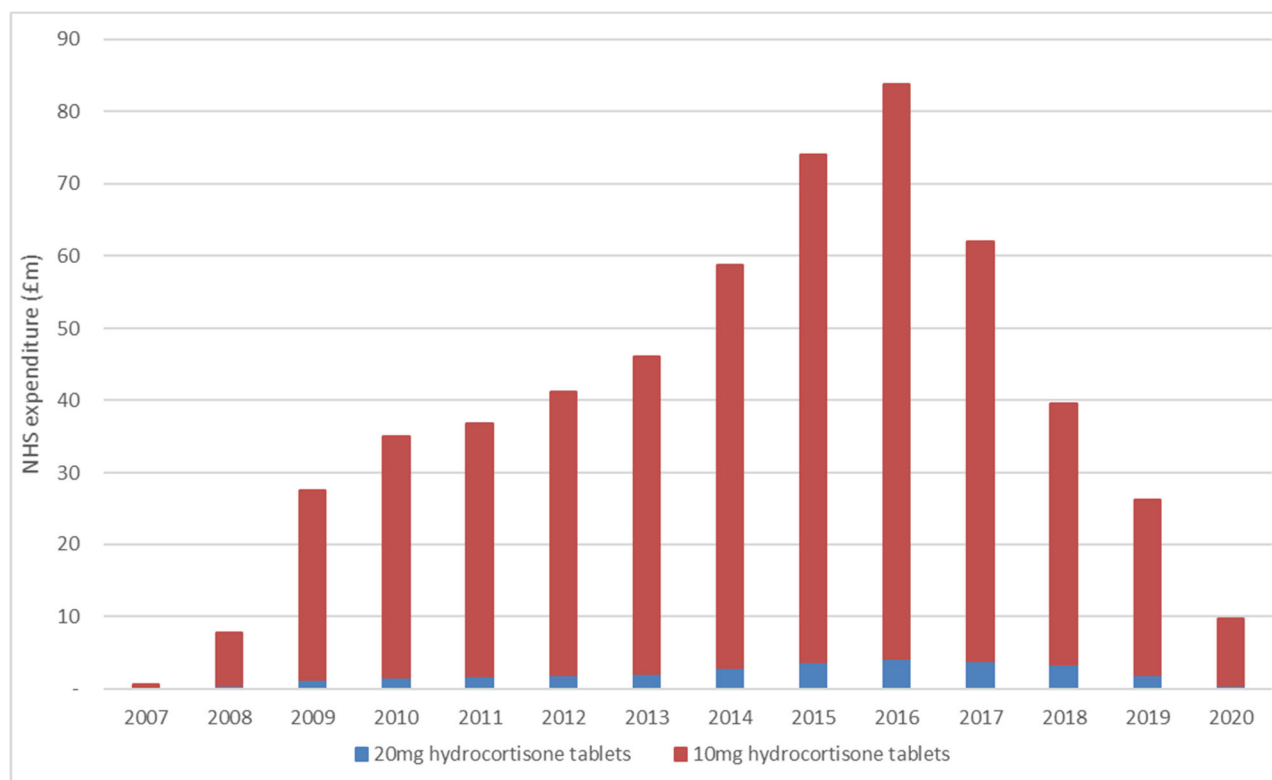
⁴⁷³ CMA calculations, from 1 October 2008 to 8 January 2017.

Table 3.24: NHS annual UK expenditure on hydrocortisone tablets

(£m)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
10mg	0.5	7.4	26.2	33.4	35.1	39.3	44.0	55.8	70.3	79.6	58.2	36.3	24.5	9.3
20mg	0.04	0.4	1.3	1.6	1.7	1.9	2.1	2.9	3.7	4.2	3.9	3.3	1.8	0.4
Total	0.5	7.8	27.5	35.1	36.8	41.1	46.1	58.7	74.1	83.8	62.1	39.6	26.3	9.6

Source: NHS BSA data based on PCA data

Figure 3.25: NHS annual UK expenditure on hydrocortisone tablets (£m)



Source: NHS BSA data based on PCA data

F. Conduct under investigation

3.335. This section sets out facts relevant to the conduct that is the subject of this Decision. In doing so, the CMA sets out below a broadly chronological narrative of the facts of each Infringement.

I. Facts relevant to the Unfair Pricing Abuses

3.336. As explained above, hydrocortisone tablets were first brought to the UK market in December 1955 when MSD sold the drug under the brand name 'Hydrocortone'.⁴⁷⁴ The MHRA granted UK MAs for 10mg⁴⁷⁵ and 20mg⁴⁷⁶

⁴⁷⁴ The 'Hydrocortone' trademark was registered (730276) in the UK on 17 May 1954 (Document 00561, response to question 1, MSD's response to the CMA's section 26 notice dated 22 June 2016).

⁴⁷⁵ PL 00025/5053R.

⁴⁷⁶ PL 00025/5054R.

hydrocortisone tablets to MSD on 23 February 1989⁴⁷⁷ which were approved for a number of indications, including for adrenal insufficiency in adults.

- 3.337. As a branded product, MSD's hydrocortisone tablets were regulated under the PPRS. MSD remained the sole supplier of hydrocortisone tablets until it sold its hydrocortisone business to Auden in April 2008. According to MSD, any patents relevant to the sale of Hydrocortone would have expired at the latest during the 1970s. As a branded product, however, Hydrocortone remained under the PPRS after loss of exclusivity, and its regulated price remained low. Between 2006 and 2008, pharmacies purchased Hydrocortone for an average price of £0.70 per pack of 10mg hydrocortisone tablets, and [£1-£4] per pack of 20mg tablets.⁴⁷⁸ Although it no longer held information relating to its cost of manufacture, MSD *'would assume that this was below the selling price of Hydrocortisone Tablets'*.⁴⁷⁹
- 3.338. In April 2008, Auden acquired the MAs⁴⁸⁰ and Hydrocortone trademark from MSD.⁴⁸¹ This transaction included the following payments by Auden:⁴⁸²
- a. £20,800, plus VAT, for hydrocortisone Active Pharmaceutical Ingredient ('API') to be supplied from MSD to Auden;⁴⁸³
 - b. £10,000, plus VAT, for the assignment of the 1989 Auden MAs;⁴⁸⁴ and
 - c. £190,000 for the assignment of the Hydrocortone trademark.⁴⁸⁵

⁴⁷⁷ Document 00623, Annex A: Hydrocortisone Tablets with Additional Data for CMA, MHRA's response to the CMA's section 26 notice dated 15 February 2016.

⁴⁷⁸ Document 00561, response to questions 1, 3 and 4, MSD's response to the CMA's section 26 notice dated 22 June 2016.

⁴⁷⁹ Document 00561, response to question 7, MSD's response to the CMA's section 26 notice dated 22 June 2016.

⁴⁸⁰ The MHRA approved the transfer on 3 June 2008, with authorisation number 17507/0097 and 17507/0098 for 10mg and 20mg hydrocortisone tablets respectively (Document 00623, Annex A: Hydrocortisone Tablets with Additional Tablets with Additional Data for CMA, MHRA's response to the CMA's section 26 notice dated 15 February 2016).

⁴⁸¹ Merck & Co., INC, a New Jersey, U.S. Corporation, was the original proprietor of the trademark and transferred it to Auden as part of the transaction to acquire the MAs for 10mg and 20mg hydrocortisone tablets. Document 00556, Trademark Assignment Agreement executed on 7 April 2008. (See also Document 00639, response to question 4, paragraph 4.1, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016; and Document 00561, response to question 1, MSD's response to the CMA's section 26 notice dated 22 June 2016).

⁴⁸² Document 00561, response to question 5, MSD's response to the CMA's section 26 notice dated 22 June 2016.

⁴⁸³ All unused stock of Hydrocortisone API owned by MSD's affiliate Merck Sharp & Dohme International Services B.V. and held by MSD at its Cramlington facility. This amounted to approximately 40 kilograms (Document 00557, clause 7.1 and Schedule D, Agreement for the Assignment of Marketing Authorisation (U.K) executed on 7 April 2008).

⁴⁸⁴ Document 00557, clause 6.1 Schedules A and B, Agreement for the Assignment of Marketing Authorisation (UK) executed on 7 April 2008.

⁴⁸⁵ Document 00556, clause 2, Trademark Assignment Agreement executed on 7 April 2008.

- 3.339. The value of the Hydrocortone brand therefore made up 95% of the price Auden paid for the right to sell hydrocortisone tablets.
- 3.340. MSD stopped accepting orders for wholesale hydrocortisone tablets under the Hydrocortone brand from 18 April 2008.⁴⁸⁶
- 3.341. Auden introduced a generic version of hydrocortisone tablets on its own licence⁴⁸⁷ which was available from 21 April 2008.⁴⁸⁸ The branded version was discontinued.⁴⁸⁹ These tablets were small and round and could not easily be halved, which led certain patients to raise this issue with the DHSC.⁴⁹⁰ Auden subsequently reintroduced the oval, ex-MSD-type tablets under the MAs granted to MSD and continued to market and sell hydrocortisone tablets under the generic name,⁴⁹¹ sourced from a third-party CMO, Tiofarma, based in the Netherlands.⁴⁹²
- 3.342. Once Auden had genericised the drug, hydrocortisone tablets were no longer controlled by the PPRS and fell under Category A of the Drug Tariff. Although, as explained above, this category is calculated by reference to a range of wholesalers' and/or manufacturers' prices,⁴⁹³ Auden – as the sole supplier in the UK – supplied all of these wholesalers with hydrocortisone tablets. Consequently, Auden was able to set (and increase) its prices without any constraint from the NHS Reimbursement Price.
- 3.343. Having de-branded the drug, Auden entered the UK market in April 2008 with a monthly average selling price ('ASP') of:
 - a. £4.54 per pack of 10mg tablets; and
 - b. £5.14 per pack of 20mg tablets.

⁴⁸⁶ Document 00561, responses to questions 1 and 3, MSD's response to the CMA's section 26 response dated 22 June 2016.

⁴⁸⁷ PL 17507/0054 for 10mg hydrocortisone tablets and PL 17507/0055 for 20mg hydrocortisone tablets.

⁴⁸⁸ Document 00618, response to question 2, DHSC's response to the CMA's section 26 notice dated 6 July 2016.

⁴⁸⁹ Document 00618, response to question 2, DHSC's response to the CMA's section 26 notice dated 6 July 2016.

⁴⁹⁰ Document 00618, response to question 2, DHSC's response to the CMA's section 26 notice dated 6 July 2016.

⁴⁹¹ Document 00020, Pharmaceutical Services Negotiating Committee, Drug Tariff News – Hydrocortisone tablets 10mg and 20mg dated 19 May 2008.

⁴⁹² Document 00452, response to question 4, Tiofarma's response to the CMA's section 26 notice dated 4 April 2016. See also Document 00639, paragraph 4.2, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016.

⁴⁹³ See section 3.C.V.d above.

II. Facts relevant to the 20mg Agreement

a. Waymade develops its own 20mg hydrocortisone tablets

3.344. In summary:

- a. Waymade launched a project to develop its own hydrocortisone tablets in late 2008.
- b. Waymade's CMO Aesica manufactured four batches of 20mg tablets between June 2009 and November 2010. Three of these batches passed all required testing although the fourth batch failed dissolution testing.
- c. In November 2010, Waymade expected to launch its 20mg tablets in 2011 and forecast that it would have sufficient stock to meet demand throughout 2011.
- d. By 28 March 2011 Waymade had satisfied all regulatory conditions to launch its 20mg tablets from the first three batches.
- e. Waymade received commercial stock on 9 May 2011. While selling this stock, Waymade planned to adjust the formulation of its product (changing the inactive ingredient) to make future batches more stable in response to the dissolution failure of the fourth batch.
- f. However, Waymade did not launch its product in 2011 and had no further communication with Aesica on 20mg tablets until August 2013.

3.345. Waymade acquired an MA for 20mg hydrocortisone tablets in 1998 as part of a basket of assets.⁴⁹⁴ The MA was 'full label' – it included the indication '*adrenal insufficiency in adults*' in its SmPC – as it predated Plenadren's orphan designation and subsequent MA (see section 3.D.III above).⁴⁹⁵

3.346. On 2 September 2008, [Waymade Senior Employee 1] noted that Auden had de-branded hydrocortisone tablets and informed Waymade's Head of Generics: '*hydrocortisone tabs 20mg we have a license [sic] and I want to launch. the brand by MSD has been discontinued.*'⁴⁹⁶

⁴⁹⁴ PL 06464/0701. The MHRA approved transfer of the MA from Knoll Limited to Waymade on 11 January 1999. The price paid for the basket of assets, including trademark and other IP rights, stock and goodwill, was £255,000. Document 200003, paragraphs 1.1 and 4.2, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁴⁹⁵ Document 200003, response to question 18, paragraph 18.1, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁴⁹⁶ Document 300705, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 3] dated 2 September 2008.

- 3.347. In or around October 2008, Waymade therefore commenced discussions with a CMO, Aesica, to develop its own hydrocortisone tablets.⁴⁹⁷
- 3.348. In June and July 2009, Aesica manufactured two validation batches of 20mg hydrocortisone tablets for Waymade. A ‘validation batch’ refers to a batch of tablets produced for ‘process validation’, a mandatory step in drug development in which the manufacturer must provide ‘*scientific evidence that the manufacturing process is capable of producing consistently good product at the intended commercial scale*’. Typically, three batches produced at the intended commercial scale must pass process validation. Unlike ‘development’, ‘engineering’ or ‘placebo’ batches, successful validation batches can be subsequently sold.⁴⁹⁸
- 3.349. The two validation batches were manufactured using an unmodified starch maize formula and totalled 237,960 20mg hydrocortisone tablets (the ‘**First and Second Batches**’⁴⁹⁹).
- 3.350. Aesica identified no material issues with the First and Second Batches, which passed quality testing (part of ‘process validation’)⁵⁰⁰ on 5 August 2009 and 12 February 2010 respectively, and commenced stability testing. Stability testing assesses pharmaceutical products’ viability for patient consumption over designated periods of time and is used to establish the products’ shelf life in specified packaging and climatic conditions.⁵⁰¹

⁴⁹⁷ Document 200292, paragraph 3.1, paragraphs 3.5 to 3.7, and Annexes 1 to 4, Aesica’s response to the CMA’s section 26 notice dated 15 June 2016. Waymade initially gave Aesica to understand that it would require 455,000 tablets (around 15,166 packs) of 10mg hydrocortisone tablets per year, and 136,000 tablets (around 2,266 packs) of 20mg hydrocortisone tablets per year. At this stage, the tablets were to be packaged in blister packs. However, before any supply took place, Waymade changed the packaging format, stipulating that the 10mg and 20mg hydrocortisone tablets were to be placed in glass bottles.

⁴⁹⁸ See Document 301329, note of call with Aesica dated 20 March 2018, paragraphs 21 to 24 and 29 to 32; Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 61, line 3 to page 62, line 8; Document 302539, transcript of [Aesica Employee] interview dated 30 October 2018, page 19, lines 449 to 454.

⁴⁹⁹ Batches 6002398 and 6002893. See Document 301886, 20mg hydrocortisone tablet comparative dissolution profiles, 7 December 2010 and Document 302554, paragraphs 1.1 and 2.1, Aesica’s response to the CMA’s section 26 notice dated 12 February 2019.

⁵⁰⁰ See Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 61; lines 3 to 25.

⁵⁰¹ Stability testing can be ‘real time’ (testing conditions and duration set an exactly corresponding shelf life, eg six months in an ambient climate) or ‘accelerated’ (more extreme testing conditions over a shorter duration set a longer shelf life in milder conditions, eg three months testing in a hot, humid climate sets a six month shelf life in ambient climate). Accelerated stability testing must be subsequently supported by real time stability testing. See Document 301329, note of call with Aesica dated 20 March 2018, paragraphs 47 to 54; Document 302539, transcript of [Aesica Employee] interview dated 30 October 2018, page 34, line 816 to page 36, line 867; Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 53, line 2 to page 54, line 2.

- 3.351. The First and Second Batches had expiry dates of June 2012 and July 2012 respectively.⁵⁰²
- 3.352. In November 2010,⁵⁰³ Aesica manufactured two further batches of 115,117 and 144,714 20mg hydrocortisone tablets respectively, using an unmodified starch maize formula: the first one in order to complete the three-batch validation process (the '**Third Batch**'⁵⁰⁴) and the second one for commercialisation (the '**Fourth Batch**'⁵⁰⁵). The Third Batch passed quality testing on 17 November 2010 and had an expiry date of 30 November 2013.⁵⁰⁶
- 3.353. In early November 2010, Waymade completed its commercial volume forecast for 20mg hydrocortisone tablets. Waymade concluded that it would have '*sufficient stock from the validation batches for 2011*' due to the '*low market volume for the 20mg strength*' and, consequently, that Aesica would '*not be required to manufacture the 20mg strength during the remainder of [...] 2011*'.⁵⁰⁷ Waymade therefore expected in November 2010 that its existing validation batches of 20mg tablets would suffice to meet demand for its product throughout 2011.
- 3.354. The three validation batches all passed 'dissolution testing' (part of 'process validation' for solid oral dosage forms such as tablets which analyses how

⁵⁰² Document 200292, paragraph 6.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016; Document 300039, email from [REDACTED] to [REDACTED], [Aesica Employee], [Amdipharm Senior Employee], [Waymade Senior Employee 3], [REDACTED] and [REDACTED] dated 8 April 2010; and Document 302554, paragraphs 1.1, 3.1 and 3.2, Aesica's response to the CMA's section 26 notice dated 12 February 2019 and attachments Document 302555, transaction history for batch 6002398 and Document 302556, transaction history for batch 6002893.

⁵⁰³ See Document 302554, paragraph 1.1, Aesica's response to the CMA's section 26 notice dated 12 February 2019.

⁵⁰⁴ Batch 6013365. See Document 301886, 20mg hydrocortisone tablet comparative dissolution profiles, 7 December 2010.

⁵⁰⁵ Batch 6013367. See Document 301708, Aesica investigation report dated 16 December 2010 attached to Document 301707, email from [Aesica Employee] to [Waymade Employee] dated 10 March 2014.

⁵⁰⁶ Document 302554, paragraphs 1.1 and 2.1, Aesica's response to the CMA's section 26 notice dated 12 February 2019 and attachment Document 302557, transaction history for batch 601335; See also Document 300119, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 2], [Waymade Employee], [REDACTED], [Waymade Employee], [REDACTED], [REDACTED], [Amdipharm Senior Employee], [Waymade Employee] and others dated 3 November 2010; Document 300120, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [Waymade Employee], [REDACTED], [Waymade Employee], [REDACTED], [REDACTED] [Waymade Employee] and others dated 8 November 2010; Document 300125, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 2], [REDACTED], [REDACTED], [REDACTED], [Waymade Employee], [REDACTED], [Waymade Employee], [Amdipharm Senior Employee], [Waymade Employee] and others dated 29 November 2010; Document 301708, Aesica investigation report dated 16 December 2010 attached to Document 301707, email from [Aesica Employee] to [Waymade Employee] dated 10 March 2014; Document 301695, email from [Aesica Employee] to [Waymade Employee] dated 3 March 2014; and Document 300544, email from [Waymade Senior Employee 4] to [REDACTED], [REDACTED] and [REDACTED] dated 13 May 2016.

⁵⁰⁷ Document 300120, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [REDACTED] and others dated 8 November 2010.

the product has dissolved).⁵⁰⁸ However, on 13 December 2010 Aesica notified Waymade that the Fourth Batch had failed dissolution testing.⁵⁰⁹

- 3.355. Aesica believed that the reason the Fourth Batch had failed dissolution testing was its formulation, specifically the use of unmodified starch. It recommended that it reformulate the product to replace the unmodified starch with partially pregelatinized starch. This would improve the tablets' dissolution.⁵¹⁰
- 3.356. Waymade noted internally that a '*decision to reformulate the 20mg tablet might need to be considered at some point in the future.*'⁵¹¹ In the meantime, it projected launching its 20mg tablets in May or June 2011. In December 2010, January 2011 and February 2011, Waymade consistently reported internally that the '*Launch of 20mg tablet is still on track for May or June 2011.*'⁵¹²
- 3.357. In preparation for launch, in December 2010 Waymade instructed Aesica to pack the Third Batch as it had the longest shelf life of the first three batches.⁵¹³
- 3.358. On 22 February 2011, process validation of Waymade's 20mg hydrocortisone tablets was completed and approved.⁵¹⁴

⁵⁰⁸ Document 301329, note of call with Aesica dated 20 March 2018, paragraphs 27 and 28.

⁵⁰⁹ Document 301708, Aesica investigation report dated 16 December 2010 attached to Document 301707, email from [Aesica Employee] to [Waymade Employee] dated 10 March 2014. See also Document 302554, paragraphs 3.1 and 3.2, Aesica's response to the CMA's section 26 notice dated 12 February 2019 and attachments Document 302555, transaction history for batch 6002398, Document 302556, transaction history for batch 6000289 and Document 302557, transaction history for batch 6013365, which confirm that the First and Second Batches and the Third Batch passed quality testing on 5 August 2009, 12 February 2010 and 17 November 2010.

⁵¹⁰ Document 301708, Aesica investigation report dated 16 December 2010 attached to Document 301707, email from [Aesica Employee] to [Waymade Employee] dated 10 March 2014. See also Document 302554, paragraphs 3.1 and 3.2, Aesica's response to the CMA's section 26 notice dated 12 February 2019 and attachments Document 302555, transaction history for batch 6002398, Document 302556, transaction history for batch 6000289 and Document 302557, transaction history for batch 6013365, which confirm that the First and Second Batches and the Third Batch passed quality testing on 5 August 2009, 12 February 2010 and 17 November 2010.

⁵¹¹ Document 300125, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 2], [Waymade Employee] and others dated 29 November 2010.

⁵¹² Document 300136, Monthly Report Sovereign Generics December 2010, page 2. The same was reported in Document 300149, Monthly Report Sovereign Generics January 2011, page 2; and in Document 300158, Monthly Report Sovereign Generics February 2011, page 2. See also Document 300138 email from [Waymade Senior Employee 3] to [Waymade Employee] dated 18 January 2011, which said, '*The timings all look positive in comparison to the original plan.*'

⁵¹³ Document 300127, email from [Waymade Senior Employee 3] to [Waymade Employee], [Waymade Employee] and others dated 13 December 2010 and Document 300177, Minutes update of joint Aesica Sovereign review 31/3/11, page 1. See also Document 301708, Aesica investigation report dated 16 December 2010 attached to Document 301707, email from [Aesica Employee] to [Waymade Employee] dated 10 March 2014.

⁵¹⁴ Document 200292, paragraph 6.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016. See also 206002, Validation Summary Report for Hydrocortisone 20mg Tablets (TSR/513).

- 3.359. By 28 March 2011, the MHRA had approved '[a]ll outstanding variations' to Waymade's 20mg MA and, consequently, the launch of Waymade's 20mg hydrocortisone tablets.⁵¹⁵
- 3.360. Waymade was now ready to launch its 20mg product. Its [REDACTED] [Waymade Employee] internally reported on 25 March 2011 that the 20mg hydrocortisone tablets '*manufactured by Aesica (30 tablets in glass bottles) can now be released for sale*' with the '*original 36 month shelf life [...]* retained'.⁵¹⁶ [Waymade Senior Employee 3] noted on 28 March 2011 that Waymade was '*now free to launch the 20mg [hydrocortisone tablet] strength in glass bottles*'.⁵¹⁷
- 3.361. Waymade's plan was to launch with its Third Batch (the validation batch with the longest shelf-life) and to reformulate to address the dissolution issue in the meantime. It believed that this batch would provide it with enough stock to last until the end of 2011, and that subsequent batches would then use the revised formulation. Work on reformulating the 20mg tablet was planned to take place '*ca mid-year*'.⁵¹⁸ In preparation for this, in April 2011 Waymade sent Aesica a request for proposal ('RFP') for the development of three reformulated batches of 20mg hydrocortisone tablets with pre-gelatinised rather than maize starch.⁵¹⁹

⁵¹⁵ Document 200003, paragraph 10.4, Waymade's response to the CMA's section 26 notice dated 5 May 2016; and Document 300736, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [Waymade Employee], [REDACTED], [REDACTED], [Waymade Employee] and others dated 28 March 2011. See also Document 301469, email from [Waymade Employee] to Regulatory Dept, Medical, Sovereign Group, Artwork Mailbox and Technical dated 23 March 2011; and Document 301478, [REDACTED]'s Projects April 2011, slide 2, attachment to Document 301477, email from [REDACTED] to [REDACTED], [Waymade Senior Employee 2], [REDACTED] and others dated 5 April 2011.

⁵¹⁶ Document 301471, email from [Waymade Employee] to [Amdipharm Senior Employee], [Waymade Senior Employee 1] and others dated 25 March 2011. See also Document 301475, email from [Waymade Employee] to [Amdipharm Senior Employee], [Waymade Senior Employee 1] and others dated 25 March 2011: '*Product manufactured at Aesica with this batch size can be released*'.

⁵¹⁷ Document 300736, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [REDACTED], [Waymade Employee], [Waymade Employee], [REDACTED], [REDACTED], [REDACTED], [Waymade Employee], [REDACTED], [REDACTED] and [REDACTED] dated 28 March 2011. See also Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 24, lines 6 to 9.

⁵¹⁸ Waymade met with Aesica on 31 March 2011. The minutes of that meeting confirmed that: regulatory approval for 20mg hydrocortisone tablets was obtained and that Waymade could '*now start selling in 30 [tablet] bottles*'; the 20mg hydrocortisone tablet '*validation batches*'⁵¹⁸ were to be '*used until stock expires (end 2011)*'; forecasted sales of 150,000 hydrocortisone tablets per annum would commence from May 2011; and reformulation of 20mg hydrocortisone tablets replacing maize starch with pre-gelatinised starch was planned '*following agreement, ca mid-year*'. Document 300166, Minutes of joint Aesica Sovereign review 31/3/11, pages 1 to 2. See also Document 300736, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2] and others dated 28 March 2011: '*It is proposed that the next manufacture of 20mg will be with a revised formulation*'; and Document 300176, email from [Aesica Employee] to [REDACTED], [REDACTED], [REDACTED] and others dated 27 April 2011; and attached Document 300177, Minutes update of joint Aesica Sovereign review 31/3/11, confirming that the '*shipping plan for [the] beginning [of] May [was] on track*' and that the reformulation was planned '*following urgent RFP [request for proposal] agreement*'.

⁵¹⁹ Document 200292, paragraph 6.1, Aesica's response to section 26 notice dated 15 June 2016. See also Document 301478, [REDACTED]'s Projects April 2011, slide 2, attachment to Document 301477, email from [REDACTED] to [REDACTED], [Waymade Senior Employee 2], [REDACTED] and others dated 5 April 2011.

- 3.362. Waymade expected to launch its 20mg tablets after Aesica delivered them in May 2011. Internal meeting minutes from April 2011 noted that ‘*[l]aunch activities*’, such as ‘*establishment of PIP code*’⁵²⁰ and ‘*pricing and communication to sales colleagues*’, were ‘*underway*’ and that the ‘*[l]aunch will occur immediately after release into stock*.’⁵²¹
- 3.363. On 9 May 2011, Aesica supplied Waymade with 20mg hydrocortisone tablets from the Third Batch packed in glass bottles ‘*for commercialisation*’.⁵²² This supply consisted of 106,800 tablets packed in 3,560 bottles of 30 tablets which had an expiry date of 30 November 2013.⁵²³ According to Waymade’s forecasts, this should have been sufficient stock to last at least for the rest of 2011.⁵²⁴
- 3.364. On 11 May 2011, Aesica submitted a proposal for the 20mg hydrocortisone tablet ‘*starch replacement project*’ set out in Waymade’s RFP of 19 April 2011.⁵²⁵
- 3.365. However, there was no further communication between Aesica and Waymade regarding 20mg hydrocortisone tablets for over two years: until August 2013.⁵²⁶
- b. Waymade enters into a supply agreement with Auden for 20mg hydrocortisone tablets and ‘freezes’ its 20mg product**
- 3.366. In summary:
- a. In the first half of 2011 Waymade approached Auden to negotiate a supply deal for 20mg hydrocortisone tablets. It chose not to release its

⁵²⁰ The PIP code is a unique seven-digit coding system used to ensure traceability and accurate product information when ordering pharmaceutical products. It is provided by Chemist Druggist (C+D) and allows for generic products to be more easily ordered, dispensed and tracked. See: [UK Sees PIP Codes Expand To Cover Hospital Drugs | Pharma Intelligence \(informa.com\)](#).

⁵²¹ Document 300167, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 2], [X], [Waymade Employee] and others dated 4 April 2011; Document 300171, email from [Waymade Employee] to [X], [Waymade Employee], [Waymade Employee] and others dated 26 April 2011. See also Document 300170, Monthly Report Sovereign Medical March 2011, page 2.

⁵²² Document 200292, paragraphs 1.3 and 6.1, Aesica’s response to section 26 notice dated 15 June 2016. See also Document 300544, email from [Waymade Senior Employee 4] to [X] and [Waymade Senior Employee 2] dated 13 May 2016; and Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 54, lines 4 to 6: ‘*in May, we had the product [...], we’d received the packed product from Aesica and it was in a condition ready to be released*’.

⁵²³ Document 200292, paragraph 3.6, Aesica’s response to the CMA’s section 26 notice dated 15 June 2016; and Document 300544, email from [Waymade Senior Employee 4] to [X] and [Waymade Senior Employee 2] dated 13 May 2016.

⁵²⁴ Waymade’s initial order for 2009 envisaged supply of 136,000 tablets per year. Document 200292, paragraph 3.5, Aesica’s response to the CMA’s section 26 notice dated 15 June 2016.

⁵²⁵ Document 200017, email from [X] (Aesica) to [Waymade Senior Employee 3] dated 11 May 2011.

⁵²⁶ Document 200292, paragraph 6.1, Aesica’s response to the CMA’s section 26 notice dated 15 June 2016.

20mg tablets for sale or progress reformulating until those negotiations reached a conclusion.

- b. On 11 July 2011 Waymade and Auden reached an agreement for Auden to supply Waymade with 20mg hydrocortisone tablets.
 - c. After concluding this agreement, Waymade held its commercial stock and explored selling it outside the UK.
- 3.367. In anticipation of bringing its 20mg hydrocortisone tablets to launch-readiness in mid-2011, Waymade approached Auden in the first half of 2011 to negotiate a supply deal for 20mg hydrocortisone tablets.⁵²⁷ Waymade's plan was to pursue the two workstreams in parallel. On 23 December 2010 [Waymade Senior Employee 3] informed [Waymade Senior Employee 1] that *'[...] the earliest launch of our Hydrocortisone product in glass bottles is May or June 2011. This is tracking with the project plan. [...] With regards to a negotiation with Auden McKenzie, I suggest that opening a discussion in January would be about right. IMS suggests that the UK market for Hydrocortisone 20mg tablets x 30 is valued at 38,000 packs and £1.6m a year'*.⁵²⁸
- 3.368. Waymade's internal documents stated that it would not release its own 20mg product for sale, or press ahead with reformulation, until its negotiations with Auden had reached a conclusion. For example:
- a. An internal Waymade report for April 2011 recorded that *'[d]elivery of the 20mg strength tablets [...] will [...] be delivered week commencing 09 May. The product will be released into stock and then frozen⁵²⁹ pending the outcome of the negotiations with Auden McKenzie'*. The report concluded that the *'Hydrocortisone project continues to progress smoothly and in a timely fashion'*.⁵³⁰

⁵²⁷ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.16; and Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 11, lines 20 to 23.

⁵²⁸ Document 300138, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] dated 23 December 2010, page 2 (emphasis added).

⁵²⁹ [Waymade Senior Employee 3] explained to the CMA that 'the product would be released into stock, it means it passes the quality aspect, such as its approved by the quality community and released into stock from a quality perspective, but then it's frozen on the system so that orders can't be inadvertently taken and product despatched. It's disabled if you like'. [Waymade Senior Employee 3] further explained the 'explicit meaning' of the April 2011 report was that the 'product could be launched but it was decided that [...] the product would not be launched', adding that the 'reference to 'frozen' means that orders couldn't be inadvertently taken and product despatched'. See Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 32, line 15 to page 33, line 7. [Waymade Employee] confirmed that 'frozen' mean that 'nobody could actually put a sales order on and process' the product. See Document 302405, transcript of [Waymade Employee] interview dated 23 November 2018, page 66, lines 25 to 27.

⁵³⁰ Document 300180, Monthly Report Sovereign Generics April 2011, page 2 (underlined emphasis added).

- b. Hydrocortisone tablets meeting minutes circulated by [Waymade Senior Employee 3] on 9 May 2011 reported that Aesica would deliver *'[f]inished packs of 20mg tablets in glass'* to Waymade that week but the *'[s]tock [would] not be released for sale pending the outcome of commercial negotiations with a third party'*.⁵³¹ The *'outcome of these discussions'* would *'inform the decision as to whether the 20mg tablet is reformulated in line with the 10mg tablet'*.⁵³² On 6 June 2011, having held regular weekly meetings to discuss the progress of the project since its inception, Waymade decided that *'no further regular Monday meetings are necessary'*.⁵³³
 - c. After Waymade received the tablets packed from the Third Batch, [Waymade Senior Employee 3] confirmed on 16 May 2011 that the *'[d]elivery of 20mg strength tablets [had been] received from Aesica, released into stock and 'frozen' pending commercial negotiations with a third party'*.⁵³⁴
- 3.369. As the negotiations with Auden progressed towards a conclusion, Waymade considered that it might not need to pursue reformulating its 20mg product. [Waymade Senior Employee 3] suggested that if Waymade was *'confident that the Auden McKenzie trading relationship is going to stick'*, then Waymade would *'not need to reformulate at the current time'*.⁵³⁵
- 3.370. Waymade and Auden reached an agreement for Auden to supply Waymade with 20mg hydrocortisone tablets on 11 July 2011. The agreed terms of supply were:
- a. Auden would supply 1,000 packs of 20mg hydrocortisone tablets per month to Waymade from July 2011 at £4.50 per pack.
 - b. Of the 1,000 packs per month:

⁵³¹ [Waymade Senior Employee 2], [Waymade Senior Employee 3], [Waymade Employee] and [Waymade Employee] told the CMA that the 'third party' was or was likely to be Auden McKenzie. See Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018 page 28 lines 1 to 8; Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018 page 29 lines 6 to 10; Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 37 line 26 to page 38 line 8; page 47 lines 6 to 14; page 53 lines 14 to 19; and Document 302405, transcript of [Waymade Employee] interview dated 23 November 2018, page 64, lines 11 to 19.

⁵³² Document 300178, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2] and others dated 9 May 2011 (emphasis added).

⁵³³ Document 300184, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 2] and others dated 6 June 2011.

⁵³⁴ Document 300182, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2] and others dated 16 May 2011.

⁵³⁵ Document 200017, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] dated 23 June 2011 (emphasis added).

- i. 200 packs would be supplied to Waymade for sale to its own customers; and
 - ii. the remaining 800 packs would be bought back immediately by Auden at a market rate of £34.50 (the '**Buyback**').⁵³⁶
- 3.371. As explained in section 6.D.II.c.i below, the CMA has found that in return, Waymade agreed not to enter the market with its 20mg hydrocortisone tablets.
- 3.372. After concluding the 20mg supply deal, Waymade continued to hold the tablets packed from the Third Batch.⁵³⁷ An internal Waymade report for the year 2011 stated that '*[d]espite hitting [its] margin target*' it had '*48 products that were below the forecasted figure*' predominately '*due to delayed launches*'.⁵³⁸ This included 20mg hydrocortisone tablets which had budgeted sales of £25,440 and actual sales of £0. Waymade's internal record of its MAs listed the Aesica-manufactured 20mg hydrocortisone tablets as '*Not marketed*', meaning '*No plans to market*' (as opposed to '*Not currently marketed*', meaning '*Plans to launch/re-launch following resolution of issues*').⁵³⁹
- 3.373. Though Waymade did not launch the tablets packed from the Third Batch in the UK, it explored the possibility of selling them overseas. On 30 January 2012, Waymade was contacted by the pharmaceutical wholesaler Ambe Limited which requested to purchase 1,500 packs of 20mg hydrocortisone tablets for a customer in Yemen. Waymade offered '*3,550 packs of 20mg*' with an '*11/2013 expiry at a good price*' stipulating that '*they MUST be exported and guarantee they do not end up back in UK*'.⁵⁴⁰ The number of packs and expiry date corresponds with the quantity and expiry date of the tablets packed from the Third Batch.
- 3.374. Junior Waymade staff later queried why it was not selling the tablets packed from the Third Batch. On 13 March 2013, [Waymade Employee] emailed

⁵³⁶ Document 300619, email from [Auden Senior Employee 2] to [Waymade Senior Employee 4] dated 11 July 2011.

⁵³⁷ Internal Waymade product manufacturing reports recorded: '*[p]acked stock of 20mg [hydrocortisone] tablets on site at Waymade*', see Document 300209, Product Manufacturing Monthly Report August 2011, page 4; and Document 301521, Product Manufacturing Monthly Report September 2011, page 4.

⁵³⁸ Document 300220, 2011 Report Sovereign Medical, page 4, attachment to Document 300219, email from [REDACTED] to [Waymade Senior Employee 1], [Waymade Employee] and [Waymade Senior Employee 4] dated 10 February 2012.

⁵³⁹ For example, Document 300345, Excel file dated March 2018 attached to Document 300344, email from [Waymade Senior Employee 4] to [REDACTED] dated 22 March 2013. See also Document 300277, email from [Waymade Employee] to [Waymade Senior Employee 4] dated 4 September 2012: '*You asked last week about the Hydrocortisone 20mg that we currently have but are not marketing*'.

⁵⁴⁰ Document 300216, email from [Waymade Senior Employee 4] to [REDACTED] dated 31 January 2012.

[Waymade Employee]⁵⁴¹ indicating that he had '*just come across the product above [subject line reads 'hydrocortisone 20mg 30 sov'] pip code 116-1108 and the description line has a dot before the description therefore no one can see this for selling*'. Noting that the '*expiry date on this [was] 11/2013*' he asked, '*do you know if you want to sell?*' [Waymade Employee] responded that Waymade would be '*holding the stock and not selling it*', adding that he would confirm with [Waymade Senior Employee 4] on how to proceed. [Waymade Senior Employee 4] subsequently instructed [Waymade Employee] to '*leave the stock where it is*', explaining that '*we area ware [sic] it is going out of date but need it available just in case*'.⁵⁴² [Waymade Senior Employee 4] explained to the CMA that the inclusion of 'sov' (for 'Sovereign Generics') in the product description indicated that this was Waymade's Aesica-manufactured stock (ie the tablets packed from the Third Batch) rather than product supplied by Auden.⁵⁴³

c. Waymade returns to its 20mg project at times during the 20mg supply deal, which ends in April 2015

3.375. In summary:

- a. The supply deal remained in place, with variations to its terms, until 30 April 2015.
- b. During that time, Waymade periodically re-engaged with its 20mg hydrocortisone tablets project – in particular after it began negotiations in February 2014 to sell its 20mg MA to AMCo, when AMCo's scepticism about its launch-readiness prompted Waymade to order fresh batches from Aesica in April 2014.
- c. From at least March 2014 onwards, Waymade had to chase Auden to obtain payment under the Buyback. Auden ceased paying Waymade under the Buyback on 30 April 2015.
- d. Between April 2014 and July 2015 Waymade experienced some delays to production and delivery of the batches it had ordered from Aesica. However, by July 2015 it was once more ready to launch its 20mg tablets.

⁵⁴¹ Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 2, page 7, lines 18 to 21.

⁵⁴² Document 300790, emails (i) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; (ii) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; and (iii) from [Waymade Senior Employee 4] to [Waymade Employee] dated 8 April 2013 (emphasis added).

⁵⁴³ Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 2, page 5, line 9 to page 6, line 9; and page 9, lines 3 to 19.

- 3.376. The supply terms agreed between Auden and Waymade in July 2011 remained in place throughout 2011 and 2012⁵⁴⁴ with some variations to the terms introduced from April 2013.⁵⁴⁵
- 3.377. On 27 March 2013, [Waymade Senior Employee 2] emailed [Waymade Senior Employee 1] a proposal which set out under the title '*Current Scenario (Annualised)*' the annual value of Auden's cash transfer to Waymade for the Buyback packs (£288,000 or 12 x £24,000) (labelled as '*Marketing Fee*')⁵⁴⁶ as well as a '*Proposed Scenario*' which increased this '*Marketing Fee*' to £400,000 (or £33,333 per month). The proposal concluded with the '*Share*' which was listed as '*33%*'.⁵⁴⁷ On the following day, 28 March 2013, [Waymade Senior Employee 1] emailed [Waymade Senior Employee 4]: '*before we order Hydrocort 20mg ,plase [sic] wait for me to speak to [Auden Senior Employee 1]*'.⁵⁴⁸ From April 2013, the monthly cash transfer from Auden to Waymade increased to £34,800 (see Table 3.26 below).

⁵⁴⁴ See, for example, Document 300336, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 1] dated 27 December 2012: '*We have also ordered the normal 200 x 20mg*'; Document 300761, email from [Waymade Senior Employee 4] to [REDACTED] dated 28 March 2012: '*We will have another 200 next week, need to shift the 300 we have collected*'; and Document 300202, Waymade purchase order to Auden dated 10 August 2011.

⁵⁴⁵ Document 200003, paragraphs 11.7 to 11.10, Waymade's response to the CMA's section 26 notice dated 5 May 2016; and Document 200010, Annex 12 of Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁵⁴⁶ The Buyback was also referred to within Waymade as '*Fee re Hydrocortisone*' and '*Promotional Fee*' – see Document 300760, spreadsheet attached to Document 300758, email from [Waymade Employee] to [REDACTED] dated 16 December 2011; and Document 300275, email from [REDACTED] to [Waymade Senior Employee 1] dated 24 July 2012. The Buyback was attributed to '*PROMO. SERVICES IN RES. OF HYDTA 20MG*' and was recorded as pure profit – see, for example, 300826, file attached to Document 300825, email from <notification.message@waymade.co.uk> to <sales-3@waymade.co.uk> dated 1 March 2014; Document 300852, file attached to Document 300851, email from <notification.message@waymade.co.uk> to <sales-3@waymade.co.uk> dated 1 August 2014.

⁵⁴⁷ Document 300785, spreadsheet titled 'Proposal' in 'Copy of Hydrocortisone 20mg 30 sales data' attached to Document 300784, email from [Waymade Senior Employee 2] to [Waymade Senior Employee 1] dated 27 March 2013.

⁵⁴⁸ Document 300352, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 4] dated 28 March 2013.

Table 3.26: variations to the terms of the 20mg supply arrangement

	Packs supplied to Waymade for sale to its own customers					Buyback Packs			
	No of packs supplied	Purchase Price (£) per pack	No of packs sold	ASP ⁵⁴⁹ (£) per pack	Value of margin transfer ⁵⁵⁰ (£)	No of packs subject to the Buyback	Purchase price (£) per pack	Buyback price (£) ⁵⁵¹ per pack	Value of cash transfer ⁵⁵² (£)
July 2011	200	4.50	50	36.12	906	800	4.50	34.50	24,000
August 2011	200	4.50	174	32.94	4,831	800	4.50	34.50	24,000
September 2011	0	-	73	36.63	2,674	800	4.50	34.50	24,000
October 2011	200	4.50	140	34.84	3,977	800	4.50	34.50	24,000
November 2011	0	-	203	35.43	7,192	800	4.50	34.50	24,000
December 2011	300	4.50	17	36.94	-722	800	4.50	34.50	24,000
January 2012	0	-	80	36.95	2,956	800	4.50	34.50	24,000

⁵⁴⁹ Calculated from Waymade's monthly sales revenue divided by Waymade's monthly sales volumes for the 20mg hydrocortisone tablet packs supplied by Auden for sale to Waymade's own customers. See Document 200345, Waymade's hydrocortisone tablet sales data provided to the CMA.

⁵⁵⁰ Calculated from Waymade's monthly sales revenue less its monthly COGs for the 20mg hydrocortisone tablet packs supplied by Auden for sale to Waymade's own customers. Waymade's monthly sales revenue is based on revenue from the 20mg hydrocortisone packs Waymade sold each month. Waymade's COGs is based on the amount Waymade paid Auden for the 20mg hydrocortisone tablets supplied each month. Document 200010, Waymade's hydrocortisone tablet purchase data provided to the CMA as Annexes 12 of Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016; and Document 200345, Waymade's hydrocortisone tablet sales data provided to the CMA.

⁵⁵¹ The price that Auden paid for each 20mg hydrocortisone tablet pack subject to the Buyback, ie Waymade's sale price.

⁵⁵² Calculated from the total amount Auden paid Waymade each month to 'buy back' the 20mg hydrocortisone tablet packs subject to the Buyback each month less the total amount Waymade paid Auden each month to 'buy' the packs subject to the Buyback. Document 200010, Waymade's hydrocortisone tablet purchase data provided to the CMA as Annexes 12 of Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016

	Packs supplied to Waymade for sale to its own customers						Buyback Packs			
	No of packs supplied	Purchase Price (£) per pack	No of packs sold	ASP ⁵⁴⁹ (£) per pack	Value of margin transfer ⁵⁵⁰ (£)	No of packs subject to the Buyback	Purchase price (£) per pack	Buyback price (£) ⁵⁵¹ per pack	Value of cash transfer ⁵⁵² (£)	
February 2012	200	4.50	29	36.90	170	800	4.50	34.50	24,000	
March 2012	0	-	71	36.99	2,626	800	4.50	34.50	24,000	
April 2012	0	-	50	36.96	1,848	800	4.50	34.50	24,000	
May 2012	400	4.50	596	32.40	17,510	800	4.50	34.50	24,000	
June 2012	650	4.50	579	33.32	16,370	800	4.50	34.50	24,000	
July 2012	400	4.50	333	31.89	8,821	800	4.50	34.50	24,000	
August 2012	200	4.50	393	32.72	11,957	800	4.50	34.50	24,000	
September 2012	200	4.50	146	34.64	4,157	800	4.50	34.50	24,000	
October 2012	400	4.50	337	34.35	9,777	800	4.50	34.50	24,000	
November 2012	200	4.50	315	34.43	9,946	800	4.50	34.50	24,000	
December 2012	200	4.50	185	33.45	5,288	800	4.50	34.50	24,000	
January 2013	400	4.50	147	34.64	3,292	800	4.50	34.50	24,000	
February 2013	0	-	273	31.38	8,568	800	4.50	34.50	24,000	

	Packs supplied to Waymade for sale to its own customers					Buyback Packs			
	No of packs supplied	Purchase Price (£) per pack	No of packs sold	ASP ⁵⁴⁹ (£) per pack	Value of margin transfer ⁵⁵⁰ (£)	No of packs subject to the Buyback	Purchase price (£) per pack	Buyback price (£) ⁵⁵¹ per pack	Value of cash transfer ⁵⁵² (£)
March 2013	200	4.50	183	34.52	5,418	800	4.50	34.50	24,000
April 2013	200	34.50 ⁵⁵³	65	37.46	-4,465	928	4.50	42.00	34,800
May 2013	200	34.50	92	37.57	-3,444	928	4.50	42.00	34,800
June 2013	0	-	40	38.50	1,540	928	4.50	42.00	34,800
July 2013	400	34.50	83	37.89	-10,655	928	4.50	42.00	34,800
August 2013	200	37.50	368	37.36	6,247	928	4.50	42.00	34,800
September 2013	200	34.50	49	40.12	-4,934	928	4.50	42.00	34,800
October 2013	200	34.50	69	47.54	-3,620	928	4.50	51.00	43,152
November 2013	200	34.50	51	47.31	-4,487	928	4.50	51.00	43,152
December 2013	200	34.50	321	45.07	7,566	982 ⁵⁵⁴	4.50	51.00	45,663
January 2014	200	34.50	308	46.00	7,268	982	4.50	51.00	45,663

⁵⁵³ Document 300357, email from [Waymade Senior Employee 4] to [X] dated 17 April 2013.

⁵⁵⁴ Waymade explained that this was probably due to an internal error. Document 200003, paragraph 11.10, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

	Packs supplied to Waymade for sale to its own customers						Buyback Packs			
	No of packs supplied	Purchase Price (£) per pack	No of packs sold	ASP ⁵⁴⁹ (£) per pack	Value of margin transfer ⁵⁵⁰ (£)	No of packs subject to the Buyback	Purchase price (£) per pack	Buyback price (£) ⁵⁵¹ per pack	Value of cash transfer ⁵⁵² (£)	
February 2014	200	40.50	355	45.75	8,141	982	4.50	51.00	45,663	
March 2014	200	43.50	426	47.58	11,569	982	4.50	51.00	45,663	
April 2014	200	55.27	155	47.72	-3,658	982	4.50	59.77	54,275	
May 2014	200	56.00	36	75.28	-8,490	982	4.50	59.77	54,275	
June 2014	200	56.00	27	67.85	-9,368	982	4.50	60.50	54,992	
July 2014	200	56.00	20	69.40	-9,812	982	4.50	60.50	54,992	
August 2014	200	56.00	82	58.52	-6,401	982	4.50	60.50	54,992	
September 2014	200	56.00	70	59.21	-7,055	982	4.50	60.50	54,992	
October 2014	200	58.00	139	58.47	-3,472	982	4.50	60.50	54,992	
November 2014	0	-	616	60.16	37,058	982	4.50	62.50	56,956	
December 2014	200	67.00	136	62.85	-4,853	982	4.50	71.50	65,794	
January 2015	200	67.00	322	64.94	7,512	982	4.50	71.50	65,794	
February 2015	200	67.00	260	67.54	4,160	982	4.50	71.50	65,794	

	Packs supplied to Waymade for sale to its own customers					Buyback Packs			
	No of packs supplied	Purchase Price (£) per pack	No of packs sold	ASP ⁵⁴⁹ (£) per pack	Value of margin transfer ⁵⁵⁰ (£)	No of packs subject to the Buyback	Purchase price (£) per pack	Buyback price (£) ⁵⁵¹ per pack	Value of cash transfer ⁵⁵² (£)
March 2015	0	-	20	61.00	1,220	982	4.50	71.50	65,794
April 2015	200	67.00	-	-	-13,400	982	4.50	71.50	65,794
May 2015	0	-	260	66.02	17,165	0	-	-	0
June 2015	200	67.00	120	67.25	-5,330	0	-	-	0
July 2015	0	-	90	69.22	6,230	0	-	-	0
August 2015	0	-	50	68.00	3,400	0	-	-	0
TOTAL					143,194				1,751,192

Source: CMA analysis based on data submitted by Waymade (Document 200010 and Document 200345). See also Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016.⁵⁵⁵

⁵⁵⁵ Waymade sent Auden monthly invoices for the agreed amount under the Buyback under the description 'PROMO.SERVICES IN RES.OF HYDTA 20MG 30'. See Documents 300563 to 300578, 300582 to 300596, 300622 to 300633, 300665 to 300672. Waymade also sent Auden monthly purchase orders for the 200 packs supplied for sale to its own customers. See, for example, Documents 300202, 300478, 300495 and 300506.

- 3.378. The 20mg supply deal remained in place, with the variations described above, until 30 April 2015. During that time – especially at moments when the 20mg supply deal did not run smoothly, or another external event provided a stimulus – Waymade periodically re-engaged with its 20mg hydrocortisone tablets project.
- 3.379. In August 2013 Waymade began to query the amount Auden invoiced it for the 200 packs supplied for resale to its own customers. On 30 August 2013, Auden informed Waymade that the *'price for Hydrocortisone 20mg tabs have been increase [sic] to £37.50'*. [Waymade Senior Employee 4] forwarded the email to [Waymade Senior Employee 2] the same day, explaining Waymade had *'placed order for September at £34.50'* and asking *'Do you want to pursue with [Auden Senior Employee 2] or shall I?'*. [Waymade Senior Employee 2] indicated he would *'follow up with [Auden Senior Employee 2]'*.⁵⁵⁶
- 3.380. In August 2013 Waymade also had its first contact with Aesica on 20mg hydrocortisone tablets since 11 May 2011. On 13 August 2013, [Waymade Senior Employee 2]⁵⁵⁷ emailed [X]⁵⁵⁸ [X] following a meeting the preceding week, indicating that Waymade *'may require a batch of hydrocortisone 20mg tabs to be made'*.⁵⁵⁹
- 3.381. In February 2014 Waymade began negotiations to sell its 20mg MA to AMCo.⁵⁶⁰

⁵⁵⁶ Document 300404, emails from [X] to [X], [Waymade Senior Employee 4] and others and between [Waymade Senior Employee 4] and [Waymade Senior Employee 2] dated 30 August 2013. See also Document 300400, email from [Waymade Senior Employee 4] to [X] dated 30 August 2013. Similar exchanges occurred in October 2013 (Document 300407, email from [X] to [X] and others dated 2 October 2013; and Document 300407, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 2] dated 2 October 2013); January 2014 (Document 301667, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 2] dated 22 January 2014); April 2014 (Document 300447, email from [X] to [X] dated 4 April 2014; Document 300448, email from [Waymade Senior Employee 4] to [X] dated 7 April 2014); September 2014 (Document 300477, email from [X] to [X] dated 17 September 2014); October 2014 (Document 300479, email from [X] to [X] dated 1 October 2014); and January 2015 (Document 300516, emails between [X] and [X] dated January and February 2015). In some instances (e.g. in January and April 2014) Auden's amended invoice price corresponded to the net amount per pack Auden paid Waymade for the packs subject to the Buyback (Document 200010, Annex 12 of Waymade's response to the CMA's section 26 notice dated 5 May 2016). See table 3.26 above.

⁵⁵⁷ [Waymade Senior Employee 2] [X]. See paragraph 3.3.d and Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018, page 7, lines 2 to 10.

⁵⁵⁸ Document 301344, CMA correspondence regarding note of call with Aesica on 20 March 2018.

⁵⁵⁹ Document 200006, emails from [Waymade Senior Employee 2] to [X] dated 13 August 2013, 21 August 2013 and 3 September 2013 attached as Annex 10(A) to Waymade's response to the CMA's section 26 notice dated 5 May 2016, pages 12 to 13. See also Document 301672, email from [Waymade Senior Employee 2] to [X] dated 24 February 2014.

⁵⁶⁰ Document 200107, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 11 February 2014. See also Document 200099, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 1] [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 11 February 2014; Document 203631, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 1], [AMCo Senior Employee 6] and [AMCo Senior Employee 2] dated 11 February 2014.

3.382. In February 2014, Waymade also returned to its 20mg development project. Because of the length of time for which the project had been inactive its staff had to research its history. In February and March 2014,⁵⁶¹ Waymade and Aesica internally reviewed the status of the 20mg hydrocortisone tablet development and established that:

- a. three '*commercial scale batches*' had been '*successfully manufactured by Aesica for validation*' (the First and Second Batches and the Third Batch),⁵⁶² with one batch '*hand packed in 30 tablet bottles for commercial supply*' (the tablets packed from the Third Batch);⁵⁶³
- b. a formulation change had been proposed after the Fourth Batch had failed dissolution testing, with maize starch to be replaced with pre-gelatinised starch to avoid potential failure of '*future batches*';⁵⁶⁴
- c. there were '*no regulatory issues preventing [Waymade] from producing packs of 30 tablets in amber glass bottles*'.⁵⁶⁵ However, '*[a]ny other pack size or type would require prior approval of variations by the MHRA*'⁵⁶⁶ and a formulation change would require '*3 months stability data on 2 batches (pilot or commercial*'⁵⁶⁷);⁵⁶⁸
- d. Waymade had decided not to '*proceed with the [...] re-formulation due to the commercial arrangement [it had] entered into which prevented us from marketing our product*';⁵⁶⁹ '*[r]eformulation was not completed on*

⁵⁶¹ Document 300512, email from [Waymade Employee] to [X] dated 11 February 2015: '*The project discussions were initiated in Feb 2014*'.

⁵⁶² Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014 attached to Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014.

⁵⁶³ Document 301695, email from [Aesica Employee] to [Waymade Employee] dated 3 March 2014.

⁵⁶⁴ Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014 and attachment Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014, Document 301693, email from [Waymade Employee] to [Waymade Employee] dated 28 February 2014, Document 301695, emails from [Aesica Employee] to [Waymade Employee] dated 28 February 2014 and 3 March 2014. See also Document 301676, email from [Waymade Employee] to [Waymade Employee] dated 25 February 2014.

⁵⁶⁵ Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2], dated 25 February 2014 (emphasis added).

⁵⁶⁶ Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2], dated 25 February 2014.

⁵⁶⁷ [Aesica Employee] explained to the CMA that there are two possible approaches to reformulation: (i) the reformulated tablets are produced and tested at '*small scale*' prior to producing demonstration then validation batches, and (ii) the reformulated batches are produced as commercial scale validation batches without initial small scale testing. The first approach would involve less risk and would take three to six months to implement, while the second would involve more risk and would take one to three months to implement. See Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 63, line 4 to page 64, line 10; and page 65, lines 11 to 26.

⁵⁶⁸ Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014 attached to Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014.

⁵⁶⁹ Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2], dated 25 February 2014. See also Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014 attached to Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014, '*Formulation change [...] not progressed as 20mg tablets were not marketed due to agreement with 3rd party*'.

the 20mg product as there was no subsequent demand for commercial supply until now;⁵⁷⁰ and *'no further batches'* were made as Waymade was *'no longer going to market the tablets'*;⁵⁷¹ and

- e. going forwards, it *'may not be feasible to produce further batches with the existing formulation'* and *'may be necessary to initiate the reformulation activities as a first step'*.⁵⁷²

- 3.383. From at least March 2014 onwards, Waymade frequently had to chase Auden to obtain payment for the Buyback. For example, on 7 March 2014 [Waymade Senior Employee 1] emailed [Auden Senior Employee 1] with the subject *'Payment for waymade'*, explaining that Waymade had *'definitely NOT received the payment'* despite [Auden Senior Employee 1]'s reassurances he had *'sent it on Friday last week'*. [Auden Senior Employee 3] responded later that day that a *'cheque [had] been sent out today by special delivery'* and would be *'with [Waymade] on Monday'*. [Waymade Senior Employee 1] forwarded the message to [X] [Waymade Senior Employee 2].⁵⁷³
- 3.384. On 10 April 2014, AMCo met with Waymade's [X] (representing [Waymade Senior Employee 1]).⁵⁷⁴ [AMCo Senior Employee 2] internally reported that the *'difficulty'* with the potential purchase of Waymade's 20mg MA was that Waymade had *'never made'* its own 20mg hydrocortisone tablets and *'despite [X]'s claims that they are developing it ready for launch, he didn't want to be drawn into getting the product to market before a sale.'*⁵⁷⁵
- 3.385. On the following day, 11 April 2014, Waymade issued a purchase order to Aesica for 14,400 30 tablet packs of 20mg hydrocortisone tablets. The packs

⁵⁷⁰ Document 301709, email from [Aesica Employee] to [Waymade Employee] dated 28 February 2014.

⁵⁷¹ Document 301693, email from [Waymade Employee] to [Waymade Employee] dated 28 February 2014.

⁵⁷² Document 301695, email from [Aesica Employee] to [Waymade Employee] dated 28 February 2014. See also Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014 attached to Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014: *'[X] advised that there is a risk that future batches will fail if not re-formulated'*; and Document 301675 and Document 302310, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014: *'An issue with the formulation [...] could cause failure of future batches'*.

⁵⁷³ Document 301697, emails between [Waymade Senior Employee 2], [Waymade Senior Employee 1] and [Auden Senior Employee 3] dated 7 March 2014. In his email, [Auden Senior Employee 3] told [Waymade Senior Employee 1] that he *'had informed [Auden Senior Employee 1] that a payment had been made but did not mention that it was for the Amco account'*, indicating that the payment [Auden Senior Employee 1] had previously confirmed related to Waymade's activities as distribution agent for AMCo, rather than the payment to Waymade as agreed under the 20mg supply arrangement.

⁵⁷⁴ Document 202639, email from [AMCo Senior Employee 1] to [Cinven Senior Employee 1] dated 7 April 2014.

⁵⁷⁵ Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 8], [AMCo Senior Employee 1] and [AMCo Senior Employee 6] dated 11 April 2014.

were divided into three validation batches using the modified formulation of pre-gelatinised starch.⁵⁷⁶

- 3.386. Ultimately, Waymade and AMCo could not agree on the sale of Waymade's 20mg MA and the proposed transaction was abandoned by 30 May 2014.⁵⁷⁷
- 3.387. Aesica manufactured the three validation batches on 6 August 2014 and anticipated completing process validation by early October 2014.⁵⁷⁸
- 3.388. On 9 February 2015, the MHRA confirmed that Waymade's reformulation of its 20mg hydrocortisone tablets had been approved as a variation on its MA.⁵⁷⁹ [Waymade Senior Employee 2], forwarded the approval to [Waymade Senior Employee 1], commenting '*[s]tock will now be packed off*'.⁵⁸⁰
- 3.389. In March 2015 Waymade once again had to chase Auden for payment. [Waymade Senior Employee 1] emailed [Waymade Senior Employee 2] on 17 March 2015, '*Did we get payment Frm Auden Mckenzie plse check [X]*'.⁵⁸¹ Following enquiries, [X] informed [Waymade Senior Employee 2] that Waymade had not received payment from Auden, noting that '*[t]he problem is that we aren't billing them for stock so I can't even put the account on stop*'. [Waymade Senior Employee 2] forwarded the email to [Waymade Senior Employee 1], asking '*Shall i ask [Auden Senior Employee 1]?*'. [Waymade Senior Employee 1] confirmed '*Call [Auden Senior Employee 1] plse*' and asked '*a dis [sic: 'and is'] our product ready or not*'.⁵⁸²
- 3.390. Auden ceased paying Waymade under the Buyback on 30 April 2015 (see table 3.26 above).

⁵⁷⁶ Document 300641, purchase order for 20mg hydrocortisone tablets dated 11 April 2014 attached to Document 301742, email from [X] to [Aesica Employee], [X], [X] and [X] dated 11 April 2014. See also Document 200292, paragraph 6.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016; Document 301731, Aesica proposal for the supply of hydrocortisone 20mg tablets in x30 bottles dated 2 April 2014; and Document 301735, email chain between [Waymade Employee] and [Aesica Employee] between 25 March 2014 and 7 April 2014. See also Document 300482, email from [Waymade Employee] to [Waymade Senior Employee 4] and [Waymade Senior Employee 2] dated 27 October 2014: '*The batches that were manufacture[d] by Aesica on our behalf are commercial batches*'.

⁵⁷⁷ Document 00444, paragraphs 1.17 and 5.2, AMCo's response to the CMA's section 26 notice dated 8 March 2016. See also Document 201094, email from [AMCo Senior Employee 8] to [X] and [X] dated 30 May 2014: '*AMCo has been trying to buy the 20mg [...] but Waymade will not sell it*'.

⁵⁷⁸ Document 301911, email from [Waymade Senior Employee 2] to [Aesica Employee] dated 11 February 2015. See also Document 301839, email from [X] to [Waymade Employee] dated 20 August 2014; and Document 301843, email from [X] to [Waymade Employee] dated 17 September 2014.

⁵⁷⁹ Document 301899, email from [Waymade Employee] to [Waymade Employee] and [Waymade Senior Employee 2] dated 9 February 2015. See also Document 300899, email from [Waymade Employee] to [Waymade Employee] dated 6 February 2015.

⁵⁸⁰ Document 301900, email from [Waymade Senior Employee 2] to [Waymade Senior Employee 1] dated 9 February 2015.

⁵⁸¹ Document 301928, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 2] dated 17 March 2015.

⁵⁸² Document 301929, email from [X] to [Waymade Senior Employee 2] dated 17 March 2015 and emails between [Waymade Senior Employee 1] and [Waymade Senior Employee 2] dated 17 March 2015.

- 3.391. On 1 June 2015, Aesica confirmed to Waymade that it had '*initiated the packing*' of the August 2014 validation batches into '*30 tablet bottle packs*'.⁵⁸³
- 3.392. By 6 July 2015, Waymade had received all of the packed August 2014 validation batches from Aesica.⁵⁸⁴
- 3.393. Between April 2014 and July 2015, Waymade had experienced various delays to the production and delivery of the August 2014 validation batches from Aesica due to:
- a. the unavailability of a manufacturing slot in Aesica's production schedule;⁵⁸⁵
 - b. difficulties in obtaining the API in July 2014;⁵⁸⁶
 - c. Aesica's delayed purchase of a new tablet counter in July 2014;⁵⁸⁷
 - d. Aesica's delay in initiating and completing process validation, as well as producing the subsequent Certificate of Analysis⁵⁸⁸ required for Waymade's MA variation application⁵⁸⁹ between August 2014 and November 2014;⁵⁹⁰
 - e. Aesica's failure to obtain the bottles and leaflets required to package the August 2014 validation batches once process validation had completed in November 2014;⁵⁹¹ and

⁵⁸³ Document 300526, email from [X] to [Waymade Employee] dated 1 June 2015. See also Document 301975, email from [X] to [Waymade Employee] dated 15 May 2015; Document 301976, email from [X] to [X] dated 15 May 2015; Document 301980, minutes of Waymade Product Quality Management Meeting on 26 May 2015; and Document 301982, minutes of Aesica and Waymade call on 28 May 2015.

⁵⁸⁴ Document 302014, email from [X] to [Waymade Employee] dated 6 July 2015. See also Document 300532, email from [X] to [X] dated 1 July 2015; and Document 301999, email from [Waymade Employee] to [Waymade Senior Employee 2], [X] and [Waymade Senior Employee 4] dated 22 June 2015. See also Document 302008, Aesica invoice to Waymade dated 1 July 2015.

⁵⁸⁵ Document 301751, email from [X] to [Waymade Employee] and others dated 15 April 2014.

⁵⁸⁶ Document 301819, email from [X] to [Waymade Employee] dated 16 July 2014; and Document 301823, emails between [X] and [Waymade Employee] dated 29 July 2014.

⁵⁸⁷ Document 301821, email from [Aesica Employee] to [Waymade Employee] dated 29 July 2014; and Document 200292, paragraph 6.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

⁵⁸⁸ A CoA states whether a batch has passed or failed process validation and provides a summary of results from the process. See Document 302539, transcript of [Aesica Employee] interview dated 30 October 2018, page 50, lines 1230 to 1238.

⁵⁸⁹ Document 301843, email chain between [X] and [Waymade Employee] dated 17 September 2014.

⁵⁹⁰ Document 301843, email from [X] to [Waymade Employee] dated 17 September 2014; Document 300484, emails from [X] to [Waymade Employee] and from [Waymade Employee] to [Aesica Employee] dated 28 October 2014; and Document 301879, email from [Waymade Employee] to [Aesica Employee] dated 25 November 2014.

⁵⁹¹ Document 300513, email from [X] to [Waymade Employee] dated 11 February 2015.

- f. a non-compliance issue raised with the hydrocortisone API used in the August 2014 validation batches in March 2015.⁵⁹²

3.394. However, by 6 July 2015 Waymade was once more ready to launch its 20mg hydrocortisone tablets, now with the revised modified pre-gelatinised starch formulation.

d. Waymade enters the market in July 2015

3.395. In July 2015, Waymade entered the market with the packed August 2014 validation batches.^{593, 594}

3.396. In its first month of sales, Waymade sold 1,293 bottles of Aesica-manufactured 20mg hydrocortisone tablets – 26% of all UK 20mg hydrocortisone tablet sales that month. For the period from market entry until the end of 2015, Waymade obtained a 30% volume share of the UK's 20mg hydrocortisone tablet sales.⁵⁹⁵

3.397. After Waymade entered with its own 20mg product it attempted to continue extracting payments from Auden under the Buyback. On 25 May 2015 and on 22 June 2015, Waymade sent Auden two further invoices for the Buyback packs, both totalling £65,794.00 for 982 packs at £67.00 per pack.⁵⁹⁶ However, Auden did not comply. Waymade did not receive payment for these invoices.⁵⁹⁷

3.398. [Waymade Senior Employee 4]'s note from a 9 October 2015 board meeting recorded that sales of 20mg hydrocortisone tablets had been the '*main*

⁵⁹² Document 300521, email from [REDACTED] to [Waymade Employee] dated 25 March 2015 and its attachments Document 300522 and Document 300523, Sanofi information letters dated 4 and 16 March 2015. Aesica found that the August 2014 validation batches were not affected by the issue raised in Sanofi's information letters dated 4 and 16 March 2015, see Document 301975, email from [REDACTED] to [REDACTED], [Waymade Employee] and [REDACTED] dated 11 May 2015.

⁵⁹³ Document 200003, paragraph 1.3, Waymade's response to the CMA's section 26 notice dated 5 May 2016. See also Document 300907, email from [REDACTED] to [Waymade Senior Employee 4] dated 20 July 2015; Document 200292, paragraph 6.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016; Document 300909, Minutes of Waymade Product Quality Management Meeting, 20 July 2015, page 3: '*Hydrocortisone 20mg Tablets to be released ready for sale before 1st August*'; Document 300917, email from [Waymade Senior Employee 4] to [REDACTED] (DE Pharma) dated 16 August 2015: '*The Hydrocortisone 20mg 30's are new Sovereign livery this month*'.

⁵⁹⁴ In light of this, Auden considered that it '*may need to reconsider our current £78 pricing before we loose [sic] business to Sovereign*' – see Document 02306, email from [Auden Senior Employee 4] to [Actavis Senior Employee 3] and [REDACTED] dated 22 July 2015.

⁵⁹⁵ CMA analysis based on data submitted by Actavis (Document 00676) and by Waymade (Document 200345).

⁵⁹⁶ Document 300583, Waymade invoice to Auden dated 25 May 2015 and Document 300563, Waymade invoice to Auden dated 22 June 2015.

⁵⁹⁷ See Document 200345, Waymade's hydrocortisone tablet sales data provided to the CMA.

contributor to Waymade's Sovereign Generics business, adding that *'that could change if and when a 3rd supplier comes to the market.'*⁵⁹⁸

3.399. On 12 January 2016, [Waymade Senior Employee 4] informed [Waymade Senior Employee 1] that the full-line wholesaler *'Alliance would be willing to list our 20mg [hydrocortisone tablets].'*⁵⁹⁹

III. Facts relevant to the 10mg Agreement

a. Waymade develops its own 10mg hydrocortisone tablets

3.400. In summary:

- a. From 2008 onwards Waymade developed its own 10mg hydrocortisone tablets alongside its 20mg tablets. It planned to obtain a 10mg MA as a line extension from its existing 20mg MA.
- b. Aesica manufactured batches of 10mg tablets for Waymade in June 2009 and July 2010. By October 2010 Aesica had completed process validation allowing it to produce future batches on a routine basis.
- c. However, Waymade did not order any further 10mg tablets for it to be in a position where it was ready to launch. Instead, Waymade focused on obtaining its 10mg MA.

3.401. In 2008, in addition to developing its own 20mg hydrocortisone tablets, Waymade also decided to obtain an MA for 10mg hydrocortisone tablets as a result of the larger demand for this strength over 20mg and because it considered it advantageous to be able to offer both strengths.⁶⁰⁰ Waymade planned to develop its 10mg hydrocortisone tablets as a line extension of its existing 20mg MA.⁶⁰¹

⁵⁹⁸ Document 300923, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 4] dated 9 October 2015, page 2. See also Document 300926, email from [Waymade Senior Employee 4] to [X] dated 14 October 2015: *'we cannot rely on Hydrocortisone 20mg to carry the whole range.'*

⁵⁹⁹ Document 300935, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 1] dated 12 January 2016.

⁶⁰⁰ Document 200003, responses to questions 1 and 10, paragraphs 1.5 and 10.3, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁶⁰¹ Document 300094, Project brief dated 17 August 2010, page 1. See also Document 300685, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Employee], [X] and others dated 17 May 2010; Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 61, lines 20 to 23; Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 9, lines 25 to 27; and Document 200026, email from [X] to [Amdipharm Senior Employee] dated 29 October 2008, *'No significant manufacturing or quality issues are foreseen for the suggested change in the formulation of the Hyrocotistab 20mg Tablet to a 10mg Tablet formulation'.*

- 3.402. Waymade regarded its development of both strengths of hydrocortisone tablets as a high priority.⁶⁰² However, [Amdipharm Senior Employee] noted that *‘while the 20mg is important, obtaining a licence for a 10mg strength is the major objective.’*⁶⁰³
- 3.403. In June 2009, Aesica manufactured development batches of 10mg hydrocortisone tablets.⁶⁰⁴ A ‘development batch’ (also known as an ‘engineering batch’ or, when not containing any active agreement, a ‘placebo batch’) refers to a batch of tablets produced as ‘proof of concept’ for a manufacturing process. Unlike a validation batch, development batches cannot be sold.⁶⁰⁵
- 3.404. Aesica identified dissolution and disintegration issues with the June 2009 10mg development batches.⁶⁰⁶ In early April 2010, Waymade commissioned the pharmaceutical research firm R5⁶⁰⁷ via Aesica to find a solution.⁶⁰⁸ By late April 2010, Aesica and R5 found that the most immediate and reliable solution was to amend the formulation by replacing maize with pre-gelatinised starch.⁶⁰⁹
- 3.405. In July 2010, Aesica manufactured further batches of 10mg hydrocortisone tablets for process validation (the **‘July 2010 10mg Validation Batches’**).⁶¹⁰ As explained above, a ‘validation batch’ refers to a batch of tablets produced for process validation, a mandatory step in drug development in which the manufacturer must provide *‘scientific evidence that the manufacturing process is capable of producing consistently good product at the intended*

⁶⁰² See, for example, Document 300124, Sovereign Generics Key Technical Transfer and Support Projects, attachment to Document 300123, email from [§] to [Waymade Senior Employee 2] and [§] dated 24 November 2010; Document 300038, email from [Waymade Senior Employee 1] to [§] dated 9 April 2010; Document 300152, email from [Waymade Senior Employee 3] to [Waymade Employee] dated 24 February 2011; Document 300039, email from [§] to [§] and [§] dated 9 April 2010; Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 21, line 25 to page 22, line 1; page 27, lines 3 to 23; page 28, lines 1 to 4.

⁶⁰³ Document 300038, email from [Amdipharm Senior Employee] to [§] dated 8 April 2010.

⁶⁰⁴ Batch 6002397 (406,061 tablets), batch 6002616 (490,512 tablets) and batch 6005537 (482,124 tablets).

These batches were destroyed in October 2012 at the request of Waymade because the shelf life had long expired: Document 200302, paragraphs 2.1 to 2.11, Aesica’s response to the CMA’s section 26 notice dated 5 September 2016; Document 200300, transaction history of June 2009 10mg development batches attached as Annex 8 to Document 200302, Aesica’s response to the CMA’s section 26 notice dated 5 September 2016.

⁶⁰⁵ Document 301329, note of call with Aesica dated 20 March 2018, paragraphs 23 to 24.

⁶⁰⁶ Document 200292, paragraph 5.1, Aesica’s response to the CMA’s section 26 notice dated 15 June 2016.

⁶⁰⁷ R5 had a small-scale manufacturing facility for new product development. See Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 10, lines 21 to 25; page 11, lines 4 to 11; page 19, lines 4 to 23.

⁶⁰⁸ Document 300039, emails from [§] to [§], [Aesica Employee] and others dated 8 April 2010; and emails from [§] to [§], [Aesica Employee], [§] and others dated 9 April 2010.

⁶⁰⁹ Document 300686, emails from [Aesica Employee] to [§], [§] and others dated 29 April 2010; and emails from [§] to [Waymade Senior Employee 3], [§] and [§] dated 4 May 2010.

⁶¹⁰ Batch 6010448 (478,307 tablets), batch 6010449 (459,648 tablets) and batch 6010450 (486,085 tablets). These batches were destroyed in February 2015 at the request of Waymade because the shelf life had long expired. Document 200302, paragraphs 2.1 to 2.11, Aesica’s response to the CMA’s section 26 notice dated 5 September 2016; Document 300291, email from [Waymade Employee] to [§] dated 25 September 2012; and Document 200309, transaction history of July 2010 10mg Validation Batches attached as Annex 9 to 200302, Aesica’s response to the CMA’s section 26 notice dated 5 September 2016.

commercial scale'. Unlike development batches, successful validation batches can be subsequently sold.⁶¹¹

- 3.406. The June 2009 10mg development batches and the July 2010 10mg Validation Batches were the only batches of 10mg hydrocortisone tablets that Aesica manufactured for Waymade.⁶¹²
- 3.407. By 28 October 2010, Aesica successfully completed process validation for Waymade's 10mg hydrocortisone tablets,⁶¹³ allowing it to '*produce and release future hydrocortisone 10mg tablets [...] on a routine basis*' and generating the relevant data for Waymade's MA application to the MHRA.⁶¹⁴
- 3.408. Aesica told the CMA that it '*would likely not have needed to take further steps before it could supply to Waymade, but for the fact Waymade had not yet been granted a MA for the product. Before Aesica could start supply, it therefore had to work with Waymade to complete a successful application to the MHRA for the grant of a MA*'.⁶¹⁵ Aesica has confirmed that the July 2010 10mg Validation Batches were the same in terms of '*drug substance, composition, specification (including quality) and stability*' as the subsequent batches with which AMCo eventually entered the market in 2016.⁶¹⁶
- 3.409. Aesica did not, however, receive a purchase order from Waymade requesting to be supplied with any product from the July 2010 10mg Validation Batches.⁶¹⁷ Aesica never supplied Waymade with any 10mg hydrocortisone tablets.⁶¹⁸ More than two years later, Waymade's internal record of its MAs from 2012/13⁶¹⁹ listed its 10mg hydrocortisone tablets as '*Not marketed*', meaning '*No plans to market*' (as opposed to '*Not currently*

⁶¹¹ See Document 301329, note of call with Aesica dated 20 March 2018, paragraphs 21 to 24 and 29 to 32; Document 302483, transcript of [Aesica Employee] interview dated 31 October 2018, page 61, line 3 to page 62, line 8; Document 302539, transcript of [Aesica Employee] interview dated 30 October 2018, page 19, lines 449 to 454.

⁶¹² Document 200302, paragraph 2.1, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

⁶¹³ Document 200302, paragraphs 2.1 to 2.11, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

⁶¹⁴ Document 200292, paragraph 5.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016; Document 200297, 10mg validation summary report dated 28 October 2010 attached as Annex 5 to Document 200292, Aesica's response to the CMA's section 26 notice dated 15 June 2016; and Document 200302, paragraph 1.2, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

⁶¹⁵ Document 200302, paragraph 1.3, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

⁶¹⁶ Document 200302, paragraph 5.1, Aesica's response to the CMA's section 26 notice dated 5 September 2016. See also Document 300121, email from [X] to [Waymade Senior Employee 3], [X], [X] and others dated 11 November 2010: '*I have just received the comparative dissolution results from Aesica for the 10mg tablets [...] All the Aesica 10mg batches give the fastest dissolution compared to MSD and Auden Mckenzie*'.⁶¹⁷

⁶¹⁷ Document 200292, paragraphs 5.1 to 5.2, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

⁶¹⁸ Document 200292, paragraph 4.2, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

⁶¹⁹ According to metadata, the spreadsheet was first created in 2012 and last edited on 18 March 2013.

marketed', meaning '*Plans to launch/re-launch following resolution of issues*').⁶²⁰

3.410. At Waymade's request, Aesica destroyed the June 2009 10mg development batches and the July 2010 10mg Validation Batches on 16 October 2012 and 14 February 2015, respectively, because their shelf life (12 months for those stored in bulk, and 18 months for those stored in blister packaging) had expired by December 2010 and January 2012, respectively.⁶²¹

3.411. Instead of obtaining market-ready 10mg tablets, Waymade focused on obtaining its 10mg MA.

b. Waymade becomes aware of the orphan designation granted to Plenadren

3.412. In summary:

- a. Waymade became aware of the orphan designation granted to Plenadren in March 2012, during correspondence with the MHRA to obtain its 10mg MA. The MHRA informed Waymade that this meant it could not be granted a full label MA.
- b. After some initial internal discussion, at the direction of [Waymade Senior Employee 1], Waymade chose not to challenge the MHRA's decision. This was consistent with its approach to the MA application process, during which Waymade opted not to challenge the MHRA on its proposals to narrow the specifications on the MA.

3.413. On 9 June 2011, Waymade submitted its 10mg MA application to the MHRA.⁶²² In contrast to its approach to obtaining market-ready 10mg tablets, Waymade pursued its MA application with urgency, at the most senior levels.⁶²³

⁶²⁰ Document 300340, 120111 Licence Master – Sovereign.

⁶²¹ Document 200302, paragraphs 2.2 and 2.5 to 2.11, Aesica's response to the CMA's section 26 notice dated 5 September 2016; and Document 200292, paragraph 5.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016. Aesica was unable to explain why the July 2010 10mg Validation Batches were not destroyed until February 2015, see Document 200302, paragraph 2.11, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

⁶²² Document 300185, email from [Waymade Employee] to [Waymade Senior Employee 1], [Amdipharm Senior Employee], [Waymade Senior Employee 3] and others dated 9 June 2011. See also Document 300184, Email from [Waymade Senior Employee 3] to [REDACTED], [Waymade Senior Employee 2], [Waymade Employee], [Waymade Employee], [REDACTED], [REDACTED], [REDACTED], [REDACTED] and [Waymade Employee], dated 6 June 2011 and Document 300180, Monthly Report Sovereign Medical April 2011, attached to Document 300179, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] and others dated 11 May 2011, page 2.

⁶²³ In June 2012, [Waymade Employee] and [Waymade Employee] emphasised to the MHRA that Waymade's 10mg hydrocortisone tablet development was an '*important project*', a '*commercially sensitive product*' and, highlighting that Waymade's '*senior management [were] anxious to finalise [Waymade's] application*', requested

- 3.414. On 15 March 2012, as part of correspondence relating to its 10mg MA application, Waymade was informed by the MHRA that *'hydrocortisone [had] recently been designated as an Orphan medicinal product'*.⁶²⁴
- 3.415. In April 2012 the MHRA informed Waymade that the *'hydrocortisone tablet subject of this application is considered to be similar to the orphan product Plenadren'* and therefore *'cannot claim the indication of Plenadren (adrenal insufficiency)'*, concluding that *'for the assessment of this application to continue, the marketing exclusivity indication of adrenal insufficiency should be deleted'*.⁶²⁵
- 3.416. Waymade considered the option to simply *'delete the indication for "adrenal deficiency"'* to remove the *'orphan drug issue'* and *'fast-track'* the application with the MHRA,⁶²⁶ but instead initially opted to challenge the MHRA's assessment of the orphan designation.⁶²⁷
- 3.417. Waymade submitted to the MHRA that the indication for adrenal insufficiency should not be deleted from its 10mg MA application, with the caveat that it would remove the indication from its application should the Commission on Human Medicines (**'CHM'**) disagree with its challenge at a hearing Waymade understood would be held to arbitrate the issue on 14 June 2012.⁶²⁸
- 3.418. The MHRA did not present Waymade's submission to the CHM.⁶²⁹ On 13 July 2012, the MHRA explained that a CHM consultation would be *'inappropriate'* as there were no *'clinical/scientific objections outstanding'* for Waymade's 10mg hydrocortisone tablet MA application. The MHRA again informed Waymade its *'proposed hydrocortisone tablet products are*

the MHRA to assist by *'expediting'* Waymade's MA application. [Waymade Senior Employee 1] provided instructions to *'rush the license through'* to [Waymade Employee], who kept [Waymade Senior Employee 1] closely updated on the status of the MA application. See Document 300253, email from [Waymade Employee] to [REDACTED] dated 11 June 2012; Document 300243, email from [REDACTED] to [REDACTED] dated 18 June 2012; Document 300285, email from [Waymade Employee] to [REDACTED] dated 20 September 2012; Document 300276, email from [Waymade Employee] to [Waymade Senior Employee 1] dated 14 August 2012; Document 300278, email from [Waymade Employee] to [Waymade Senior Employee 1] dated 4 September 2012; Document 300282, email from [Waymade Employee] to [Waymade Senior Employee 1] dated 14 September 2012; Document 300284, email from [Waymade Employee] to [Waymade Senior Employee 1] copied to [Amdipharm Senior Employee] dated 18 September 2012; and Document 300288, email from [REDACTED] to [Waymade Employee] dated 24 September 2012.

⁶²⁴ Document 300223, email from [REDACTED] to [Waymade Employee] dated 15 March 2012.

⁶²⁵ Document 300227, the MHRA RFI dated 5 April 2012.

⁶²⁶ Document 300226, email from [Waymade Employee] to [Waymade Senior Employee 1] dated 10 April 2012.

⁶²⁷ Document 300248, Waymade's response to MHRA RFI dated 24 April 2012.

⁶²⁸ Document 300248, Waymade's response to MHRA RFI dated 24 April 2012. See also Document 301565, May 2012 Monthly Report Regulatory Affairs Department, page 7.

⁶²⁹ Document 300243, emails [REDACTED] to [REDACTED] dated 29 June 2012 confirming that the decision on the implication of the orphan designation would *'not [...] be made at the CHM'* but at the MHRA.

*considered to be similar to the orphan product Plenadren’ and therefore ‘cannot claim the indication for adrenal insufficiency’.*⁶³⁰

- 3.419. Waymade decided not to challenge this decision. Although on 13 July 2012 Waymade’s regulatory team prepared correspondence challenging the MHRA’s decision, they were directed by [Waymade Senior Employee 1] to *‘not [...] write anything re envisaging legally at this stage’* as Waymade could accept the *‘license as it is now’* without *‘giving up any rights to go back’* and challenge the MHRA’s decision at a later date.⁶³¹ [Waymade Senior Employee 1] warned that *‘any legal threats and they will shy away and put it [Waymade’s 10mg MA application] in a SPIN FOR YEARS IS THAT CLEAR’.*⁶³² [Waymade Employee] confirmed to [Waymade Senior Employee 1] that Waymade’s regulatory team would *‘send [...] a polite email’* to the MHRA *‘accept[ing] the MA without the indication and fight this on another day’.*⁶³³
- 3.420. This direction not to challenge the orphan designation, despite Waymade’s internal reservations about its validity, was consistent with Waymade’s approach to the MA application process, which prioritised obtaining the MA over improving details such as the shelf life and ‘assay limits’ the MHRA would authorise.⁶³⁴ For example:
- a. In response to an internal Waymade discussion over the shelf life the MHRA proposed to grant to the packaging types included on the MA (bottles and blister packs), [Waymade Senior Employee 1] instructed [Waymade Employee] on 11 April 2012, *‘...at the moment do no delay*

⁶³⁰ Document 300274, email from [REDACTED] to [Waymade Employee] dated 13 July 2012. See also Document 300253, email from [Waymade Employee] to [REDACTED] dated 11 June 2012: [Waymade Employee] requested the MHRA to communicate the outcome of 12 June 2012 CHM hearing as early as possible. See also Document 300243, emails between [REDACTED] and [REDACTED] dated 18, 20, 28 and 29 June 2012 in which Waymade and the MHRA communicate over how a decision on the inclusion or exclusion of the indication would be reached.

⁶³¹ Document 300271, emails between [Waymade Employee] and [Waymade Senior Employee 1] dated 13 July 2012.

⁶³² Document 300267, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 13 July 2012 (emphasis in the original).

⁶³³ Document 300274, email from [Waymade Employee] to [Waymade Senior Employee 1] copied to [Amdipharm Senior Employee] dated 13 July 2012.

⁶³⁴ An assay is a qualitative or quantitative analysis of a pharmaceutical product to determine the strength or quality of its components. The assay limits establish the maximum acceptable deviation in the active substance content of the finished product. These are set by the marketing authorisation applicant such that the specifications proposed at the end of shelf life are guaranteed. Under Module 3 of Part 1 of Annex 1 to Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, the maximum acceptable deviation in the active substance content of the finished product shall not exceed $\pm 5\%$ at the time of manufacture, unless there is appropriate justification (see <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:02001L0083-20190726>).

anything With changes just accept what they say just rush the license through [sic]'.⁶³⁵

- b. While Waymade initially proposed an assay limit range of 90 to 105%, the MHRA proposed a narrower range of 95-105%. On 20 April 2012, [Aesica Employee] highlighted a '*significant risk of batch failure either on production or during stability testing*' with this narrower range. [Waymade Employee] indicated that Waymade was prepared to accept this risk in order to obtain the MHRA's approval and would re-visit the issue '*post approval*'.⁶³⁶
- c. On 16 July 2012, [Amdipharm Senior Employee] and [Waymade Employee] discussed whether Waymade would '*need to vary the MA when granted to facilitate marketing*'.⁶³⁷ [Waymade Employee] commented that '*the assay limits are tight for shelf-life. Release is not a problem. When we tried to extend them, twice the assessor rejected it. We decided at the time not to argue it without having more data but to get the MA instead*'. Ultimately, [Waymade Employee] considered that, after being granted the MA, Waymade could '*launch the product at risk and variation the MA limits for shelf-life but the QP [Qualified Person] probably won't release it. This is the only issue I can see at the moment preventing us from launch*'.⁶³⁸

3.421. Ultimately, Waymade realised that the assay method had to be optimised to improve the testing method's accuracy in producing stability data ('*[t]he problem is the assay method not the product*').⁶³⁹ By the end of July 2012, Waymade commissioned DSG Biotec GmbH ('**DSG**') to '*develop a method for the assay of Hydrocortisone, validate it and transfer it to Aesica Queensborough in the UK*' since the '*assay used gives assay results that are typically 4% low*'.⁶⁴⁰

⁶³⁵ Document 300228, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 11 April 2012 (emphasis added). See also Document 300242, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 26 June 2012, subject line reads '*hav e [sic] you heard from MHRA re Hydrocortisone tabs license*'.

⁶³⁶ Document 300232, emails between [Aesica Employee], [X] and [Waymade Employee] dated 20 April 2012. See also Document 300288, email from [Waymade Employee] to [X], [X], [X], [X], [Waymade Employee], [X] and [X] dated 10 April 2012.

⁶³⁷ Document 202227, email from [Amdipharm Senior Employee] to [Waymade Employee] dated 16 July 2012.

⁶³⁸ Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012 (emphasis added).

⁶³⁹ Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012.

⁶⁴⁰ Document 202238, email from [X] to [X] dated 27 July 2012. See also Document 301612, Amdipharm's Product Manufacturing Monthly Report for September 2012, page 4. It reported that '*DSG have been commissioned to improve the Hydrocortisone assay method to eliminate the low assay results that are causing the assay on stability being borderline above 95%. Aesica are to supply samples to DSG to complete Hydrocortisone assay improvement process [...] Amdipharm and Aesica QPs need to agree shelf life / release conditions*'.

c. Waymade obtains its 10mg MA

- 3.422. On 24 September 2012, the MHRA informed Waymade that its 10mg MA application was ‘satisfactory’ and there were ‘no outstanding issues’ precluding the grant of the MA expected that week.⁶⁴¹
- 3.423. On 27 September 2012, the MHRA granted an MA for 10mg hydrocortisone tablets to Waymade plc which did not include the indication ‘adrenal insufficiency in adults’.⁶⁴² Waymade plc was granted a ‘skinny label’ 10mg MA (despite that MA being a line extension of its existing full label 20mg MA). [Waymade Employee] reported internally: ‘new Marketing Authorisation has been approved [...] New products can be implemented at our own discretion [...] Quality: - Product manufactured at Aesica according to registered details can now be released [...] Sovereign: - Product manufactured at Aesica according to registered details can now be released for sale’.⁶⁴³

d. Waymade enters into a supply agreement with Auden for 10mg hydrocortisone tablets

- 3.424. The supply deal that Waymade had entered into with Auden in July 2011 included 10mg hydrocortisone tablets as well as 20mg. However, while Waymade secured an 87% discount to market rate for 20mg tablets, Auden charged Waymade market rate for 10mg tablets.
- 3.425. From July 2011 until 30 September 2012, Auden supplied Waymade with 10mg hydrocortisone tablets at roughly the prevailing market price range of between £31.50 to £34.50 per pack.⁶⁴⁴ The quantities available under this supply arrangement were approximately 1,500 packs per month, with a one-off delivery of 3,120 packs in July 2011.⁶⁴⁵

⁶⁴¹ Document 300288, email from [§] to [Waymade Employee] dated 24 September 2012.

⁶⁴² PL 06464/2876. Waymade had applied to MHRA for the MA on 13 June 2011 (Document 00444, paragraph 1.6, AMCo’s response to the CMA’s section 26 notice dated 15 April 2016). Aesica submitted to the CMA that ‘Aesica was therefore only in the position to supply Waymade 10mg hydrocortisone tablets for sale in the UK from this date.’ Document 200302, paragraph 1.7, Aesica’s response to CMA’s section 26 Notice dated 25 August 2016. See also Document 301607, email from [Waymade Employee] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [Waymade Senior Employee 1], [Waymade Employee] and others dated 27 September 2012.

⁶⁴³ Document 202298, email from [Waymade Employee] to Waymade staff dated 27 September 2012.

⁶⁴⁴ Document 200003, paragraph 11.6, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016.

⁶⁴⁵ Document 200010_Annex 12 to Waymade’s response to the CMA’s section 26 notice dated 5 May 2016. See also Document 300189, email from [Auden Senior Employee 2] to [Waymade Senior Employee 4] and [Amdipharm Senior Employee] dated 5 July 2011: ‘[§] thought the 10mg volume was a little on the high side but I have persuaded him to honour the initial order and well discuss next month once you’ve had a chance to assess the market from your side’; Document 300749, email from [Waymade Senior Employee 4] to [§] dated 25 August 2011: ‘We have had our order for 3100 packs restricted to 900 as they say they are short of stock. Not sure if this is just being applied to us or its in general [...]’; and Document 301313, transcript of [Waymade Senior

3.426. Having obtained its 10mg MA on 27 September 2012, Waymade entered into discussions with Auden with a view to agreeing a new 10mg supply deal on the same basis as the 20mg supply deal:

a. [Amdipharm Senior Employee] explained to the CMA that:

'Once Waymade was granted the reduced indication 10mg licence in September 2012, Waymade looked to get a better supply price from Auden Mckenzie ... I was involved in representing Waymade in these negotiations in late 2012'.⁶⁴⁶

b. [Amdipharm Senior Employee] further explained that the supply deal between Auden and Waymade *'started with the 20mg, then became the 10mg. We added the 10mg to that.'*

'we approached Auden Mckenzie and asked them if they would be willing to supply us ... and we did that first with the 20mg and then later when we had the 10mg licence with that also ... that started with the 20mg, then became the 10mg. We added the 10mg to that ... That was around the time that Amdipharm was being sold to Cinven.'⁶⁴⁷

[Amdipharm Senior Employee] stated that Waymade's goal was to 'do the same deal with Auden Mckenzie on the 10mg that we had with the 20mg'.⁶⁴⁸

3.427. In October 2012 Auden and Waymade entered into a further agreement, relating to 10mg hydrocortisone tablets. From October 2012, Auden reduced its supply price to Waymade for 10mg hydrocortisone tablets to £1 per pack,⁶⁴⁹ while its monthly ASP to all of its other customers remained at £31.55 per pack in October 2012. The £1 price applied to a maximum volume of 2,000 packs of 10mg tablets (Waymade obtained additional tablets at market rate).⁶⁵⁰

Employee 4] interview dated 28 March 2018, part 3, page 2, line 27; page 3, lines 1 to 4, 8, and 12 to 13: *'...history will show us that we had a one-off delivery in the very beginning [...] it was three thousand and something. And then [Auden Senior Employee 2] was going to set the limit because he thought that was a bit high [...] and he was going to set the limit in the future, which transpired to be 1,500 [...] that they would allow us to have'; 'It was only the first lot that ever came in that was 3,000. From there onwards it was determined that our allowance would be 1,500. [...] I could have sold 3,000'.*

⁶⁴⁶ Document 200354, Witness statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraphs 1.19 and 1.22.

⁶⁴⁷ Document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 11 lines 20-24 and page 12 lines 1-4.

⁶⁴⁸ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 15 lines 7-12.

⁶⁴⁹ Effective price following the grant of rebates. See Document 200003, paragraph 11.6, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁶⁵⁰ Document 200010, data supplied by Waymade on its purchases of hydrocortisone tablets from Auden.

3.428. The first order for these new 10mg supplies was placed on 23 October 2012.⁶⁵¹

3.429. The price listed for the 2,000 packs on the order was £34.50 per pack – the price Waymade had paid Auden to date. However, the CMA concludes that by 23 October 2012 Auden and Waymade had agreed that the supply price for the 2,000 monthly packs of 10mg tablets would be heavily discounted. On the corresponding invoice issued by Auden, the price was circled and a handwritten note added: ‘Await credit note [Waymade Senior Employee 4]’.⁶⁵² This indicates that Auden would issue a rebate to reduce the net price. [Amdipharm Senior Employee] stated in interview with CMA officials:

*‘At the start of the process Auden Mckenzie had been invoicing – it would have been Waymade at the time before the licence came across [to Amdipharm: see next section]. Auden Mckenzie had been invoicing at a high price and then rebating back to the agreed net price. We had agreed a price of a cost of goods of £1*⁶⁵³

*‘My recollection is that that was a request from Auden that they invoice at that price and then rebate it back to us. I think my assumption at the time would have been that Auden wanted to maximise their sales revenue. By invoicing to us at the high price, that gave them a bigger top-line sales figure.’*⁶⁵⁴

3.430. The rebate applied to orders beginning with the order on 23 October:

- a. The evidence shows that a new deal was struck between Waymade and Auden in October 2012. As explained above, the data provided to the CMA by Waymade shows that between July 2011 and September 2012, Waymade obtained an average of 1,500 packs of 10mg hydrocortisone tablets per month from Auden, at market rate. In October 2012, Waymade bought its usual 1,500 packs at market rate – plus this additional order for 2,000 packs.⁶⁵⁵ Data provided by Auden confirms that it began supplying 2,000 packs per month in October 2012.⁶⁵⁶ The data Waymade provided shows that in October 2012 Waymade obtained 3,500 packs of 10mg hydrocortisone tablets from

⁶⁵¹ Document 300321, email from [Waymade Senior Employee 4] to [Auden Senior Employee 1] dated 23 October 2012; document 300322, purchase order attached to document 300321.

⁶⁵² Document 300645, invoice dated 23 October 2012.

⁶⁵³ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 18 lines 22-27 and page 19 line 1 (emphasis added).

⁶⁵⁴ Document 200349, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 12 lines 1-5.

⁶⁵⁵ Document 200010, data supplied by Waymade on its purchases of hydrocortisone tablets from Auden.

⁶⁵⁶ Document 00674, data provided by Auden on its sales of hydrocortisone tablets to Waymade and AMCo.

Auden at a total cost of £53,750:⁶⁵⁷ indicating that it obtained its usual 1,500 packs at £34.50, and the additional 2,000 packs were therefore supplied at £1 per pack.

- b. The negotiations leading to that deal were premised on Waymade using its 10mg MA to extract a heavily discounted supply price, roughly equivalent to its cost of goods from Aesica: approximately **[£1-£4]** per pack. [Amdipharm Senior Employee] stated in interview: *'To get the price that we got, of £1 ... I would have been looking to get a price that approximated to what my cost of goods would be had I purchased the product from Aesica'*.⁶⁵⁸ This had also been Waymade's strategy when negotiating the 20mg supply deal, when it asked Auden to supply it *'at cogs'*.⁶⁵⁹ The 10mg cost of goods from Aesica was approximately **[£1-£4]** per pack.⁶⁶⁰
- c. Waymade informed the CMA that *'For a short period prior to its sale in October 2012, Amdipharm [UK Limited] acquired 10mg hydrocortisone tablets from Auden Mckenzie at an effective price of £1, following the grant of rebates'*; and that *'from the period just prior to Waymade's sale of Amdipharm to [Cinven] until the end of 2012, Amdipharm acquired 10mg hydrocortisone tablets for an effective price of £1. Under this arrangement, Auden Mckenzie would supply products to Amdipharm at £38 per pack and then Auden Mckenzie would issue a rebate to Amdipharm for £37 per pack.'*⁶⁶¹
- d. A hard-copy document recovered by the CMA during its inspection at Waymade's premises lists Waymade's orders of 10mg hydrocortisone tablets from Auden between October 2010 and January 2013. It shows that Waymade began ordering 2,000 packs per month on 26 October 2012, the date of this first order, which is given a 'Stock value' of £69,000. A handwritten asterisk has been added next to each order from 26 October 2012 onwards.⁶⁶² Read in conjunction with [Waymade Senior Employee 4]'s handwritten annotation to the 23 October invoice for the 2,000 packs supplied to Waymade on 26 October discussed above, this indicates that the rebate applied from this date onwards.

⁶⁵⁷ Document 200010, data supplied by Waymade on its purchases of hydrocortisone tablets from Auden.

⁶⁵⁸ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 12 line 27 and page 13 lines 1-6.

⁶⁵⁹ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

⁶⁶⁰ Document 300303, email from [X] to [Waymade Senior Employee 1] dated 1 October 2012: *'We have a COGs for Hydrocortisone 10mg tablets 1 x 30 blister pack of **[£1-£4]**. This is from early 2009.'*

⁶⁶¹ Document 200003, Waymade's response to the CMA's section 26 notice dated 27 May 2016, paragraphs 11.6 and 13.2 (emphasis added).

⁶⁶² Document 300646, hand-annotated list of Waymade's 10mg hydrocortisone tablets orders from Auden.

- 3.431. It is therefore clear that by 23 October 2012 the parties had agreed on a heavily discounted price for 2,000 packs per month.
- 3.432. As explained in section 6.C.II.c.ii below, the CMA has found that in exchange, Waymade agreed not to enter the market with its 10mg hydrocortisone tablets.

i. The roles of Amdipharm UK Limited and Waymade plc within the Waymade undertaking

- 3.433. Two legal entities within the Waymade undertaking – the sister companies Amdipharm UK Limited and Waymade plc, [REDACTED] (see figure 3.2 above) – were involved in concluding and implementing this new 10mg supply deal:
- a. As explained above, [Amdipharm Senior Employee] stated in interview: *'I was involved in representing Waymade in these negotiations in late 2012'*.⁶⁶³ [Amdipharm Senior Employee] was an employee of Amdipharm UK Limited [REDACTED].⁶⁶⁴
 - b. The first order under the new 10mg deal was placed by Waymade plc.⁶⁶⁵ The order was sent by [Waymade Senior Employee 4], on the instructions of [Waymade Senior Employee 1]. [REDACTED].⁶⁶⁶ [Waymade Senior Employee 4] specified that the order was *'required on URGENT delivery as per [Waymade Senior Employee 1]'s [sic] request'* (indicating that [Waymade Senior Employee 1] had spoken to [Auden Senior Employee 1] about the order).⁶⁶⁷ Auden fulfilled that order by supplying the first quantity of 2,000 packs to Waymade plc on 26 October 2012 and [Waymade Senior Employee 4] immediately instructed [REDACTED] to sell the packs: *'Extra 2000 available now'*.⁶⁶⁸

⁶⁶³ Document 200354, Witness statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraphs 1.19 and 1.22.

⁶⁶⁴ [Amdipharm Senior Employee] stated in interview that *'At one time or another most of the individual departments within the company [Amdipharm] would have reported through me'* (document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 8 lines 16-18).

⁶⁶⁵ Document 300321, email from [Waymade Senior Employee 4] to [Auden Senior Employee 1] dated 23 October 2012; document 300322, purchase order attached to document 300321. The purchase order was on 'Waymade Healthcare plc' headed paper. Waymade Healthcare plc changed its name to Waymade plc on 12 October (Companies House filings). The header on its purchase orders had yet to be adjusted (there was no other entity named Waymade Healthcare plc at the time).

⁶⁶⁶ Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, response to question 3. Document 302243, structure chart of the Waymade group. Companies House filings.

⁶⁶⁷ Document 300321, email from [Waymade Senior Employee 4] to [Auden Senior Employee 1] dated 23 October 2012. [Waymade Senior Employee 1] instructed [Waymade Senior Employee 4] to place the order an hour earlier, enclosing [Auden Senior Employee 1]'s email address: Document 300320, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 4] dated 23 October 2012.

⁶⁶⁸ Document 300329, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 1] dated 26 October 2012. Document 300328, email from [Waymade Senior Employee 4] to [REDACTED] dated 26 October 2012. [REDACTED] was [REDACTED]. Document 300302, email from [REDACTED] to [Waymade Senior Employee 1] dated 28 September 2012 (as explained above, Waymade plc was named Waymade Healthcare plc until 12 October 2012).

ii. The sale of the Amdipharm group

3.434. By the time the negotiations that led to the 10mg supply deal began, the negotiations for the sale of Waymade's Amdipharm group to Cinven were close to complete. As explained above, [Amdipharm Senior Employee] stated that he had approached Auden to negotiate the 10mg deal *'around the time that Amdipharm was being sold to Cinven.'*⁶⁶⁹ The 10mg MA was to be included in that sale:

- a. Waymade had begun negotiations to sell its Amdipharm group to Cinven in mid-2012, when the process of obtaining its 10mg MA was still ongoing. Waymade issued an information memorandum on the Amdipharm group to Cinven in July 2012. The memorandum identified the prospective 10mg MA as a potential generator of significant revenue for the Amdipharm group. It stated, as part of the *'Organic Growth Case'* for the UK: *'Line extensions offer significant upside. In particular, the development of a Hydrocortisone tablets 10mg x30 SKU provides the opportunity to tap into a market now worth over £30m'.* The relevant slide included a graph showing the volumes of 10mg hydrocortisone tablets and the dramatic increases in the value of sales over the previous four years, following the price increases implemented by Auden.⁶⁷⁰
- b. Once these statements had been made Cinven *'was very insistent on acquiring'* the 10mg MA.⁶⁷¹ Waymade stated: *'That the 10mg MA would be included with the sale of the Amdipharm business was an important point of negotiation during the transaction.'*⁶⁷²

3.435. The agreement for the sale of the Amdipharm group was signed on 13 October 2012.⁶⁷³ On the same day, the beneficial interest in the newly-obtained 10mg MA was transferred intra-group within the Waymade undertaking – from Waymade plc to Amdipharm UK Limited – to ensure that it would be within the Amdipharm group when the sale completed. The legal transfer was to be effected as soon as reasonably practicable (Waymade plc having delivered to Amdipharm UK Limited the required forms duly executed). All associated product knowhow and intellectual property, raw

⁶⁶⁹ Document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 11 lines 20-24 and page 12 lines 1-4.

⁶⁷⁰ Document 202512, slide pack entitled *'PROJECT AMPULE Information memorandum'* dated 6 July 2012, slide 39.

⁶⁷¹ Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016, paragraph 6.1.

⁶⁷² Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, paragraph 5.5.

⁶⁷³ Document 200476, Amdipharm group sale and purchase agreement.

material and finished or partly finished product was also transferred.⁶⁷⁴ The agreement that effected the intra-group transfer (signed for Amdipharm UK Limited by [Waymade Senior Employee 1]) provided that Amdipharm UK Limited would have the exclusive right to sell 10mg hydrocortisone tablets and that Waymade plc would sell 10mg hydrocortisone tablets only as agent of Amdipharm UK Limited.⁶⁷⁵

3.436. From 13 October 2012, therefore, Amdipharm UK Limited held the beneficial interest in Waymade's 10mg MA and sales of 10mg hydrocortisone tablets. Amdipharm UK Limited remained within the Waymade undertaking, [X], until the sale of the Amdipharm group completed on 31 October 2012.

3.437. The sale of the Amdipharm group was publicly announced on 15 October 2012.⁶⁷⁶ In interview, [Amdipharm Senior Employee] stated:

'during the sale process, of course, I didn't say anything to Auden Mckenzie that the company was being sold up until it was in the public domain, but once it became public domain I then had to speak to Auden to say that I was actually going as part of the Amdipharm

⁶⁷⁴ The relevant transfer agreement (document 302245, Annex 4.1(a) to Waymade's response to the CMA's section 26 notice dated 8 October 2018 – see clauses 1.1, 2.1, 5.1 and 5.2.2) was between Waymade UK plc (then known as Waymade plc, company number 03677276, a subsidiary of the company now known as Waymade plc) and Amdipharm UK Limited (then known as Amdipharm plc). The agreement did not explicitly include the 10mg MA in the list of assets to be transferred in Schedule 2. However, Waymade informed the CMA that this omission 'was a simple error, possibly related to the fact that the MA had been granted on 27 September 2012', only shortly before the agreement was signed (document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, paragraph 5.5). Waymade stated that 'the 10mg MA was treated as having been beneficially transferred to Amdipharm [UK Limited] as if it had been listed within Schedule 2 of the [agreement] from 13 October 2012' (document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, paragraph 5.6). No other party disputed this account. These statements are consistent with the contemporaneous evidence. On 18 October 2012 [Amdipharm Senior Employee] sent an email to Waymade and Amdipharm staff attaching 'the list of MAs which will transfer (timetable to be agreed) from Waymade to Amdipharm'. Attached was a table identical to Schedule 2 to the transfer agreement, with the addition of Waymade's MA for 10mg hydrocortisone tablets. Document 302253 and Document 302254, Annexes 5.4(a) and 5.4(b) to Document 302242, email from [Amdipharm Senior Employee] dated 18 October 2012 and attachment. The CMA therefore concludes that the 10mg MA was treated as included in Schedule 2 to the transfer agreement executed on 13 October 2012. This was clearly the intention, as the recitals to the agreement illustrate.

⁶⁷⁵ Document 302245, Annex 4.1(a), asset transfer agreement dated 13 October 2012, clause 5.4. As explained above, the transfer agreement was with Waymade UK plc rather than Waymade plc, but was intended to encompass the 10mg MA previously owned by Waymade plc. Waymade informed the CMA that 'From 13 October 2012 onwards transferring products, including 10mg hydrocortisone, were sold by Waymade [plc] entirely for the benefit of Amdipharm [UK Limited]. In accordance with clause 5.4 of the [intra-group transfer agreement], from 13 October 2012 Waymade [plc] would have purchased and sold 10mg hydrocortisone, including the 10mg Supplies [under the 10mg Agreement], only as agent for, and at the direction of, Amdipharm [UK Limited].' From 13 October 2012, therefore, 'while the mechanics of the purchase and distribution of 10mg hydrocortisone may have been similar, Waymade [plc] acted as agent for Amdipharm [UK Limited] until the 10mg MA could be formally transferred into Amdipharm [UK Limited]'s name.' Document 302242, paragraphs 5.7 and 5.9, Waymade's response to the CMA's section 26 notice dated 8 October 2018.

⁶⁷⁶ www.cinven.com/media/news/121015-cinven-invests-in-amdipharm/.

*business, that I would continue to be in that business and that I was keen for the supply [of 10mg hydrocortisone tablets] to continue*⁶⁷⁷

- 3.438. Once the sale became public, [Amdipharm Senior Employee] therefore informed Auden that going forwards it would continue to deal with [Amdipharm Senior Employee], whose company would have a new owner.
- 3.439. On 31 October 2012 Waymade completed the sale of its Amdipharm group to Cinven. Cinven went on to combine the Amdipharm group with the Mercury Pharma group to create the AMCo group.
- 3.440. Amdipharm UK Limited became part of the AMCo undertaking. [✂],⁶⁷⁸ and Waymade plc acted as agent for Amdipharm UK Limited in relation to the 10mg hydrocortisone tablets it obtained from Auden. [Amdipharm Senior Employee] explained in interviews:

*‘while the 10mg [MA] became beneficially owned by Amdipharm and then Cinven it was still in the legal ownership of Waymade ... So the licence finally came over into Amdipharm’s name [legally] around May 2013, something like that. But from the period of completion through until then, Waymade was selling the product on behalf of Amdipharm, so Waymade would sell the product and then the benefits, the sale proceeds would come across to Amdipharm*⁶⁷⁹

*‘the stock still came into Waymade and Waymade sold it on Amdipharm’s behalf, but the value went to Amdipharm.*⁶⁸⁰

- 3.441. In addition to its obligations under the intra-group transfer agreement, from 31 October 2012 onwards Waymade plc also distributed 10mg hydrocortisone tablets for Amdipharm UK Limited, including pricing orders and invoicing customers in Amdipharm UK Limited’s name and on terms supplied by Amdipharm UK Limited and transferring the proceeds into an Amdipharm UK Limited bank account, pursuant to a supply chain services

⁶⁷⁷ Document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 16 lines 2-8.

⁶⁷⁸ See section 9.B.III.d (*Liability of the Cinven Entities*) below.

⁶⁷⁹ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 17 lines 15-27. See also Document 302140, [Amdipharm Senior Employee] interview transcript dated 7 June 2018, pages 66 line 5 to page 67 line 20. [Waymade Senior Employee 1] explained that after the sale of the Amdipharm group to Cinven, ‘we used to procure everything for them as per their instructions and distribute for them’ (Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 151, lines 21 to 22). [Waymade Senior Employee 4] stated, ‘anything that we were doing on hydrocortisone 10 got transferred in, into them’ (Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 3, page 29, lines 5 to 6).

⁶⁸⁰ Document 302140, [Amdipharm Senior Employee] interview transcript dated 7 June 2018, pages 66 line 5 to page 67 lines 13-20.

agreement. This agreement provided for Waymade plc to provide these services to Amdipharm UK Limited for a period of two years.⁶⁸¹

3.442. As part of Cinven's acquisition of the Amdipharm group, on 31 October 2012 AMCo therefore acquired Waymade's 10mg MA, product development and relevant staff,⁶⁸² and the benefit of the 10mg Agreement.⁶⁸³

e. AMCo succeeds Waymade as counterparty to the 10mg Agreement and negotiates to triple its volumes from Auden

3.443. From 31 October 2012 onwards, Auden continued to supply AMCo with 10mg hydrocortisone tablets at £1 per pack (a 97% discount to market rate).

3.444. As explained in section 6.D.II.c.ii, the CMA has found that in return AMCo agreed not to enter the market with its 10mg hydrocortisone tablets.

3.445. In each of November and December 2012, Auden supplied AMCo (through Waymade) with 2,000 packs of 10mg tablets at £1 per pack.⁶⁸⁴ [Auden

⁶⁸¹ Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, paragraph 5.8. Document 302251, Annex 4.1(g), supply chain services agreement dated 31 October 2012, Schedule 2, part 1, paragraph 2. The term of the agreement was specified in clause 21.1.2.

⁶⁸² The key staff involved in Waymade's 10mg product development who transferred with the Amdipharm group were specified in the SPA (Document 200476, schedule 7 Part B). They included: [Waymade Senior Employee 2]; [Amdipharm Senior Employee]; [Waymade Employee]; [X].

⁶⁸³ Amdipharm Limited also transferred to Cinven's ownership as part of the Amdipharm group on 31 October 2012. Advanz Pharma Services (UK) Limited, the other Amdipharm Company, was originally part of the Mercury Pharma group that Cinven had separately acquired in July 2012. It was renamed Amdipharm Mercury Company Limited in March 2013. The Mercury Pharma group had a pre-existing 10mg hydrocortisone tablets development project with a German CMO called MIBE GmbH Arzneimittel ('MIBE'). See Document 202185, Dossier Licence Agreement between MIBE and Mercury dated 12 June 2012; Document 202186, Supply Agreement between MIBE and Mercury dated 14 June 2012. Mercury and the MIBE development became part of AMCo as a result of Cinven merging the Mercury and Amdipharm groups between 31 October and 31 December 2013. AMCo progressed the MIBE development at points over the following years, but the Aesica project took priority: MIBE was described as *'a back-up project strategy to the Amdipharm product'* (Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8] and others dated 14 January 2014). In January 2014, in parallel with difficulties encountered during negotiations for a formal supply agreement with Auden, as described in section 3.f.iii.f below (see for example, Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8] and others dated 14 January 2014), AMCo submitted an MA application for MIBE-manufactured 10mg hydrocortisone tablets (Document 201761, email from [X] to [AMCo Senior Employee 2] and other AMCo staff dated 15 January 2014), noting a few days later in its [X] Report that the MIBE Development was *'being vigorously pursued'* (Document 202621, [X] Report – December 2013 dated 22 January 2014, page 2).

However, the MHRA invalidated the application on 17 February 2014 (Document 201823, email from [X] (MHRA) to [X] dated 17 February 2014). AMCo continued to correspond with the MHRA until July 2015, when its hydrocortisone development projects were reported to be *'on hold' 'as management are deciding how to proceed with the different hydro opportunities (Aesica development, Mibe and Focus)'* (Document 202810, email from [X] to [X], [AMCo Senior Employee 3] and other AMCo staff dated 7 July 2015). However, in early May 2016 AMCo became concerned over the increasing competition in the market, as explained in section 3.F.III.q below. This prompted AMCo to review its strategy with respect to 10mg hydrocortisone tablets and as a result, AMCo decided to *'not commercialise'* the MIBE development (Document 202910, email from [AMCo Employee] to [AMCo Employee], [AMCo Senior Employee 5] and [AMCo Senior Employee 3] dated 24 May 2016. See also Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016).

⁶⁸⁴ Document 200010, data supplied by Waymade on its purchases of hydrocortisone tablets from Auden.

Senior Employee 1] stated that *'after the move from Waymade to Amdipharm ... In 2012, we supplied Amdipharm at a price of £1 per pack'*.⁶⁸⁵

3.446. Having acquired the 10mg MA and the benefit of the 10mg Agreement on 31 October 2012, in November 2012 AMCo made contact with Auden to negotiate an increase in the volumes available to it at the £1 supply price:

- a. On 13 November 2012 [Waymade Senior Employee 1] emailed [Amdipharm Senior Employee]: *'I one [spoke] to [AMCo Senior Employee 1]. I told him that you are handling hydrocortisone 10mg with [Auden Senior Employee 1] at Auden mac Menzies [sic] He was vey [sic] happy about that I told him that we will be looking to receive 15000 packs per month on a supply agreement'*.⁶⁸⁶
- b. In interview, [AMCo Senior Employee 1] explained that by [Waymade Senior Employee 1]'s reference to 'we' he *'doesn't mean Waymade, he means AMCo'*.⁶⁸⁷

3.447. [Waymade Senior Employee 1] had therefore agreed with AMCo's Chief Executive that [Amdipharm Senior Employee] – now employed by AMCo, the new holder of Waymade's 10mg MA – would be in charge of the 10mg supply deal AMCo had acquired from Waymade, and of negotiating an increase in the monthly volume of 10mg hydrocortisone tablets available from Auden at the £1 supply price on behalf of AMCo. [Waymade Senior Employee 1] confirmed in interview that he had told [Amdipharm Senior Employee], *'[y]ou are handling it [10mg hydrocortisone tablets] so sort [AMCo Senior Employee 1] out'*.⁶⁸⁸

3.448. By the end of November 2012, [AMCo Senior Employee 1] arranged a meeting with [Auden Senior Employee 1]. On 29 November 2012, [AMCo Senior Employee 1] emailed [Auden Senior Employee 1], copying [Amdipharm Senior Employee], with the subject *'Meeting up'*: *'[g]ood to speak to you. As discussed let's you [Amdipharm Senior Employee] and me meet up asap'*.⁶⁸⁹ The meeting between [AMCo Senior Employee 1], [Amdipharm Senior Employee] and [Auden Senior Employee 1] was

⁶⁸⁵ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.

⁶⁸⁶ Document 300331, email from [Waymade Senior Employee 1] to [Amdipharm Senior Employee] dated 13 November 2012.

⁶⁸⁷ Document 201997, transcript of [AMCo Senior Employee 1] interview dated 7 June 2018, page 41, lines 17 to 18.

⁶⁸⁸ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 153, line 4.

⁶⁸⁹ Document 202378, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 29 November 2012.

arranged for 20 December 2012,⁶⁹⁰ but [Auden Senior Employee 1] *'called in sick'* and the meeting was rescheduled for the *'first week of Jan'*.⁶⁹¹ [Waymade Senior Employee 1] noted: *'[k]now this guy [Auden Senior Employee 1], it is his style. He will do his utmost to delay, but the thing is handle him correctly and [Amdipharm Senior Employee] knows him very well and he will handle him going forward.'*⁶⁹²

3.449. In January 2013, the volumes of 10mg hydrocortisone tablets given to AMCo under the 10mg Agreement tripled to 6,000 packs per month. From this moment on until June 2014, AMCo received 6,000 packs per month at £1 per pack.⁶⁹³

3.450. The new volumes are reflected in the data provided by Auden⁶⁹⁴ and in contemporaneous documentary evidence. For example: on 1 August 2013, [Amdipharm Senior Employee] explained that AMCo *'have been receiving 6,000 packs per month since January'*.⁶⁹⁵

3.451. Prior to or during January 2013, therefore, AMCo negotiated an increase in its volumes under the 10mg Agreement with Auden. In context, the meetings between [Auden Senior Employee 1], [AMCo Senior Employee 1] and [Amdipharm Senior Employee] that were scheduled in December 2012 and January 2013 related to these negotiations.

f. AMCo moves to formalise the 10mg supply arrangement and once more triple its volumes, and explores buying Auden's hydrocortisone business

3.452. In summary:

- a. From March 2013 onwards, AMCo targeted obtaining a formal 10mg supply agreement with Auden. AMCo entered into negotiations in late 2013 and aimed once more to triple its monthly volumes to 18,000 packs.
- b. These negotiations coincided with negotiations for AMCo to buy Auden's hydrocortisone tablets business. AMCo quickly reached the

⁶⁹⁰ Document 202386, calendar invite *'Accepted: Meeting with [AMCo Senior Employee 1], [Amdipharm Senior Employee] & [Auden Senior Employee 1]'* for 20 December 2012. See also Document 202383, calendar invite *'Please keep free - Possible meeting with [Auden Senior Employee 1] + [Amdipharm Senior Employee]'* for 20 December 2012.

⁶⁹¹ Document 202425, email from [AMCo Senior Employee 1] to [Waymade Senior Employee 1] dated 21 December 2012.

⁶⁹² Document 202425, email from [Waymade Senior Employee 1] to [AMCo Senior Employee 1] dated 21 December 2012.

⁶⁹³ In January 2013, AMCo received 7,000 packs; thereafter, 6,000 packs per month.

⁶⁹⁴ Document 00674, Annex 4 to AM Pharma's response to the CMA's section 26 notice dated 23 June 2016.

⁶⁹⁵ Document 202526, email from [Amdipharm Senior Employee] to [X] dated 1 August 2013.

view that it should not proceed with this acquisition as Auden's business was vulnerable to competition; however AMCo continued the negotiations in order to facilitate obtaining this new supply deal.

- c. During the negotiations, AMCo investigated the orphan designation and formed the view that it would not preclude its skinny label 10mg tablets from competing with Auden's full label tablets. It therefore continued to negotiate for a new supply deal with increased volumes.
 - d. However, in January 2014 Auden refused to increase AMCo's volumes and it appeared that the relationship between Auden and AMCo had broken down.
- 3.453. Until 25 February 2014, Auden supplied AMCo with 10mg hydrocortisone tablets without any signed supply agreement. Initially, Auden charged AMCo e.g. £38 per pack and then issued a rebate of £37 per pack back to AMCo.⁶⁹⁶ The rebate arrangement was brought to an end in September 2013, after which Auden continued to supply AMCo at a price of £1 per pack.⁶⁹⁷
- 3.454. By the beginning of March 2013, AMCo began to target obtaining a formal supply agreement with Auden to address the issue that it was receiving supplies under an informal arrangement that would be vulnerable to sudden termination and with it the loss of a substantial portion of the Amdipharm group's value.⁶⁹⁸

⁶⁹⁶ Document 200003, paragraph 13.2, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

⁶⁹⁷ See, for example, Document 202537, email from [Amdipharm Senior Employee] to [AMCo Employee] dated 3 October 2013; and Document 201100, AMCo Competition Audit Report by Pinsent Masons dated 27 January 2014, paragraph 8.1.3. See also Document 202503, email from [X] to [X] and others dated 12 June 2013; and Document 00051C, Excel spreadsheet entitled 'Hydrocortisone 10mg@10.01.2014': the selling price to Amdipharm as of 10 January 2014 was recorded as £1.

⁶⁹⁸ Document 200059, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4] dated 3 March 2013, where [AMCo Senior Employee 1] recognised that good February 2013 results were not only dependent on 'price increases', but also on 'getting hydrocortisone from Auden Mac'. In this regard, [AMCo Senior Employee 1] stated: '[I]et's hope [Amdipharm Senior Employee] keeps at them. I will suggest we get a signed supply agreement from them'. See also Document 202473, email from [Waymade Senior Employee 2] to [Amdipharm Senior Employee] dated 18 February 2013: [Waymade Senior Employee 2] responded to a request from [AMCo Senior Employee 1] to 'jot down few bullet points [...] of some key events in Amdipharm during January or early Feb. [...] For example [...] your attempts to persuade them [Auden McKenzie] to supply us with Hydrocortisone'. [X] set out: 'Hydrocortisone 10mg tabs MA starts to generate revenue: Following conclusion of a supply agreement with Auden McKenzie; Hydrocortisone 10mg 30s were sold for the first time in January. Sales were £272,102 on 7,887 units.' This was reflected in the January 2013 [X]'s Report – see Document 202478, January 2013 [X]'s Report, page 2.

- 3.455. The negotiations to formalise the terms of supply with Auden were primarily led by [Amdipharm Senior Employee],⁶⁹⁹ with [AMCo Senior Employee 1]⁷⁰⁰ and [AMCo Senior Employee 8]⁷⁰¹ also involved on AMCo's side. [Auden Senior Employee 1] led for Auden.⁷⁰²
- 3.456. [Amdipharm Senior Employee] and [AMCo Senior Employee 1] met on 12 November 2013. The agenda included 'Hydrocortisone'.⁷⁰³ Following this meeting, [Amdipharm Senior Employee] sent the first draft supply agreement to [Auden Senior Employee 1] on 15 November 2013.⁷⁰⁴ It proposed a three-year supply of 10mg hydrocortisone tablets to AMCo for a price of £1 per pack and specified an 'Estimated Order Quantity' of 18,000 packs per month.⁷⁰⁵ AMCo was therefore targeting a further threefold volume increase: from 6,000 to 18,000 packs per month, for a new three-year term. The 18,000 packs a month was equivalent to what AMCo expected it could sell if it entered independently with its own product.⁷⁰⁶

⁶⁹⁹ AMCo's February 2013 [§]s Report dated 21 March 2013 stated: '*[h]ydrocortisone is performing well as a result of supply from Auden Mackenzie [sic]. [Amdipharm Senior Employee] is trying to formalise this arrangement in a [...] supply agreement. In the meantime we are attempting to manufacture our own product via Cenexi. Development of the Mercury [MIBE] product is also progressing well though this is two years away from launch*' – see Document 200060, [§]s Report – Feb 2013 dated 21 March 2013, page 3 (the reference to Cenexi appears to have been an error: Aesica was intended). [Amdipharm Senior Employee]'s objective [§] was to '*[s]et up contracts with Audon McKenzie [sic] for [...] Hydrocortisone*' and to get '*[c]ontracts agreed and signed by the end of November 2013*' – see Document 203648, AMCo's [§] Objectives 2013, slide 15. Document 202530, email from [§] to [§] dated 16 September 2013 stating that '*the only issue as far as I am aware is still getting the contract price agreed by [Amdipharm Senior Employee].*' Document 202532, email from [AMCo Senior Employee 4] to [Amdipharm Senior Employee] dated 18 September 2013, describing [Amdipharm Senior Employee] as '*the main contact for Auden McKenzie*'. Document 202545, email from [AMCo Employee] to [§] dated 8 November 2013, stating that '*[i]f there is any written agreement only [Amdipharm Senior Employee] would have it*'. Document 202554, email from [AMCo Senior Employee 1] to [§] dated 18 November 2013, where [AMCo Senior Employee 1] noted that he would like [Amdipharm Senior Employee] '*to sort out the Auden Mackenzie [sic] contracts. Apart from that it's really just having him for a bit of corporate memory.*' Document 201563, transcript of [AMCo Senior Employee 1] interview dated 20 October 2017, CD 1, Track 2, page 10, lines 1 to 5. Document 201591, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, CD 1, page 21, line 14 to page 22, line 3.

⁷⁰⁰ See, for example, Document 200059, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], dated 3 March 2013; Document 201563, transcript of [AMCo Senior Employee 1] interview dated 20 October 2017, CD 1, Track 2, page 10, lines 1 to 5; and Document 201591, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, CD 1, page 21, line 14 to page 22, line 3.

⁷⁰¹ See, for example, Document 202937, email from [AMCo Senior Employee 8] to [Amdipharm Senior Employee] dated 12 July 2013; and Document 201563, transcript of [AMCo Senior Employee 1] interview dated 20 October 2017, CD 1, Track 2, page 10, lines 1 to 5.

⁷⁰² Document 201563, transcript of [AMCo Senior Employee 1] interview dated 20 October 2017, CD 1, Track 2, page 11, lines 10 to 12. See also Document 201591, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, CD 1, page 21, line 14 to page 22, line 3.

⁷⁰³ Document 202547, calendar invite 'Update: Amdipharm Senior Employee] & [AMCo Senior Employee 1]' for 12 November 2013.

⁷⁰⁴ Document 202552, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 15 November 2013

⁷⁰⁵ Document 202553, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden McKenzie (Pharma Division) Limited and Amdipharm Limited, page 20, Schedule A. See also Document 202557, email from [Amdipharm Senior Employee] to [§] dated 15 November 2013.

⁷⁰⁶ See 'Product X' figures in the 'assume generics launched' and 'Sheet 1' tabs of Document 202660, spreadsheet attached to Document 202659, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 4] dated 23 May 2014. Although the spreadsheet was attached to an email in May 2014, it is likely that it was prepared in late 2013: it modelled all potential scenarios, including competitive entry, from January 2014 onwards

- 3.457. The negotiations to formalise the 10mg supply arrangement coincided with negotiations for AMCo to acquire Auden's hydrocortisone tablets business, which began in earnest in November 2013.⁷⁰⁷
- 3.458. Having been approached by [Auden Senior Employee 1] about this potential acquisition, AMCo's management and owners quickly reached the view that they should not pursue it because the value of the hydrocortisone tablets business was likely to fall following the entry of competitors. On 2 December 2013 [AMCo Senior Employee 2], [X], stated: *'There's too much risk around the value of the assets, and his [[Auden Senior Employee 1]'s] expectations would be pretty high. I suspect he's keen to sell because he knows generics may be around the corner.'* [AMCo Senior Employee 1] agreed: *'[AMCo Senior Employee 2] is right. Cinven scoffed at me when I suggested acquiring them (or indeed the product).'*⁷⁰⁸
- 3.459. However, AMCo continued to engage in the negotiations with Auden in order to increase its chance of securing a new formal 10mg supply agreement. AMCo's view was that [Auden Senior Employee 1] was seeking to position a formal supply agreement as conditional on AMCo's continued interest in the acquisition.⁷⁰⁹ [Amdipharm Senior Employee] responded to [AMCo Senior Employee 2]'s and [AMCo Senior Employee 1]'s observations: *'We need to show interest to get the supply agreements signed and keep our supply of hydrocortisone in place for as long as possible.'*⁷¹⁰
- 3.460. AMCo therefore carried out some preliminary due diligence in December 2013⁷¹¹ and internally obtained prescribing information about hydrocortisone

and assumed (subject 'to check') an Auden ASP of £40 (Auden's ASP in May 2014 reached £53.65). The 'Proposed' tab shows that AMCo proposed to increase its supply volumes from Auden to 17,000 packs per month in January 2014. The 'current' tab shows the volume of hydrocortisone tablets ('Product X') Auden was supplying AMCo in 2013: 6,000 packs a month.

⁷⁰⁷ See Document 202555, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 18 November 2013 and its attachment Document 202556; Document 00041, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 18 November 2013; and Document 00042, Confidentiality agreement between Amdipharm Limited and Auden Mckenzie (Pharma Division) Limited). See also Document 200068, [X]'s Report – November 2013, page 2; and Document 200101, AMCo Group December 2013 Management Accounts FY2013, page 25.

⁷⁰⁸ Document 200018, emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 2 and 4 December 2013.

⁷⁰⁹ See, e.g., Document 201100, AMCo competition audit, paragraph 8.6.1: *'various comments in early January 2014 by Auden have suggested that Auden would only formalise the supply contracts in return for an agreed sale of the hydrocortisone MA'*; and Document 200452, note of State of Play meeting between the CMA and AMCo dated 18 May 2016, paragraph 22, where [AMCo Senior Employee 8] explained that *'Auden's response to AMCo's request for a written contract had been to push for AMCo to buy Auden's whole business or its hydrocortisone business.'*

⁷¹⁰ Document 200018, email from [Amdipharm Senior Employee] to AMCo management dated 4 December 2013.

⁷¹¹ Document 200071, email from [X] to [Auden Senior Employee 1] dated 11 December 2013.

tablets (which was later used to inform the assessment of the importance of the orphan designation to the skinny label product).⁷¹²

3.461. While both sets of negotiations were ongoing, AMCo internally reported that: *'Auden are still supplying hydrocortisone but are being increasingly aggressive and threatening that the orphan drug status of their product means that our product ... is not comparable to theirs'*.⁷¹³

3.462. The extent of the market that was contestable to suppliers of skinny label hydrocortisone tablets was relevant to both sets of negotiations: to the proposed acquisition of Auden's hydrocortisone business because it would determine the true value of that business in the face of competition; and to the formalising of the 10mg supply arrangement because the terms of that arrangement, in particular the quantities Auden was to supply AMCo, depended on both parties' assessment of the volume Auden stood to lose to AMCo if it entered with its own product. This connection was expressed in two emails sent by [AMCo Senior Employee 2] on 2 January 2014:

a. In the first, [AMCo Senior Employee 2] told [Amdipharm Senior Employee]: *'According to the data on IMS, only 22% of prescriptions are specifically identified as Adrenal, with a long list of others. That gives us a bit more strength to say to [Auden Senior Employee 1] that we don't mind having limited labelling. Pharmacists will dispense it anyway, regardless of labelling. Therefore, we should still be arguing using 100% of the market as our negotiating position for supply volumes!'*⁷¹⁴

b. In the second, sent five minutes later, [AMCo Senior Employee 2] told [AMCo Senior Employee 1]: *'I have just received the prescribing data for Hydrocortisone 10mg ... It shows that only 22% of Rx's are specified as Adrenal, and there are multiple other indications widely in use, not the 90+% for adrenal insufficiency that [Amdipharm Senior Employee] was once referring to. That means labelling shouldn't be that important, hopefully Pharmacists will dispense our product, regardless of label, and [Auden Senior Employee 1]'s claim that we have an inferior product is irrelevant anyway, when it can be shown to be bioequivalent. It just doesn't have the labelling for one protected*

⁷¹² Document 202580, email from [X] to [AMCo Employee] dated 11 December 2013.

⁷¹³ Document 200510, Minutes of MPGL Management meeting on 19 December 2013, page 3.

⁷¹⁴ Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.

*indication. Therefore I think we can push back a bit harder! I've sent an email to [Amdipharm Senior Employee] suggesting the same.*⁷¹⁵

- 3.463. [AMCo Senior Employee 2]'s emails arose out of discussions between AMCo's management about the due diligence materials provided by Auden as part of the prospective sale of its hydrocortisone business. In that context, the bioequivalence of AMCo's product and the openness of prescriptions meant AMCo could argue for a lower price to reflect the value of Auden's full label product.
- 3.464. However, the primary context for [AMCo Senior Employee 2]'s emails was the negotiations being conducted by [Amdipharm Senior Employee] for a formal supply arrangement. [AMCo Senior Employee 2]'s email to [AMCo Senior Employee 1] followed an exchange in which [AMCo Senior Employee 1] informed him *'We aren't thinking of buying it [Auden's hydrocortisone business]'* and [AMCo Senior Employee 2] responded: *'[Amdipharm Senior Employee] was wanting us to look and behave really interested to facilitate signing the deal ... having just spoken to [Amdipharm Senior Employee], he says that he still needs us to look interested to close the deal.'*⁷¹⁶ [AMCo Senior Employee 2] suggested using the latest prescription data to argue for *'100% of the market as our negotiating position for supply volumes'* on the basis that all volumes were contestable notwithstanding the orphan designation and *'[Auden Senior Employee 1]'s claim that we have an inferior product is irrelevant'*.
- 3.465. Following this exchange, on 8 January 2014 [Amdipharm Senior Employee] sent [Auden Senior Employee 1] a signed supply agreement asking him to *'countersign'* it.⁷¹⁷ The attached draft hydrocortisone supply agreement set out the supply of 10mg hydrocortisone tablets to AMCo for a price of £1 per pack and specified an *'Estimated Order Quantity'* of 7,000 packs per month.⁷¹⁸
- 3.466. At this stage, in anticipation of Auden signing the supply contract, AMCo understood that it would get an increase to 7,000 packs per month (down from its initial goal of 18,000 packs) and receive a one-off order of 10,000 packs:

⁷¹⁵ Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014.

⁷¹⁶ Document 200165, emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 2 January 2014.

⁷¹⁷ Document 200072, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 8 January 2014.

⁷¹⁸ Document 200029, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden McKenzie (Pharma Division) Limited and Amdipharm Limited, page 21, Schedule A.

- a. On 10 January 2014, [AMCo Senior Employee 4] forwarded the draft supply agreement to [AMCo Senior Employee 6] and [AMCo Employee] explaining: *'the agreement is that on Hydrocortisone we will now get 7000 to sell instead of 6000 with an additional 9-10k packs in the next 3 months our selling price for this will be £42.50.'*⁷¹⁹
- b. On 13 January 2014, [AMCo Senior Employee 4] informed [AMCo Employee] *'the monthly volume will be 7000 packs instead of 6000, please can you ensure this months [sic] PO is for 7000 packs? Also they have agreed to supply an additional 10,000 packs as a one off, please can you also get a purchase order raised for this separately?'*⁷²⁰

3.467. AMCo sent these purchase orders to Auden on 13 January 2014.⁷²¹

3.468. However, Auden refused these orders. [Auden Senior Employee 1] called [AMCo Senior Employee 2] asking:

*'Why was an order sent for the higher amount? I said that I believed it was in anticipation of the newly-agreed volumes. He said that he had explained to [§] that agreement on these volumes was contingent on our interest in acquiring the product and giving him an offer.'*⁷²²

3.469. [Auden Senior Employee 1]:

*'then went onto [sic] say that if we don't make an offer to buy the product, and thus that he implied that he therefore wouldn't sign the supply agreement, he would then take action to protect his product by advising all parties (mentioning DoH and MHRA amongst others, including major multiples) that our product should not be dispensed against generic prescriptions.'*⁷²³

3.470. Following this threat, on 14 January 2014 AMCo withdrew its offer to contract in the signed supply agreement it had sent on 8 January.⁷²⁴ On 29 January 2014 the minutes of AMCo's top company board reported that it

⁷¹⁹ Document 200077, email from [AMCo Senior Employee 4] to [AMCo Senior Employee 6] and [AMCo Employee] dated 10 January 2014. See Document 200082, email from [AMCo Employee] to [AMCo Senior Employee 6] dated 14 January 2014: *'[t]his is a supply contract for £1 – for 7000 packs'*. See also the 'proposed 1' tab of Document 202660, spreadsheet attached to Document 202659, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 4] dated 23 May 2014.

⁷²⁰ Document 200080, email from [AMCo Senior Employee 4] to [AMCo Employee] dated 13 January 2014. [§] asked [AMCo Employee] to contact [§] and *'communicate our requirements and get their confirmation that they will proceed to execute our requirements'* on the same day (see the same document, email from [AMCo Employee] to [AMCo Employee] dated 13 January 2014).

⁷²¹ Document 200085, email from [AMCo Employee] to [§] dated 13 January 2014.

⁷²² Document 200085, email from [AMCo Senior Employee 2] to AMCo management dated 14 January 2014.

⁷²³ Document 200085, email from [AMCo Senior Employee 2] to AMCo management dated 14 January 2014.

⁷²⁴ Document 00052A, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 14 January 2014.

would not be proceeding with the acquisition of Auden's hydrocortisone business '*due to the vendor's price expectations and the threat of generic competition to many of its products.*'⁷²⁵

3.471. This was the nadir of relations between AMCo and Auden. It appeared that both strands of negotiation had failed and that the relationship would break down.

i. AMCo's Aesica product between November 2012 and January 2014

3.472. In summary, after acquiring the 10mg hydrocortisone tablet development and the 10mg MA from Waymade on 31 October 2012, AMCo engaged only sporadically with Aesica in the 14 months prior to the January 2014 crisis in relations with Auden. Its senior management had limited involvement in the project, which had yet to be submitted to the AMCo board for approval:

- a. Shortly after acquiring the 10mg MA, AMCo's project development team recorded that it needed to address the '*assay method issue*' causing low stability results in early 2013.
- b. Rather than dealing with the assay issue, AMCo decided to order a single batch of tablets from Aesica, which were manufactured in early October 2013. AMCo did not relay any instructions on how to package the batch, which was stored in bulk as a result.
- c. By December 2013, AMCo became aware that the July 2010 10mg Validation Batches that Aesica had produced for Waymade were failing stability testing by yielding low results, an issue that Waymade had predicted could happen unless the assay method was optimised. As a result, the single batch of product manufactured in October 2013 was blocked subject to an investigation to resolve the matter.
- d. This investigation was to inform AMCo's decision on whether to pursue commercialising the product, which it characterised as a '*Protective project to ensure continuity of supply*'.⁷²⁶ AMCo predicted that it would likely need to apply to the MHRA to vary the terms of the 10mg MA. AMCo anticipated being able to launch by June 2014, but whether it would in fact launch was still an open question.

⁷²⁵ Document 200498, Minutes of a Meeting of the Board of Directors of Amdipharm Mercury Limited on 29 January 2014, page 15. See also Document 200102, Strategic Development, Monthly Report, Product Acquisitions, January 2014, page 3

⁷²⁶ Document 202593, Hydrocortisone 10mg Tablets, slide 1, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

- 3.473. As explained in section 3.F.III. a to b above, before being granted the MA, Waymade had established that it needed to optimise the assay method to improve the testing method's accuracy in producing stability data and commissioned DSG to come up with a new assay method. Waymade staff had described the assay method as *'the only issue I can see at the moment preventing us from launch'* in late July 2012.⁷²⁷
- 3.474. Prior to the sale of Amdipharm to Cinven, Amdipharm's internal reports recorded that Aesica *'supplied samples to DSG to complete Hydrocortisone assay improvement process'*⁷²⁸ and that *'Amdipharm and Aesica QPs need to agree shelf life / release conditions'*.⁷²⁹ In October 2012, Waymade's product development team recorded that it needed to *'get Aesica's QPs to agree [shelf life / release conditions], as some individual [stability] results are below the limits but the trend is above and we may end up rejecting the odd batch due to low assay that really was good'*.⁷³⁰
- 3.475. An internal Amdipharm project list from mid-December 2012 laid out the main actions and the amount of resource that were required for the hydrocortisone development with Aesica. AMCo predicted that it would only need *'0.2 FTEs'* (full-time employees) to resolve the *'assay issue'* in *'Q1 2013'* and to *'extend shelf life'* registered in the MA in *'Q4 2013'*.⁷³¹
- 3.476. Instead of following up and addressing the assay issue, on 20 December 2012 AMCo asked Aesica to schedule the production of a batch of 10mg tablets in bottles.⁷³² However, Aesica immediately responded that it could not do so until AMCo provided a forecast.⁷³³
- 3.477. AMCo met with Aesica in early February 2013. AMCo asked Aesica to confirm the earliest production date for the batch of 10mg tablets. Aesica informed AMCo that given the time elapsed since it had purchased raw materials for the project (Waymade's only batches having been produced in June and July 2010), Aesica would need to purchase new stock, entailing a significant lead time.⁷³⁴ Aesica indicated that it should be able to manufacture the tablets in bulk in June 2013 and supply them to AMCo in late July or early August, but would need AMCo to submit purchase orders

⁷²⁷ Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012.

⁷²⁸ Document 202380, Amdipharm's Product Manufacturing Monthly Report for November 2012, page 4.

⁷²⁹ Document 301612, Amdipharm's Product Manufacturing Monthly Report for September 2012, page 4.

⁷³⁰ Document 300319, email from [X] to [Amdipharm Senior Employee] and others dated 19 October 2012.

⁷³¹ Document 202412, Amdipharm Product Manufacturing Project List of December 2012.

⁷³² Document 202418, email from [X] to [Aesica Employee] dated 20 December 2012. See also Document 202422, Aesica project steering group meeting minutes dated 13 December 2012, page 3.

⁷³³ Document 202418, email from [Aesica Employee] to [X] dated 20 December 2012.

⁷³⁴ Document 202459, email from [AMCo Employee] to [X], [Amdipharm Senior Employee] and [Waymade Senior Employee 2] dated 13 February 2013.

'in order for us to formally start the ball rolling and procure the necessary materials'.⁷³⁵

- 3.478. However, AMCo did not submit a purchase order. On 10 April 2013, Aesica chased AMCo for the order, explaining that it was needed *'asap now, as we are at purchase leadtime now for some materials, so additional delay will compromise bulk production date we have scheduled for you.'*⁷³⁶ No purchase order was submitted by AMCo.
- 3.479. On 10 May 2013, AMCo and Aesica staff met. The meeting's minutes recorded that *'Aesica not sure if we [AMCo] are to run the Hydrocortisone 10mg product – can we confirm?'* Nonetheless, it was agreed that *'Aesica will issue a quote for Hydrocortisone.'*⁷³⁷
- 3.480. Aesica sent its proposal *'for the manufacture and bottle packaging of 1 batch of 10mg Hydrocortisone tablets'* to AMCo on 13 August 2013.⁷³⁸ The proposal amounted to *'455,000 tablets packed as 30 tablets per bottle (total of around 15,000 bottles)'* for a price of **[£1-£4]** per bottle⁷³⁹ and noted that *'[o]nly 1 batch will be required in this order.'*⁷⁴⁰
- 3.481. [AMCo Employee], [X], forwarded Aesica's proposal to [Amdipharm Senior Employee] on 20 August 2013, adding: *'[Amdipharm Senior Employee], I need to know the future strategy for this as Aesica are pushing us to provide a production forecast.'*⁷⁴¹
- 3.482. Over a month later, on 24 September 2013 Aesica emailed AMCo to follow up on its proposal, noting that Aesica needed an updated order from AMCo in order to progress and that *'It had been mentioned that this was being circulated for AMCo approval'* though none had yet been given.⁷⁴²
- 3.483. However, during further correspondence between AMCo and Aesica in late September it emerged that Aesica's proposal, which had been prepared following AMCo's instructions,⁷⁴³ was based on a packaging format that was

⁷³⁵ Document 202481, email from [Aesica Employee] to [AMCo Employee] and [X] dated 25 February 2013.

⁷³⁶ Document 201719, emails between [Aesica Employee] and [X] dated 10-11 April 2013.

⁷³⁷ Document 202501, Draft Minutes of Meeting 10/05/2013, page 3.

⁷³⁸ Document 202577, email from [Aesica Employee] to [AMCo Employee] dated 13 August 2013. See also Document 200292, paragraph 11.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

⁷³⁹ The cost of API was not included in this price as it was to be *'handled under a separate agreement between Amdipharm Mercury Company Ltd and Aesica. The estimated cost is [£0-£1] per bottle'* – see Document 202578, letter from [Aesica Employee] to [AMCo Employee] dated 13 August 2013.

⁷⁴⁰ Document 202578, letter from [Aesica Employee] to [AMCo Employee] dated 13 August 2013.

⁷⁴¹ Document 201720, email from [AMCo Employee] to [X], [Amdipharm Senior Employee], [X] and [X] dated 20 August 2013.

⁷⁴² Document 201721, email from [Aesica Employee] to [AMCo Employee] dated 24 September 2013.

⁷⁴³ See Document 200027, Aesica's proposal for commercial supply – hydrocortisone 10mg tablets in bottles of 13 August 2013.

not authorised on AMCo's 10mg MA: 30 tablet bottles.⁷⁴⁴ Notwithstanding, Aesica emailed AMCo to inform it that *'[t]he bulk manufacture is going ahead as scheduled. We will require approval of the new proposal [for the packaging format] urgently in order to setup and prepare the packaging for this batch, for supply in November'*.⁷⁴⁵

- 3.484. Aesica manufactured the first batch of bulk 10mg hydrocortisone tablets on 2 October 2013, consisting of 455,000 tablets.⁷⁴⁶ At this stage, however, AMCo had not given Aesica instructions on how to pack them, and at AMCo there was uncertainty as to whether or not it should submit a request to the MHRA to add bottles of 30 tablets to its licence.⁷⁴⁷
- 3.485. On 7 November 2013, [Aesica Employee] (Aesica) asked [AMCo Employee] for an *'update regarding a decision on the packaging format'*.⁷⁴⁸ [AMCo Employee] raised this internally on the same day and asked for [Amdipharm Senior Employee]'s steer on this matter:

*'Aesica are chasing for a forecast which to my knowledge does not exists [sic] as we currently have no plan to market Aesica manufactured material. [...] Aesica have all the starting materials ready to commence manufacture once all the approval issues are resolved. Would very much appreciate you providing your guidance on if we are to continue with requested manufacture, if so do you approve the stability studies to be put in place. Are we to market the Aesica product, if so what is the strategy to switch from Auden and what would the marketing strategy be?'*⁷⁴⁹

- 3.486. As of November 2013, a year after taking over the Aesica 10mg development from Waymade, AMCo therefore had *'no plan to market'* the product and had yet to resolve whether and how to pack the bulk stock.
- 3.487. In early December 2013, while in negotiations with Auden, AMCo became aware of the issue that had remained outstanding since it had acquired the

⁷⁴⁴ The MA AMCo had acquired from Waymade provided for 30 tablet blister packs or 100 tablet bottles, but not 30 tablet bottles, which had been removed from the application during Waymade's ownership. [Aesica Employee] explained: *'only 30 tablet blisters and 100 tablet bottles were placed on stability ... where we have all gotten confused is that we have forgotten, in the long gap between filing, approval and commercialisation, that the 30 tablet bottle was removed from the dossier, so when it was decided to launch with bottles rather than blisters we have all assumed direct replacement from 30 tablet blisters to 30 tablet bottles, not realising this was not possible according to the filed pack types.'* See Document 202535, email from [Aesica Employee] to [AMCo Employee] dated 27 September 2013. See also Document 202560, email from [Waymade Employee] to [X] dated 18 October 2013 which confirms [Aesica Employee]'s explanation.

⁷⁴⁵ Document 202535, email from [Aesica Employee] to [AMCo Employee] Dated 26 September 2013.

⁷⁴⁶ Document 202601, email from [Aesica Employee] to [AMCo Employee] dated 17 December 2013; and Document 200090, Product Development: Hydrocortisone 10mg tablets, 22nd Jan 2014, PPRM, slide 3.

⁷⁴⁷ Document 202539, email from [AMCo Employee] to [X] and [X] dated 9 October 2013.

⁷⁴⁸ Document 200066, email from [Aesica Employee] to [AMCo Employee] dated 7 November 2013.

⁷⁴⁹ Document 200066, email from [AMCo Employee] to [Amdipharm Senior Employee] dated 7 November 2013.

10mg MA: the July 2010 10mg Validation Batches that Aesica had produced for Waymade were failing stability testing *'at various time points (18 months onwards)'*.⁷⁵⁰

- 3.488. AMCo initially believed that this was due to the tight assay limits registered on its licence. As explained in sections 3.F.III.a to b above, during the application process Waymade had opted not to challenge the MHRA's decision to reduce the assay limit for the licence from 90-110% to 95-105%⁷⁵¹ and to re-visit the issue *'post approval'*.⁷⁵² Waymade was also prepared to accept the fact that *'the assay limits are tight for shelf-life ... We decided at the time not to argue it without having more data but to get the MA instead'*. Yet, ultimately, Waymade established that *'[t]he problem is the assay method not the product'*.⁷⁵³ While acknowledging that this was outstanding in December 2012, AMCo had not revisited the issue.
- 3.489. On 10 December 2013 AMCo decided that the batch Aesica had manufactured *'is not likely to pass the current Assay limit ... this batch needs to be blocked at Aesica until Assay specifications are resolved'*.⁷⁵⁴ [AMCo Employee] responded: *'At the moment I don't believe the blocking of this batch at Aesica is a major concern but I will consult my colleagues and confirm.'*^{755 756}
- 3.490. AMCo researched the history of Waymade's 10mg MA application and corresponded with [Waymade Employee] who informed AMCo that Waymade had looked into the *'[d]evelopment of a new assay method'* and suggested that AMCo follow up with Aesica.⁷⁵⁷ AMCo further ascertained that although the MHRA had asked for a narrower shelf life limit than Waymade had applied for (90-105% rather than 90-110% as requested), in fact no shelf life limit was ultimately included on the 10mg MA.⁷⁵⁸

⁷⁵⁰ Document 202591, email from [X] to [AMCo Employee], the Deviations team and others dated 3 December 2013.

⁷⁵¹ Document 202591, email from [X] to [AMCo Employee] dated 3 December 2013.

⁷⁵² Document 300232, emails between [Aesica Employee], [X] and [Waymade Employee] dated 20 April 2012. See also Document 300288, email from [Waymade Employee] to [X], [X], [X], [X], [Waymade Employee], [X] and [X] dated 10 April 2012.

⁷⁵³ Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012.

⁷⁵⁴ Document 202591, email from [X] to [AMCo Employee] dated 10 December 2013.

⁷⁵⁵ Document 202591, email from [AMCo Employee] to [X] dated 10 December 2013.

⁷⁵⁶ By 11 December 2013, AMCo had still not decided whether to pursue the Aesica development. [AMCo Employee] reported that *'[w]e have an outstanding invoice for bulk tablets but as far as I am aware, no agreement to cover the development work and subsequent finished product supply (if we indeed decide to go ahead)'*. See Document 202963, email from [AMCo Employee] to [AMCo Senior Employee 8] dated 11 December 2013.

⁷⁵⁷ Document 202599, email from [X] to [AMCo Employee] dated 11 December 2013.

⁷⁵⁸ Document 202599, email from [X] to [AMCo Employee] dated 11 December 2013.

- 3.491. AMCo explored submitting an application for a ‘variation’ to the terms of its 10mg MA to ‘*add a shelf-life specification for the product*’.⁷⁵⁹
- 3.492. A variation is defined as a change to an MA. Variations can be:
- a. an administrative change such as a change of company name and/or address;
 - b. a change to the characteristics of a product that can affect its quality, such as a change to its composition; or
 - c. a change to the safety, efficacy or pharmacovigilance of the product.
- 3.493. Changes are classed as minor (Type 1A or 1B) or major (Type II). A major (Type II) variation is ‘*a variation that is not an extension of the marketing authorisation (line extension) and that may have a significant impact on the quality, safety or efficacy of a medicinal product*’.⁷⁶⁰
- 3.494. A batch-specific variation (‘**BSV**’) is a variation application to request agreement for a single or small number of batches of product to be released outside of the usual conditions of the MA – ie a variation that allows specific batches to be sold without requiring a change to the MA itself.⁷⁶¹
- 3.495. Notwithstanding the issues it had uncovered with the terms of the MA, on 13 December 2013 AMCo still considered that ‘*we may be instructing Aesica to pack next week*’.⁷⁶²
- 3.496. The Aesica project was discussed at AMCo’s Pipeline Project Review Meeting (‘**PPRM**’) on 18 December 2013. The slides for that meeting described the development as a ‘*Protective project to ensure continuity of supply*’. They noted that Aesica had manufactured a batch in bulk but that it was ‘*waiting on packing instructions and payment from AMCo*’ and set out AMCo’s options for packing the bulk tablets in pursuit of a ‘*Clear route forward*’.⁷⁶³
- a. Pack the tablets in blister packs of 30. In this scenario the tablets were ‘*Ready to pack*’ and would have a shelf life of 18 months (ie the amount

⁷⁵⁹ Document 202591, email from [AMCo Employee] to [§<] dated 13 December 2013.

⁷⁶⁰ Commission Regulation (EC) No 1234/2008 (the Variations Regulation) (see www.ema.europa.eu/en/human-regulatory/post-authorisation/variations/type-ii-variations-questions-answers).

⁷⁶¹ See www.gov.uk/guidance/medicines-apply-for-a-variation-to-your-marketing-authorisation#minor-variations and <https://medregs.blog.gov.uk/2017/02/09/when-the-unexpected-happens-batch-specific-variations/>.

⁷⁶² Document 202584, emails between [AMCo Employee] and [AMCo Employee] dated 13 December 2013.

⁷⁶³ Document 202593, Hydrocortisone 10mg Tablets, slide 1, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

of time for which the stability results had been satisfactory, see paragraph 3.487 above).

- b. Pack the tablets in bottles of 30. In this scenario AMCo would need to obtain stability data in order to secure a variation to the terms of its MA and determine the shelf life. In this scenario the tablets would be ready to pack in three months' time.
- c. Pack the tablets in bottles of 100. In this scenario the tablets would have a shelf life of 24 months and would also be ready to pack in three months' time.⁷⁶⁴

3.497. The slides noted that since the July 2010 10mg Validation Batches were failing stability tests on the narrow assay limit accepted by Waymade in mid-2012 – '*Stability problems – failing shelf-life spec 95% - 105%*' – a Type II variation to the terms of the 10mg MA '*to reduce lower limit to 90%*' may be necessary ('*tbc*'), which was anticipated to take three to six months.⁷⁶⁵ Taking this into account, AMCo anticipated being ready to launch its 10mg product, whether in blister packs of 30 or bottles of 100, in June 2014.⁷⁶⁶

3.498. The recommendation of the PPRM was to pack the bulk tablets in 30-tablet blister packs and use a portion of the tablets to generate stability data for 30-tablet bottles. The questions for discussion included whether to '*Manufacture further batches?*' and '*Would we launch?*'⁷⁶⁷

3.499. Following the PPRM, AMCo's Regulatory Affairs team explained that in order to support an application to vary the terms of AMCo's MA to widen the assay limit, it would need '*Batch analysis data on two production batches of FP [finished product]*' and that an application for a Type II variation '*can take up to 90 days for approval depending on the nature of the RFIs issued.*'⁷⁶⁸ [AMCo Senior Employee 7] noted that '*The fact we need data from two batches means we will need to manufacture another batch whether we commercialise or not.*'⁷⁶⁹

3.500. In summary, at the end of 2013 AMCo believed that whatever format it chose to pack its 10mg tablets in, it would likely need to vary the terms of its MA to

⁷⁶⁴ Document 202593, Hydrocortisone 10mg Tablets, slide 2, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

⁷⁶⁵ Document 202593, Hydrocortisone 10mg Tablets, slide 3, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

⁷⁶⁶ Document 202593, Hydrocortisone 10mg Tablets, slide 4, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

⁷⁶⁷ Document 202593, Hydrocortisone 10mg Tablets, slide 6, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

⁷⁶⁸ Document 202599, email from [X] to [AMCo Employee] dated 18 December 2013.

⁷⁶⁹ Document 201745, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 4], [AMCo Employee] and [AMCo Employee] dated 19 December 2013.

widen the assay limit to 90–105% and specify a shelf life, and that this would require the production of a further batch and entail some lead time (between three to six months) to generate the necessary stability data. This belief was later proven to be incorrect (see paragraphs 3.515 and 3.528.c below) as AMCo soon became aware that the issue affecting the stability data was the assay method which Waymade had already taken steps to optimise in July 2012 and which had been left unattended since the acquisition of Amdipharm by Cinven. In any event, AMCo anticipated being ready to launch by June 2014, though it had not decided whether it would in fact launch.

ii. The January 2014 breakdown in relations with Auden prompts AMCo to engage with the Aesica project in earnest and at senior level

3.501. In summary:

- a. The apparent breakdown in negotiations between AMCo and Auden in January 2014 prompted AMCo's senior management to engage with its Aesica project. The prospect that the 10mg supply deal would end sooner than anticipated meant the Aesica project became a priority and was submitted to the AMCo board for approval at the end of the month.
- b. As a result of the prioritisation of the Aesica project, AMCo confirmed that the assay method used for testing the stability of the July 2010 10mg Validation Batches was the reason behind the low stability results, a fact Waymade had already established in July 2012 and AMCo's development team had identified as an outstanding issue in December 2012. AMCo instructed Aesica to conduct an expedited investigation into the assay method to determine whether registering a new assay method would resolve the low stability results.
- c. The Aesica project was approved by the AMCo board on 22 January 2014. Two days later AMCo ordered three further batches from Aesica.

3.502. As explained in section 3.F.III.e above, between November 2012 and January 2014 AMCo continued to receive monthly supplies of 10mg hydrocortisone tablets from Auden at £1 per pack. While AMCo's technical and product development staff engaged in developing the product which had only been dealt with seriously since December 2013, its management team focused on negotiating with Auden to agree a new, forward-looking 10mg supply arrangement with increased monthly volumes. In order to facilitate this AMCo also allowed Auden to believe that it was interested in acquiring its hydrocortisone business.

- 3.503. Throughout this period, AMCo's staff assumed that if it did ultimately launch its Aesica product, this would mean the end of the supply deal with Auden. For example:
- On 17 October 2013, [AMCo Senior Employee 4] asked [Amdipharm Senior Employee]: *'Where are we up to with the agreements with Auden McKenzie? I believe we may be getting our own stock from Aesica in February 14 so would then terminate the agreement with Auden.'*⁷⁷⁰
 - As explained above, when in November 2013 [AMCo Employee] asked [Amdipharm Senior Employee] *'Are we to market the Aesica product[?]'*, he went on to ask: *'if so what is the strategy to switch from Auden[?]'*⁷⁷¹
- 3.504. The apparent breakdown in negotiations between AMCo and Auden in January 2014 prompted AMCo's senior management to engage with its Aesica project. The prospect that the 10mg supply deal would end sooner than anticipated meant AMCo might need its *'Protective project to ensure continuity of supply'*.⁷⁷² It was therefore submitted to the AMCo board for approval at the end of the month.
- 3.505. On 2 January 2014 [AMCo Senior Employee 2] explained to its business development and technical staff:
- 'We need to be in place to be able to supply the market ASAP in the event that other supply sources fail us, for whatever reason.*
- ... It's a very important product to protect in our 2014 budget plan, and there's real risk around continuity of supply from the current source (Auden McKenzie), so we need to be able to supply the market as quickly as we can.'*⁷⁷³
- 3.506. On the same day, [AMCo Senior Employee 2] explained to [AMCo Senior Employee 1] that he was concerned that AMCo would not succeed in agreeing its new supply deal with Auden (*'My worry is that it won't now get signed'*), and went on to report that [Amdipharm Senior Employee]:

⁷⁷⁰ Document 202959, email from [AMCo Senior Employee 4] to [Amdipharm Senior Employee] dated 17 October 2013.

⁷⁷¹ Document 200066, email from [AMCo Employee] to [Amdipharm Senior Employee] dated 7 November 2013.

⁷⁷² Document 202593, Hydrocortisone 10mg Tablets, slide 1, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

⁷⁷³ Document 202599, email from [AMCo Senior Employee 2] to [AMCo Employee], [REDACTED], [AMCo Employee] and [REDACTED] dated 2 January 2014.

*'said that we need to get our back-up option moving, which has been a bit of a ham-fisted effort to date, and I've just asked [AMCo Employee] to chase up. She's got a TC booked with Quality to see if we can release current batch (unlikely) but is still waiting for information from [REDACTED] about regulatory strategy. I've asked her to set [REDACTED] a deadline, to make sure that it gets priority. We need to get working on it ASAP.'*⁷⁷⁴

- 3.507. [AMCo Senior Employee 2] therefore anticipated that AMCo might fail to secure a new supply deal with Auden, and that Auden might terminate the existing supply deal. This would leave AMCo with no option but to launch its Aesica product. He (and/or [Amdipharm Senior Employee], whose words he reported) described the Aesica project as *'our back-up option'* and recognised that it had *'been a bit of a ham-fisted effort to date'*. He therefore asked AMCo's staff to establish a strategy to get the Aesica product *'on the market (but compliant) at the earliest opportunity'* and to *'make sure we submit to PPRM this month'*.⁷⁷⁵
- 3.508. By 6 January 2014, AMCo decided to proceed with packing of the bulk tablets in blisters *'as soon as possible'*⁷⁷⁶ and [AMCo Employee] informed Aesica about this: *'I know this project has been rumbling on for some time (our fault), but we'd actually like to push this ahead quite urgently now.'* After Aesica informed AMCo of the cost, AMCo agreed to raise a purchase order to pack the batch held in bulk (15,166 packs).⁷⁷⁷
- 3.509. On 7 January 2014, [AMCo Employee] emailed different teams within AMCo to lay out the following *'[a]ctions from Hydrocortisone cross-functional meeting'* that had been held the day before:
- a. *'initiate a BSV [batch specific variation: see paragraph 3.494 above] (to add a shelf life specification of 90-105%) for the batch that Aesica have already manufactured to allow release of the product. Timelines for completion are 60-90 days';*
 - b. *'[i]nitiate a change control request for type II variation';*

⁷⁷⁴ Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014.

⁷⁷⁵ Document 202599, email from [AMCo Senior Employee 2] to [AMCo Employee], [REDACTED], [AMCo Employee] and [REDACTED] dated 2 January 2014.

⁷⁷⁶ Document 201748, email from [AMCo Senior Employee 7] to [AMCo Employee], [REDACTED] and [REDACTED] dated 6 January 2014.

⁷⁷⁷ Document 202601, emails between [AMCo Employee] and [REDACTED] on 6 and 7 January 2014.

- c. *'initiate a type II variation to include [...] a shelf life specification of 90-105%. This is a type II variation and will require batch analysis data from 2 batches. Timelines for completion are 60-90 days'; and*
- d. *'Contact Aesica and arrange for the current batch to be packed asap. Also discuss lead-times for a 2nd batch to be manufactured as required for the type II variation and COGs quote for the finished product.'*⁷⁷⁸

3.510. At this point AMCo anticipated that it could launch its bulk October 2013 batch in three months' time, after obtaining the BSV: on 8 January 2014 [AMCo Senior Employee 2] reported to AMCo management, *'Good news from [AMCo Employee]'s multi-functional meeting is that it seems we can be on the market in around 3 months.'*⁷⁷⁹ AMCo expected that the bulk October 2013 batch would *'cover approx. 2 months supply. Current consumption is ~8,000 packs per month and our batch is 15,000 packs.'*⁷⁸⁰

3.511. On 14 January 2014 [AMCo Senior Employee 2] reported to AMCo's management that [Auden Senior Employee 1] had refused AMCo's order for the new higher monthly volume AMCo believed had been agreed. [AMCo Senior Employee 2] also reported that [Auden Senior Employee 1] had threatened to *'take action to protect his product'* by warning stakeholders against dispensing AMCo's skinny label product. [AMCo Senior Employee 2] continued:

'This supply deal is not going to happen (in my opinion), and I'm not sure we want it to happen from what I hear from [AMCo Senior Employee 8]. I think we need to now get a really clear plan in place how to launch our product, and to prepare for next batch, and also to counter-lobby the relevant stakeholders and point out that our product is in no way "inferior" from a quality perspective, and to clearly establish whether the adrenal insufficiency claim is a red herring or not. Is it really 95% of prescriptions that [Auden Senior Employee 1] claims, or nearer the 22% of prescriptions that was apparent from [AMCo Employee]'s IMS MDI data.'

3.512. [AMCo Senior Employee 2] also asked AMCo's business development and technical staff to *'keep the pace up on the launch of the Amdipharm hydrocortisone ASAP, as a matter of urgency.'*⁷⁸¹

⁷⁷⁸ Document 201759, email from [AMCo Employee] to AMCo staff dated 7 January 2014.

⁷⁷⁹ Document 200071, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 8], [AMCo Senior Employee 6] and [AMCo Senior Employee 1] dated 8 January 2014.

⁷⁸⁰ Document 201759, email from [AMCo Employee] to RegAffairs dated 13 January 2014.

⁷⁸¹ Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8] and others dated 14 January 2014.

- 3.513. The crisis in relations between Auden and AMCo therefore prompted AMCo to consider getting *'a really clear plan in place'* for launching its Aesica product and taking protective action to *'counter-lobby'* stakeholders to explain that its skinny label product was in no way inferior to Auden's full label product. It also made the question of the extent of the contestable market, already subject to considerable discussion within AMCo (see paragraph 3.462 above) acute: AMCo anticipated that the 10mg supply deal would end and it would have no option but to launch its Aesica product and compete with Auden.
- 3.514. AMCo's staff continued to emphasise this point in the run-up to the PPRM:
- a. On 14 January 2014, [AMCo Employee] suggested to discuss 10mg hydrocortisone tablets and *'map out a clear timeline when to pack/launch/manufacture another batch. This is becoming more and more urgent'*.⁷⁸²
 - b. On 15 January 2014, [AMCo Employee] emailed internally: *'the situation regarding Hydrocortisone is becoming rather urgent and it is imperative that we are able to release and launch our Aesica product as soon (and as safely) as possible'*.⁷⁸³
 - c. On 17 January 2014, [AMCo Employee] referred to the Aesica 10mg Development as *'an unusual project and really urgent, its [sic] going straight to PPRM'*.⁷⁸⁴
- 3.515. By 20 January 2014, AMCo was made aware that an investigation into the assay method could resolve the issue,⁷⁸⁵ as Waymade had already identified in July 2012 (see paragraph 3.421 above). Aesica was tasked with an investigation that consisted of analysing the batches with low assay results through the newly developed assay method in order to secure batch release.⁷⁸⁶ AMCo communicated to Aesica that *'this project has become a priority within AMCo right now and therefore the board are keen to know how we can expedite things in terms of the investigation. This would allow us to move to releasing the current batch and schedule in further batch manufacture as soon as possible'*.⁷⁸⁷ Aesica confirmed in response that *'the*

⁷⁸² Document 202606, email from [AMCo Employee] to [AMCo Employee] dated 14 January 2014.

⁷⁸³ Document 202607, email from [AMCo Employee] to RegAffairs, [REDACTED], [REDACTED] and others dated 15 January 2014.

⁷⁸⁴ Document 202609, email from [AMCo Employee] to [REDACTED] dated 17 January 2014.

⁷⁸⁵ Document 200302, Consort Medical's response to the CMA's section 26 notice dated 25 August 2016, response to question 4. Aesica told the CMA that *'[t]he change of assay sample preparation was instigated by Aesica's quality control department following issues with extraction of the active pharmaceutical ingredient and low assay results using the sample preparation registered under the MA. [...] Approval therefore had to be sought to vary it, before the product could be released'*.

⁷⁸⁶ Document 202636, email from [REDACTED] to [AMCo Employee] and [Aesica Employee] dated 30 January 2014.

⁷⁸⁷ Document 202610, email from [AMCo Employee] to [Aesica Employee] dated 20 January 2014.

assay method may be the focus here'.⁷⁸⁸ On 21 January 2014 [AMCo Senior Employee 2] reported internally that *'we'll have to wait 2 weeks to find out if we can do anything, until we assess if it's an analytical method issue first'*.⁷⁸⁹

3.516. AMCo's PPRM was held on 22 January 2014. The slides for the meeting forecast revenue for AMCo's Aesica product on the assumption that it would win 12,000 packs per month and that *'Indication limitations do not restrict sales.'*⁷⁹⁰ The slides also showed the course of action AMCo would follow if Aesica's *'investigation and trials (whole tablets)'* revealed that the low stability results were due to the assay method: AMCo would submit a variation to the MHRA to register the new assay method, obtain approval by mid-April and pack and release the batch held in bulk by mid-April / early May.⁷⁹¹ The PPRM agreed to recommend the project to the AMCo board.⁷⁹²

3.517. The recommendation to the AMCo board stated that the *'Rationale'* for the project was:

*'Back-up product to ensure continuity of supply in case our existing distribution agreement with Auden McKenzie for Hydrocortisone is not renewed. Also more beneficial to be the IP owner vs. rely on a distribution agreement'*⁷⁹³

3.518. The project was approved by the AMCo board on 22 January 2014. Another PPRM was held that day, with respect to which it was recorded that *'the technical investigation is still ongoing but due to the high strategic importance of this project to us, it was decided that we'd like to manufacture further batches at risk.'*⁷⁹⁴

3.519. On 24 January 2014, AMCo requested a purchase order to be raised for the manufacture of three batches of 10mg hydrocortisone tablets with a *'Launch volume'* of 45,000 packs.⁷⁹⁵

⁷⁸⁸ Document 202636, email from [Aesica Employee] to [AMCo Employee] dated 21 January 2014.

⁷⁸⁹ Document 200091, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1], [AMCo Senior Employee 8] and [AMCo Senior Employee 6] dated 21 January 2014.

⁷⁹⁰ Document 200090, Product Development: Hydrocortisone 10mg tablets, 22nd Jan 2014, PPRM, slide 10.

⁷⁹¹ Document 200090, Product Development: Hydrocortisone 10mg tablets, 22nd Jan 2014, PPRM, slide 6.

⁷⁹² Document 200102, Strategic Development – Monthly Report dated January 2014, page 4. See also Document 202633, Excel spreadsheet 'PPRM Approved Projects – Monthly Report (Jan-14)'.

⁷⁹³ Document 202632, January 2014 Business Development & Licensing Report PPRM Recommendations for Board Approval, page 3. See also Document 202630, January 2014 Business Development & Licensing Report EPRM approvals, slide 3.

⁷⁹⁴ Document 202616, email from [AMCo Employee] to [Aesica Employee] dated 22 January 2014.

⁷⁹⁵ Document 202618, email from [AMCo Employee] to [AMCo Employee] dated 24 January 2014. In response, [AMCo Senior Employee 7] requested to *'treat this as urgent'* (see the same document).

g. The First Written Agreement and AMCo's plans to launch its Aesica product

- 3.520. The apparent breakdown in negotiations between Auden and AMCo meant that in addition to approving its Aesica project at board level, AMCo abandoned its plans for a new forward-looking supply deal and instead sought to agree a written document that would formalise the supply arrangement as it had existed since January 2013 and bring it to a close. Ten days after AMCo withdrew the revised supply agreement, on 24 January 2014 [AMCo Senior Employee 8] told colleagues: *'[Amdipharm Senior Employee] tells me that he has agreed with Auden that we will document the agreement to date, and will bring it to a close.'* [AMCo Senior Employee 8] went on to explain that this would mean *'we end the arrangement as we get ready to launch our own hydrocortisone from Aesica'*.⁷⁹⁶
- 3.521. [AMCo Senior Employee 8] also stated: *'This mean [sic] that we achieve the clarity that Pinsents have advised'*.⁷⁹⁷ This referred to AMCo's engagement of the external law firm Pinsent Masons LLP:
- a. In July 2013, AMCo instructed Pinsent Masons *'to perform a competition / anti-trust review and audit'*.⁷⁹⁸
 - b. In an audit report first issued on 28 August 2013, Pinsent Masons advised AMCo that the undocumented supply arrangement with Auden posed a *'medium'* competition law compliance risk for AMCo and should be formalised; and in an updated report issued on 27 January 2014, that the risk could be reduced to *'low'* provided the arrangement was brought to an end.⁷⁹⁹
- 3.522. On 27 January 2014, [AMCo Senior Employee 8] sent the *'revised agreements to end March'* to [Amdipharm Senior Employee], explaining that he had *'inserted Friday's date as the signing date, with 1 January 2013 as the start date, so that these reflect the agreement that has been in place*

⁷⁹⁶ Document 200166, email from [AMCo Senior Employee 8] to AMCo staff dated 24 January 2014.

⁷⁹⁷ Document 200166, email from [AMCo Senior Employee 8] to AMCo staff dated 24 January 2014.

⁷⁹⁸ Document 201089, Minutes of a meeting of the Board of Directors of Amdipharm Mercury Limited dated 29 January 2014, item 10. In December 2013, AMCo separately instructed Pinsent Masons to advise on the MHRA's refusal to grant a full label 10mg MA to AMCo as a result of the orphan designation for Plenadren. On 20 December 2013, Pinsent Masons confirmed that the orphan status granted to Plenadren *'preclude[s] the MHRA from permitting AMCo's 10mg form such an indication.'* Document 201088, pages 3, 5 and 7, Advice in relation to Orphan Status Protection for Plenadren; and Document 200018, email from [Amdipharm Senior Employee] to [AMCo Senior Employee 1] dated 4 December 2013. However, on 2 January 2014 both [AMCo Senior Employee 2] and [AMCo Senior Employee 1] were sceptical about Pinsent Masons' advice, with [AMCo Senior Employee 1] stating: *'I wonder if we believe Pinsents know what they are talking about?'* (Document_200165 email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 2 January 2014).

⁷⁹⁹ Document 201100, external law firm competition law compliance audit report dated 27 January 2014, paragraphs 8.5.1 and 8.6.2.

during the past 12 months.’⁸⁰⁰ On the same day, [Amdipharm Senior Employee] forwarded these to [Auden Senior Employee 1].⁸⁰¹ The attached revised draft hydrocortisone supply agreement set out the supply of 10mg hydrocortisone tablets to AMCo for a price of £1 per pack and specified an ‘*Estimated Order Quantity*’ of 6,000 packs per month.⁸⁰²

- 3.523. The formal supply agreement between AMCo and Auden was finally signed by [Auden Senior Employee 1] on 25 February 2014.⁸⁰³ It is hereafter referred to as the ‘**First Written Agreement**’.⁸⁰⁴
- 3.524. The First Written Agreement was backdated – it had an effective date of 1 January 2013 and a duration of 15 months (ie until the end of March 2014).⁸⁰⁵ Therefore, at the time of signing the First Written Agreement, there was only a month remaining until its expiry.
- 3.525. Under the First Written Agreement, AMCo agreed to ‘*order and acquire the estimated monthly volumes*’ of 6,000 packs of 10mg hydrocortisone tablets per month for a price of £1.00 per pack.⁸⁰⁶ The First Written Agreement set out that ‘*Amdipharm’s estimated monthly order quantities are [6,000 packs per month] and Auden agrees to use all reasonable commercial efforts [...] to accept those levels.*’⁸⁰⁷
- 3.526. AMCo also agreed to ‘*procure all its requirements for the Product [10mg hydrocortisone tablets] in the Territory [the UK] from Auden on an exclusive basis*’ and to ‘*not, directly or indirectly, distribute, supply or sell in the Territory any third party product which competes*’ with Auden’s 10mg hydrocortisone tablets.⁸⁰⁸

⁸⁰⁰ Document 200092, email from [AMCo Senior Employee 8] to [Amdipharm Senior Employee] dated 27 January 2014.

⁸⁰¹ Document 00058, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 27 January 2014.

⁸⁰² Document 00059, draft “Own Label” Product Supply Agreement (for Hydrocortisone) by and between Auden McKenzie (Pharma Division) Limited and Amdipharm Limited, page 21, Schedule A.

⁸⁰³ Document 202634, emails from [X] to [Amdipharm Senior Employee] dated 25 February 2014. [Auden Senior Employee 1] would provide hard copies of the contract to [Amdipharm Senior Employee] the following day when they were due to meet.

⁸⁰⁴ Document 00445, “Own Label” Product Supply Agreement (for Hydrocortisone) by and between Auden McKenzie (Pharma Division) Limited and Amdipharm Limited, effective date 1 January 2013 (Annex 1 to Document 00444, AMCo’s response to the CMA’s section 26 notice dated 8 March 2016).

⁸⁰⁵ First Written Agreement, page 4, clause 1.9; page 5, clause 1.28.

⁸⁰⁶ First Written Agreement, page 7, clause 5.1; and page 21, Schedule A.

⁸⁰⁷ First Written Agreement, page 8, clause 6.1.

⁸⁰⁸ First Written Agreement, page 6, clause 3.2.

3.527. AMCo now anticipated that the 10mg supply deal would expire at the end of March 2014 (and not be renewed), at which point AMCo would enter the market with its own Aesica-manufactured 10mg hydrocortisone tablets.⁸⁰⁹

3.528. In preparation for this, AMCo:

- a. Instructed Aesica on 29 January 2014 to pack its October 2013 bulk batch in 30 tablet blister packs and agreed to pay for an automated blister feeder to facilitate this.⁸¹⁰
- b. Submitted its order for the three further batches of 10mg tablets from Aesica on 30 January 2014, to be packed in 30 tablet blister packs. This would amount to 45,000 packs, with an expected delivery date of 7 May 2014.⁸¹¹
- c. In the meantime, conducted testing to confirm whether the low assay results on the July 2010 10mg Validation Batches were due to the analytical method.⁸¹² On 17 February 2014 the tests confirmed that this was the case and that the issue could be addressed by applying for a Type 1B variation to AMCo's MA (a minor variation with a shorter lead time than a more significant 'Type II' variation: see paragraph 3.493).⁸¹³ AMCo expected that this Type 1B variation would be obtained in time to release the first batch at the end of April 2014.⁸¹⁴

⁸⁰⁹ On 11 February 2014, AMCo expected that Auden's supply of 10mg hydrocortisone tablets 'is coming to an end in the next month or so' with last shipment in March 2014. Document 202627, email from [AMCo Senior Employee 4] to [AMCo Employee] and [AMCo Employee] dated 11 February 2014; and email from [Amdipharm Senior Employee] to [AMCo Senior Employee 4] and [AMCo Employee] dated 14 February 2014.

⁸¹⁰ On 10 February 2014, Aesica provided AMCo with a proposed quotation for the 'automated feeder equipment required to pack commercial scale batches of Hydrocortisone tablets' and informed that '[i]t is expected that procurement and installation of this equipment will not impact lead-time on planned batches' – see Document 201814, email from [Aesica Employee] to [AMCo Employee] dated 10 February 2014. The purchase order for the blister feeder was sent to Aesica on 21 February 2014 – see Document 201828, email from [AMCo Employee] to [Aesica Employee] dated 21 February 2014.

⁸¹¹ Document 202624, emails between from [AMCo Employee] and [AMCo Senior Employee 1] dated 30 January 2014; and Document 201770, Purchase Order dated 27 January 2014, attached to Document 201790, email from [AMCo Employee] to [Aesica Employee] and [Aesica Employee] dated 30 January 2014.

⁸¹² On 7 February 2014, [AMCo Senior Employee 2] became aware of positive preliminary results of the investigation: 'results are looking like 100% (which would allow release of product). Therefore, if that's correct, the hypothesis that it's an analytical method issue is correct, the product is OK, and we should have a product that can be sustainably manufactured and supplied to the market!!!'. See Document 202962, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4] and others dated 7 February 2014.

⁸¹³ Document 201829, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 21 February 2014. See also Document 203633, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 19 February 2014; Document 202966, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 2], [AMCo Senior Employee 1], [AMCo Employee] and others dated 17 February 2014; Document 202947, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 7 February 2014.

⁸¹⁴ Document 201829, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 21 February 2014. See also Document 202783, email from [AMCo Employee] to [AMCo Employee] dated 14 April 2015. [AMCo Employee] explained what the change in the assay involved: '[t]he old assay method asked for the tablets to be ground and this causes losses [sic]. The current method uses whole tablets to overcome this'.

- 3.529. AMCo therefore expected to be in a position to launch its Aesica product in April/May 2014:
- a. When [AMCo Senior Employee 8] asked '*when we will have product to sell in the market*', [AMCo Employee] responded: '*[i]f we stay on schedule (which it seems we will be able to), 1st batch will be available End-April and the following 3 early May.*'⁸¹⁵
 - b. On 25 February 2014, the day the parties entered into the First Written Agreement, AMCo expected that its own 10mg product '*will hopefully be available in April or May*'.⁸¹⁶
 - c. AMCo's February 2014 Strategic Development Report recorded: '**Hydrocortisone tablets [...] launch strategy complete ... [...] a plan is underway to register a variation (Mar-14) to potentially be ready for launch by end-April 14**'.⁸¹⁷
- 3.530. On 21 March 2014, AMCo reported that '*Auden contracts in place and ending on 31 March 2014. We are about to place our last orders of hydrocortisone and will look to get about 2 months stock to cover the period until our Aesica-sourced product is launched. [...] Aesica-sourced product due for our planned launch in May.*'⁸¹⁸
- 3.531. AMCo did indeed acquire two months' worth of '*bridging stock*' (ie 12,000 packs in total) on 16 and 28 April 2014, at the same price as under the First Written Agreement (£1 per pack). These orders covered April and May. It made no orders during the month of May.⁸¹⁹

i. Volumes supplied to AMCo between January 2013 and June 2014

- 3.532. As explained above, the First Written Agreement stated that AMCo's '*estimated monthly volumes*' would be 6,000 packs. Auden was only obliged to use all reasonable commercial efforts to supply those volumes.
- 3.533. As also explained above, the First Written Agreement was almost entirely retrospective, documenting the arrangement that had been in place since

⁸¹⁵ Document 202947, emails between [AMCo Employee] and [AMCo Senior Employee 8] dated 7 February 2014. See also Document 201805, email from [AMCo Employee] to [AMCo Employee] dated 5 February 2014, and Document 201829, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 21 February 2014.

⁸¹⁶ Document 200511, minutes of MPGL Management meeting on 18 February 2014, page 2.

⁸¹⁷ Document 200183, Strategic Development – Monthly Report, February 2014, page 7 (emphasis in original).

⁸¹⁸ Document 200104, minutes of MPGL Management meeting on 21 March 2014, page 3.

⁸¹⁹ Document 200258, response to question 15, AMCo's response to the CMA's section 26 notice dated 23 August 2016; Document 200288, Chronology of '*Amdipharm's Development of Reduced Indication 10mg Hydrocortisone*', submitted by AMCo on a voluntary basis on 14 October 2016; Document 202642, emails between [X], [AMCo Senior Employee 4] and [X] dated 26 March 2014, 1 April 2014 and 11 April 2014; and Document 202640, emails between [AMCo Senior Employee 4] and [X] dated 9 April 2014.

January 2013. Between January 2013 and June 2014, the maximum volume of 10mg hydrocortisone tablets available to AMCo at the £1 price was 6,000 packs per month. This is demonstrated by data provided by the parties and by contemporaneous documentary evidence, set out in table 3.27 below.

Table 3.27: volumes supplied to AMCo between January 2013 and June 2014

Document	Evidence
00674, data supplied by Auden on its sales of hydrocortisone tablets to Waymade and AMCo	Auden supplied AMCo with 7,000 packs in January 2013 and an average of 6,000 packs per month between February 2013 and May 2014 at the £1 price If in any month AMCo failed to order or Auden failed to supply this allocation, quantities were adjusted in the subsequent month to correct this: in two months (May 2013 and September 2013) AMCo did not receive any 10mg tablets – however, AMCo's allowance was adjusted in June and October 2013 to 12,000 packs to ensure a consistent average of 6,000 per month throughout this period.
202008, purchase orders and invoices relating to 10mg hydrocortisone tablets supplied by AMCo 00448, data supplied by AMCo on its purchases of 10mg hydrocortisone tablets	Purchase orders and invoices and AMCo's data confirm the data in 00674 above The only exceptions are discussed in 00052 and 200085 below: AMCo attempted to order 10,000 packs and to increase its monthly volumes to 7,000 in January 2014. Auden refused both requests
202526, email from [Amdipharm Senior Employee] to AMCo staff dated 1 August 2013	<i>'We should be receiving credits which will net the price per pack down to £1. We have been receiving 6,000 packs per month since January although initially this was via Waymade'</i>
202597, email from [AMCo Senior Employee 4] to AMCo staff dated 20 December 2013	<i>'The reason we only sell 6000 packs per month is that is all the stock we currently get'</i>
00052, emails between AMCo and Auden dated 13 and 14 January 2014	AMCo: <i>'We have planned to raise a new order with quantity of 10000 packs for Hydrocortisone tab 10mg and to revise the order quantity for PO7108 from 6000 to 7000 packs.'</i> [Auden Senior Employee 1]: <i>'I have said no'</i>
200085, emails between [AMCo Senior Employee 4], [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 14 January 2014	[AMCo Senior Employee 4]: <i>'Auden have refused our order of the new volume of 7000 packs and said we can only have 6000.'</i> [AMCo Senior Employee 1]: <i>'Do we normally receive 6000?'</i> [AMCo Senior Employee 4]: <i>'Yes its always been 6000 but the new agreement is 7000 from this month.'</i> [AMCo Senior Employee 2]: <i>'I received a call from [Auden Senior Employee 1] today, who was not happy with the higher order being sent ... He said that he had explained to [Amdipharm Senior Employee] that agreement on these volumes was contingent on our interest in acquiring the product'</i>

Document	Evidence
200452, note of state of play meeting with AMCo dated 18 May 2016, paragraph 22	[AMCo Senior Employee 8]: <i>'AMCo had been pushing for more than the 6000 packs in the negotiations for a written contract which had started around September/October 2013, but Auden were not prepared to supply more'</i>
201100, Pinsent Masons competition law compliance report dated 27 January 2014, paragraph 6.1.3	<i>'Amdipharm has an undocumented arrangement with Auden, under which Auden supplies a limited volume of its 10mg hydrocortisone'</i>
200106, emails between [AMCo Senior Employee 1] and [AMCo Senior Employee 5] dated 17 and 22 April 2014	[AMCo Senior Employee 1]: <i>'do you know the volumes that we currently get from Auden?'</i> [AMCo Senior Employee 5]: <i>'Monthly volumes from Auden is 6000 packs per month typically Price is £1.00'</i>

h. Auden devises 'Project Guardian' in anticipation of AMCo entering the market

3.534. Like AMCo, Auden's awareness of the orphan designation and understanding of its implications evolved over time. In or around June 2012, Auden first became aware that because of Plenadren's orphan designation, the MHRA would not grant any new MAs for hydrocortisone tablets for the same therapeutic indication.⁸²⁰ In September 2013 Auden clarified with the MHRA its understanding that this meant *'a license will not be granted for any dosage form or strength for hydrocortisone for the treatment of adrenal insufficiency in adults over 10 years orphan exclusivity period.'*⁸²¹ As explained in paragraph 3.461 above, in December 2013 AMCo recorded that Auden *'are being increasingly aggressive and threatening that the orphan drug status of their product means that our product (which does not have adrenal insufficiency as an indication) is not comparable to theirs.'*⁸²²

3.535. The January 2014 breakdown in negotiations between Auden and AMCo and the resulting agreement simply to document the existing supply arrangement and bring it to an end meant Auden became concerned that AMCo would soon enter the market with its 10mg hydrocortisone tablets.

⁸²⁰ Document 00032E, email from [X] to [Auden Senior Employee 1] dated 20 June 2012. In relation to this email, [Auden Senior Employee 1] stated that *'I cannot recall precisely when I first became aware of the orphan designation and its implications. However, I would have been aware of the orphan designation as early as June 2012 which is when I received an email from [X] from YJB Port. I would have read this email from [X], but I do not have specific recall as to when I was fully aware of the implications of the orphan designation status on Auden Mckenzie's hydrocortisone tablets.'* (Document 00725, paragraph 1.15, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016).

⁸²¹ Document 00632, email from [X] on behalf of [X] to [X] dated 24 September 2013. See also Document 00038A, email from [X] to [X] dated 2 September 2013, and Auden's June 2014 description of the position in Document 00157, email from [Auden Senior Employee 4] to [X] dated 5 June 2014.

⁸²² Document 200160, minutes of MPGL Management Meeting on 19 December 2013, item 2.2.

- 3.536. As explained in paragraph 3.511 above, when rejecting AMCo's purchase orders for higher volumes on 14 January 2014 [Auden Senior Employee 1] threatened to *'take action to protect his product'* by informing stakeholders that AMCo's skinny label tablets *'should not be dispensed against generic prescriptions.'*⁸²³
- 3.537. Auden's concern about the competitive threat AMCo's 10mg hydrocortisone tablets posed (despite their skinny label) led it to devise a plan it called 'Project Guardian' to protect Auden's position as the incumbent sole supplier of hydrocortisone tablets.
- 3.538. Project proposal documents stated that the aim of Project Guardian was to preserve Auden's market position specifically in response to the threat posed by AMCo's anticipated imminent entry:
- a. Auden met [Auden's External Consultant], on 3 February 2014 and subsequently engaged him to *'develop and deliver a strategy designed to ensure that its current market share for the supply of hydrocortisone tablets (10mg and 20mg respectively) is maintained or strengthened at a time when a competitors [sic] product (namely Amdipharm Mercury Company Limited [AMCo] hydrocortisone tablets 10mg and 20mg) threatens to weaken Auden McKenzie's market share.'*⁸²⁴
 - b. Auden separately engaged with another consultancy, MAP Biopharma, to explore reintroducing the *'Hydrocortone'* brand in an attempt to preserve its high prices. On 12 February 2014 [Auden Senior Employee 4], explained to MAP: *'The other MA for the generic is held by Amdipharm, who will launch their product in Q2/3 2014'*.⁸²⁵
- 3.539. The details of the Project Guardian strategy were set out in a February 2014 presentation by [Auden's External Consultant]. The presentation concluded that despite Auden's *'strong position'*, *'new competitor entry remains a real threat and action is necessary to avoid unnecessary decline in share (driven by prescriber ignorance or dispensers chasing margin on reimbursement)'*:
- 'It is therefore essential to be proactive ahead of Amdipharm's [AMCo's] product entry into the UK market in an attempt to hold Auden*

⁸²³ Document 200085, email from [AMCo Senior Employee 2] to AMCo management dated 14 January 2014.

⁸²⁴ Document 00062F, Professional Advice (Hydrocortisone) Proposal Prepared for Auden McKenzie (Pharma Division) Ltd by [Auden's External Consultant], page 2, dated 6 February 2014; sent to [Auden Senior Employee 4] (Auden McKenzie) see Document 00062E, email from [X] to [Auden Senior Employee 4] dated 10 February 2014.

⁸²⁵ Document 00164, email from [Auden Senior Employee 4] to MAP BioPharma dated 12 February 2014.

Mckenzie share above 50% and as close to the existing position as possible'.⁸²⁶

- 3.540. The presentation recommended contacting specialists, patient groups, regulators, GPs and pharmacists, customers and health departments, specialist endocrinologists and superintendent pharmacists to warn against off-label dispensing.⁸²⁷ In this way Auden hoped *'to raise the profile of the issues concerning liability and risk'* of off-label dispensing and preserve its position as the only full label supplier.⁸²⁸
- 3.541. Between February and April 2014 Auden and its consultants developed letters to be sent to the Chief Pharmaceutical Officer, the MHRA, patient groups, specialists, superintendent pharmacists and pharmacy bodies in pursuit of this strategy.⁸²⁹ Auden sought to highlight the purported risk profile to pharmacists, and the template letters to the Chief Pharmaceutical Officer and superintendent pharmacists asked whether they would find it appropriate to issue guidance to senior pharmacists on off-label dispensing.⁸³⁰
- 3.542. Separately, Auden also explored re-introducing the brand *'Hydrocortone'* to distinguish its product from the product belonging to *'Amdipharm, who will launch their product in Q2/3 2014'*.⁸³¹
- 3.543. Throughout this period Auden continued to perceive an acute competitive threat from the launch of AMCo's skinny label tablets, which it believed to be imminent. On 4 April 2014 [Auden Senior Employee 4] told [Auden's External

⁸²⁶ Document 00135, *Project Guardian* presentation dated February 2014, page 9.

⁸²⁷ Document 00135, *Project Guardian* presentation dated February 2014, pages 3, 11, 21-29 and 33.

⁸²⁸ Document 00135, *Project Guardian* presentation dated February 2014, page 16 (emphasis in the original). See also Document 00064, untitled report containing analysis on hydrocortisone attached to Document 00063, email from [X] (H2 Pharma) to [Auden Senior Employee 4] dated 18 February 2014: *'Strategy: make physicians aware that Auden's product is licenced [sic] for the broader adrenal insufficiency indication and the Amdipharm product is ONLY licenced [sic] only [sic] for congenital adrenal hyperplasia in children Make it clear that treatment of adrenal insufficiency in patients with primary (Addison's) and secondary (hypo-pituitarism) diseases will NOT be covered under the Amdipharm product licence.'*

⁸²⁹ Document 00082, email from [Auden's External Consultant] to [X] dated 31 March 2014. Document 00093, titled Key Contact First Engagement Email / Letter (Draft Text) attached to Document 00082, email from [Auden's External Consultant] to [X] dated 31 March 2013. 'Final' template letters were circulated on 7 April 2014 following feedback from Auden: Document 00117, email and attachments from [Auden's External Consultant] to [X] copying [Auden Senior Employee 4] dated 7 April 2014. See, for example, attached Document 00119.

⁸³⁰ Document 00121, template letter to Chief Pharmaceutical Officers dated 14 April 2014; Document 00126, template letter to Superintendent Pharmacists dated 14 April 2014.

⁸³¹ Document 00164, email from [Auden Senior Employee 4] to MAP BioPharma dated 12 February 2014. See also Document 00076E, '20140316 – PPRS Report Summary Based on Discussion with PPRS Team' prepared by MAP BioPharma. Ultimately, and despite having a meeting with the Department of Health's PPRS team, Auden decided to cease in its efforts to reintroduce the brand two days before entering into the Second Written Agreement with AMCo. See Document 00164, email from [Auden Senior Employee 4] to MAP BioPharma dated 23 June 2014.

Consultant]: *'The competitor product will launch mid-May/beginning June...so we should get these letters out asap.'*⁸³²

3.544. Auden also pursued engagement with other key stakeholders in pursuit of its objective of discouraging off-label dispensing and therefore preserving its own position. Auden:

- a. Wrote to the MHRA seeking to understand whether differences between the indications for full and skinny label hydrocortisone tablets could be highlighted on the packaging and patient information leaflets. Auden alleged that the unintentional supply of an *'unlicensed'* medicine raised issues of liability for the prescriber and the pharmacist.⁸³³
- b. Engaged a public relations consultancy, Salix Consulting, to devise a plan for handling media *'prior to and during deployment of Project Guardian'*. Salix noted that:

'Auden Mckenzie is reacting to a potential threat to its market share of hydrocortisone 10mg tablets

The threat comes from new arrival, Amdipharm [AMCo], whose product may be adopted as a cheaper alternative to the current market leader.

*Auden Mckenzie's [sic] has developed a reactive sales and marketing programme, Project Guardian.*⁸³⁴

- c. Sought feedback from [Professor of Endocrinology] on its materials and general strategy relating to Project Guardian, and in particular draft pharmacist materials and a handout for patients that had been prepared by the National Pharmacy Association.⁸³⁵
- d. Through [Auden's External Consultant], approached pharmacy chains, pharmaceutical officers and professional bodies and arranged meetings.⁸³⁶

⁸³² Document 00110A, email from [Auden Senior Employee 4] to [Auden's External Consultant] dated 4 April 2014.

⁸³³ Document 00129, letter from [X] to [X] (MHRA) dated 14 April 2014. This followed an email to the Patient Information Quality Unit at the MHRA on 8 April 2014 where Auden highlighted similar issues and requested that the text *'To treat adrenal insufficiency in adults and children'* be inserted on to the label of its product (Document 00629, email from [X] to [X] dated 8 April 2014).

⁸³⁴ Document 00139, *A communications proposal to support Project Guardian*, Salix Consulting, slide 3, dated 16 April 2014.

⁸³⁵ Document 00140, email exchange between [Professor of Endocrinology] and [Auden's External Consultant] copying [Auden Senior Employee 1] dated 22-29 April 2014.

⁸³⁶ Document 00142, "Project Guardian Phase 2 & 3: Actions, Meetings and Selling the Proposition: Work in Progress Summary" attached to Document 00141, email from [Auden's External Consultant] to [Auden Senior Employee 4] dated 8 May 2014.

i. Stakeholder responses to Project Guardian

3.545. In May 2014, Auden received a clear response from the Chief Pharmaceutical Officer for NHS England that full and skinny label hydrocortisone tablets were bioequivalent, and therefore that there were no risks to patient safety from off-label dispensing as Auden had suggested.

3.546. On 20 May 2014, [Chief Pharmaceutical Officer for NHS England] wrote to Auden in response to a Project Guardian letter Auden had sent him on 23 April. Auden received [Chief Pharmaceutical Officer for NHS England]'s letter on 22 May 2014. [Chief Pharmaceutical Officer for NHS England] wrote:

'Colleagues at the Medicines and Healthcare Products Regulatory Agency (MHRA) have informed me that there are no material differences between the available generic immediate release hydrocortisone tablets and they are all bioequivalent to the brand leader.'

3.547. [Chief Pharmaceutical Officer for NHS England] observed that the difference between full and skinny label MAs was a consequence of the timing of the orphan designation for Plenadren and concluded:

*'I note that you are in contact with clinicians and patient support groups. Based on the advice I have received so far, I do not see that there are any risks to patient safety that would warrant any communication to senior pharmacists.'*⁸³⁷

3.548. [Chief Pharmaceutical Officer for NHS England]'s feedback echoed that of [Professor of Endocrinology], who had observed in response to a draft Auden letter he reviewed that *'[m]y main concern is that it looks as if you are worried about the competition rather than more altruistic reasons'*.⁸³⁸

3.549. Having received this negative response from senior individuals, Auden continued to pursue Project Guardian with other stakeholders until mid-June 2014:

⁸³⁷ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden Senior Employee 1], [Auden Senior Employee 4] and [Auden's External Consultant], dated 20 May 2014.

⁸³⁸ Document 00140, email from [Professor of Endocrinology] to [Auden Senior Employee 1] and [Auden's External Consultant], dated 22 April 2014. See also Document 02046.B, note of call on 17 November 2017 between [Professor of Endocrinology] and the CMA where [Professor of Endocrinology] said that he *'was not familiar with the distinction between 'full' and 'skinny' label HTs, and did not see the rationale for making such a distinction if both drugs were bioequivalent. As long as the products are HT, and so bioequivalent, there would be no risk associated with prescribing skinny label HTs'* (paragraph 3(a)).

- a. Having written to the Royal Pharmaceutical Society to request a meeting on 30 April 2014 (before receiving [Chief Pharmaceutical Officer for NHS England]’s feedback), [Auden Senior Employee 4] and [Auden’s External Consultant] attended that meeting on 12 June 2014 and expressed Auden’s concern about off-label dispensing, which it characterised as ‘*a patient safety issue*’. The note of the meeting indicates that a ‘*training pack*’ Auden had developed with the National Pharmaceutical Association to raise awareness of adrenal insufficiency would be sent to all independent pharmacies later in June; and that ‘*Auden Mckenzie product has MHRA approval for quartering, other products may not be suitable for use in this way. Auden Mckenzie discussing with MHRA adding indication to packaging.*’⁸³⁹ In May 2014 Auden issued a ‘*guide for patients*’ on adrenal insufficiency, advising patients to ‘*check with your pharmacist to ensure that the product you are receiving is licensed for this indication.*’⁸⁴⁰ In April and May 2014 Auden also prepared a document comparing the indications of licensed products and warning against ‘*unlicensed*’ (off-label) use.⁸⁴¹
 - b. In June 2014 Auden issued a ‘*guide for pharmacists and their teams*’ on adrenal insufficiency, stating: ‘*Not all hydrocortisone preparations are indicated for use by patients with adrenal insufficiency – pharmacists should check product literature to ensure the product they are supplying is indicated.*’⁸⁴²
- 3.550. Project Guardian appeared to have some success in influencing communications to patients from support groups – not in relation to off-label dispensing but in relation to the alleged difficulties of dividing AMCo’s tablet into quarters. The ‘*Addison’s Disease Self Help Group Newsletter*’ was published in June 2014. The newsletter stated that: ‘*A rival manufacturer of generic 10mg hydrocortisone tablets, Amdipharm, has been licensed by the UK regulator, the MHRA, for distribution in the UK. Amdipharm’s new tablets are round, convex tablets that will not be easy to split down to 2.5mg dose sizes. Anyone who regularly quarters their hydrocortisone tablets will need to inform their pharmacist and insist on getting the current oval, Auden Mckenzie product. Both drugs have the same price... inexplicably, the Amdipharm generic 10mg tablet is approved for adrenal replacement in*

⁸³⁹ Document 00160, email exchange between [X] (Royal Pharmaceutical Society) and [Auden’s External Consultant], forwarded internally from [Auden Senior Employee 4] to [Auden Senior Employee 3], [X] and [Auden Senior Employee 1], dated 12 June 2014.

⁸⁴⁰ Document 00435, AM Pharma patient guide to adrenal insufficiency dated May 2014.

⁸⁴¹ Document 00437, AM Pharma guide to adrenal insufficiency dated May 2014.

⁸⁴² Document 00436, AM Pharma pharmacist guide to adrenal insufficiency dated June 2014.

children with Congenital Adrenal Hyperplasia – but not for adults for Addison's.⁸⁴³

j. Auden and AMCo resume negotiations for a forward-looking 10mg supply arrangement, culminating in the Second Written Agreement

3.551. In summary:

- a. By April 2014 negotiations for a new forward-looking supply deal had restarted between Auden and AMCo.
- b. On 25 June 2014 the parties agreed a new two-year supply deal, under which Auden agreed to double AMCo's monthly volumes at a 97% discount to market rate.
- c. As part of that supply deal, AMCo was required to give Auden three months' notice if it intended to supply its own hydrocortisone tablets, which triggered a right for Auden to terminate the supply arrangement on the same notice period.
- d. Two days prior to entering into that supply deal, AMCo expected its Aesica product to be available for launch the following month, July 2014. AMCo forecast selling 10,000 packs of its own product per month (approximately 13% of total volumes).

3.552. On 4 April 2014, [Auden Senior Employee 1] called [AMCo Senior Employee 1] and got through to his assistant, who reported to [AMCo Senior Employee 1] that [Auden Senior Employee 1] said *'you wanted to meet (lunch) soon?'* [AMCo Senior Employee 1] confirmed that it *'[w]ould be good to meet him [Auden Senior Employee 1] for lunch'*.⁸⁴⁴

3.553. That lunch took place in May 2014 (see paragraph 3.557 below). However, it is clear that [AMCo Senior Employee 1] and [Auden Senior Employee 1] spoke between 4 and 19 April 2014: on 19 April [AMCo Senior Employee 1] told colleagues, *'[Auden Senior Employee 1] offered to continue to supply us'*.⁸⁴⁵ AMCo's April management pack reporting on its March 2014 results recorded that AMCo was considering Auden's *'offer to continue supplying AMCo with Hydrocortisone on an ongoing basis. We would need to have a long term supply agreement with agreed price and volume for the period but if the economics are ok this would have the advantage to AMCo of selling a*

⁸⁴³ Document 00171, Addison's Disease Self Help Group Newsletter, June 2014 attached to Document 00166, email from [X] (Addison's Group) to [Auden Senior Employee 4] dated 7 July 2014.

⁸⁴⁴ Document 202637, email exchange between [X] and [AMCo Senior Employee 1] dated 4 April 2014.

⁸⁴⁵ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014: 'No email record of the communication of Auden McKenzie's offer has been found.'

*product with the full range of indications.*⁸⁴⁶ It was also noted that launch of the Aesica 10mg product was '*assumed end of May/Early June*'.⁸⁴⁷

3.554. Therefore, by April 2014, negotiations between AMCo and Auden with respect to a forward-looking written supply agreement had restarted. [AMCo Senior Employee 1] was the principal negotiator on the AMCo side, and [Auden Senior Employee 1] was the principal negotiator on the Auden side.

3.555. Between 17 and 22 April 2014, AMCo considered the merits and the price and volume of a possible new formal supply agreement with Auden against bringing its own Aesica-manufactured 10mg hydrocortisone tablets to the market:

- a. On 19 April 2014, [AMCo Senior Employee 1] emailed [AMCo Senior Employee 2]:

*'Yes this is an interesting one
[Auden Senior Employee 1] offered to continue to supply us [...] I think that he is not keen to get into a battle over the orphan drug status and its validity and so probably would do a better deal on better term.
I have asked [AMCo Senior Employee 5] what our Aesica cost and volume expectations are and I would say if [Auden Senior Employee 1] could get close to them it would be worth having a long term supply agreement with him.
I am also not keen on having a fight over the status or indeed having customers that see our product as somehow risky.'*⁸⁴⁸

- b. [AMCo Senior Employee 5] supplied this information to [AMCo Senior Employee 1] between 17 and 22 April 2014:

- i. On 17 April 2014, [AMCo Senior Employee 5] told [AMCo Senior Employee 1] that the cost of goods for a pack of Aesica-manufactured 10mg hydrocortisone tablets was [~~£1-£4~~].⁸⁴⁹
- ii. On 22 April 2014, [AMCo Senior Employee 5] explained in response to a follow-up request that '*[m]onthly volumes from Auden is 6000 packs per month typically Price is £1.00. Forecast slightly higher 10000 from Aesica*'. [AMCo Senior Employee 4] subsequently told [AMCo Senior Employee 1] that the size of the

⁸⁴⁶ Document 200108, AMCo Monthly Management Pack, March 2014, slide 6. The Pack is undated, but it is likely that it was drafted after March 2014, as it records actual sales made in that month.

⁸⁴⁷ Document 200108, AMCo Monthly Management Pack, March 2014, slide 54. The likelihood was described as '*Medium*' (ie between 25-50%).

⁸⁴⁸ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.

⁸⁴⁹ Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 17 April 2014.

market '*[I]ast year [...] was 923k packs for the year so 77,000 packs per month.*'⁸⁵⁰

- 3.556. By 15 May 2014, AMCo had sold all 12,000 packs of the '*bridging stock*' (see paragraph 3.531) supplied by Auden and was out of stock.⁸⁵¹
- 3.557. On 16 May 2014, [AMCo Senior Employee 1] and [Auden Senior Employee 1] met for lunch at the Mint Leaf Lounge (City of London), the lunch described in the email exchange of 4 April 2014 (see paragraph 3.553 above).⁸⁵²
- 3.558. In late May 2014, AMCo and Auden held further discussions with respect to the new formal supply agreement. On 24 or 25 May 2014 – the weekend after Auden received [Chief Pharmaceutical Officer for NHS England]'s letter rebuffing Project Guardian (see paragraph 3.546 above), [Auden Senior Employee 1] sent a text message to [AMCo Senior Employee 1].⁸⁵³ [AMCo Senior Employee 1] responded by email on 28 May 2014, setting out AMCo's requirements with respect to a new written supply agreement:

*'Many thanks for your text over the weekend. Looking forward to talking to you later this week. I thought it would help if I wrote down what we are looking for on Hydrocortisone. We are looking for Auden Mackenzie [sic] to supply Hydrocortisone 10mg to AMCo for a new 3 year term at a supply price of £1.00 per pack. I suggest we use the previous contract [the First Written Agreement] as the basis for this new agreement. We are currently forecasting 12k packs per month. We obviously would prefer our own livery though we would be happy to work towards this over the coming months.'*⁸⁵⁴

- 3.559. As is clear from later evidence (see paragraph 3.569 below), [AMCo Senior Employee 1]'s forecast of '*12k packs per month*' was a negotiating tactic. He had based the number on the 10,000 packs per month that AMCo had forecast it would sell if it entered with the Aesica-manufactured product,⁸⁵⁵

⁸⁵⁰ Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 22 April 2014 and email from [AMCo Senior Employee 4] to [AMCo Senior Employee 1] of the same date. See also Document 202646, email exchange between [AMCo Senior Employee 5] and [AMCo Employee] dated 17-22 April 2014.

⁸⁵¹ Document 200288, Chronology of '*Amdipharm's Development of Reduced Indication 10mg Hydrocortisone*', submitted on a voluntary basis by AMCo's external lawyers on 14 October 2016.

⁸⁵² Document 202953, [AMCo Senior Employee 1] expenses claim, which included for this date: '*Lunch: [AMCo Senior Employee 1] + [Auden Senior Employee 1]*'.

⁸⁵³ The CMA has not obtained a copy of this text from [X], see section 2.B.IX.b.i above.

⁸⁵⁴ Document 00149, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 28 May 2014. An earlier draft of this email proposed a '*long supply agreement (3? 5? Years)*' and '*a supply price of below £1.16*' – see Document 200198, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] dated 27 May 2014.

⁸⁵⁵ Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 22 April 2014.

assuming that by starting negotiations with 12,000 packs AMCo might end up with the forecast 10,000 packs.

- 3.560. [Auden Senior Employee 1] forwarded [AMCo Senior Employee 1]'s email to [Auden Senior Employee 4] of Auden on the same day noting that '*[w]e need to respond fairly quickly*'.⁸⁵⁶
- 3.561. Between 28 May and 5 June 2014, [AMCo Senior Employee 8] discussed the prospective supply arrangement between AMCo and Auden with Pinsent Masons over email and telephone.⁸⁵⁷
- 3.562. [AMCo Senior Employee 1]'s calendar indicates that he spoke to [Auden Senior Employee 1] on 29 May 2014.⁸⁵⁸ This was followed by an email exchange to find a time for a discussion between [AMCo Senior Employee 1], [AMCo Senior Employee 8], [Auden Senior Employee 1] and their respective lawyers to talk about '*a supply agreement*'. This took place on 6 June 2014.^{859,860}
- 3.563. Following this discussion, Pinsent Masons circulated a summary of the terms agreed in principle:

'AmCo could not be stopped from developing its own 10mg hydrocortisone, however, if AmcO were to launch its own product it would provide Auden with at least three months notice of its intention to do so. At which point Auden would have the opportunity to serve notice of contract termination on AmCo. A reciprocal period of 3 months notice was discussed but was not agreed.

[...]

⁸⁵⁶ Document 00149A, email from [Auden Senior Employee 1] to [Auden Senior Employee 4] dated 28 May 2014.

⁸⁵⁷ Document 201092, email from [AMCo Senior Employee 8] to [X] and [X] dated 28 May 2014; Document 201094, email from [X] to [AMCo Senior Employee 8] and [X] dated 30 May 2014; Document 201970, email from [AMCo Senior Employee 8] to [X] dated 30 May 2014; Document 201093, email from [AMCo Senior Employee 8] to [X] dated 30 May 2014; and Document 201095, emails between [X] and [AMCo Senior Employee 8] dated 5 June 2014.

⁸⁵⁸ Document 202668, [AMCo Senior Employee 1]'s calendar entry '*Call with [Auden Senior Employee 1]*' for 29 May 2014.

⁸⁵⁹ Document 202955, email exchange between [X] and [AMCo Senior Employee 1] dated 30 May 2014. See also Document 201970, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 30 May 2014. See also Document 203489, [AMCo Senior Employee 1]'s calendar for 31 May 2014, which included an entry: '*Tentative – slot to speak to [Auden Senior Employee 1]*'.

⁸⁶⁰ Document 202975, [AMCo Senior Employee 8]'s acceptance of [X] calendar invitation for 6 June 2014: '*Accepted: CONFIRMED APPT – Speak to [Auden Senior Employee 1]*'. Document 201097, email from [AMCo Senior Employee 8] to [Auden Senior Employee 1] dated 5 June 2014.

A mechanism for AmcO (upon notice to Auden), to be able to supply its own product within the Territory should Auden fail to fulfil AmCo's monthly order was also discussed⁸⁶¹

3.564. The terms agreed in principle were therefore that AMCo would have to give Auden three months' prior notice of its intention to launch, triggering a reciprocal right for Auden to terminate supply on the same time frame; and that AMCo would only have the right to supply its own product if (and for as long as) Auden failed to fulfil its obligation to supply AMCo (the email continued: *'this feels like it will need some thought as to how it will be practically managed. Should there be a % volume which if Auden fail to make that you can supply? ... Also will it be practical for you to remove your product from the market should Auden fulfil the following month's requirements[?]'*).

3.565. Pinsent Masons also stated:

'Prior to the call I discussed with you the extent to which AmCo would be considered a competitor of Auden in relation to the 10mg product (which AmCo has a pipeline source). As a result of the orphan designation for 10mg hydrocortisone, AmCo cannot supply its 10mg hydrocortisone into the market in respect of the main therapeutic use, i.e. the treatment of adrenal insufficiency. The orphan designation is akin to an IP right and as such, from a competition law perspective in respect of this product and the orphan indication AmCo and Auden would not be considered competitors whilst the orphan designation was in place⁸⁶²

3.566. On 11 June 2014, [AMCo Senior Employee 1] sent a revised draft of the supply agreement to [AMCo Senior Employee 8], stating that [Auden Senior Employee 1] had agreed to the revised version and to supply AMCo for the month of June.⁸⁶³

⁸⁶¹ Document 201971, email from Pinsent Masons to [AMCo Senior Employee 8] dated 6 June 2014.

⁸⁶² Document 201971, email from Pinsent Masons to [AMCo Senior Employee 8] dated 6 June 2014.

⁸⁶³ Document 201097, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] dated 11 June 2014. [AMCo Senior Employee 1] said that [Auden Senior Employee 1] wanted to charge AMCo a higher price of 'say £3 per pack' and rebate AMCo back. However, on 12 June 2014 [AMCo Senior Employee 8] indicated that he wanted to 'discuss the rebate' as he did not 'understand/like this concept.'

- 3.567. On 13 June 2014, AMCo sent a purchase order to Auden for 12,000 packs of 10mg hydrocortisone tablets for delivery on 18 June 2014.^{864,865}
- 3.568. On the same day, [AMCo Senior Employee 8] forwarded the draft supply agreement to [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Senior Employee 2]. [AMCo Senior Employee 8] explained his understanding of the *'non-compete that is set out in clause 2.2'* as follows: *'It basically means that we cannot sell any other products during the 2 year term of this Agreement which compete with Auden's hydrocortisone product, unless we first given [sic] Auden 3 months notice (and Auden can terminate supply to us on 3 months notice if we say we are going to do so).'* [AMCo Senior Employee 8] further stated with respect to volumes that Auden *'are now suggesting that they would satisfy their obligations if they deliver at least 85% of the 12,000'* and asked: *'Shall I insist upon 12,000 packs per month?'* Finally, [AMCo Senior Employee 8] confirmed that the price was still £1 per pack.⁸⁶⁶
- 3.569. With respect to supply volumes, [AMCo Senior Employee 4] suggested that *'[p]referably it should just be at 12k per month or worst case made up in the following month.'*⁸⁶⁷ [AMCo Senior Employee 1] agreed with [AMCo Senior Employee 4]'s suggestion and added: *'If they fall short they should make up the following month. Having said that I went in with 12k per month when I knew that [AMCo Senior Employee 4] had forecast 10k per month with the view that we would have to negotiate – I suppose at that stage I thought I would settle for 10k.'*⁸⁶⁸

⁸⁶⁴ Document 302393, purchase order dated 13 June 2014. [AMCo Senior Employee 4] had urged the sending of the purchase order during the previous days – see Document 202677, emails from [AMCo Senior Employee 4] to [AMCo Employee] and [REDACTED] dated 11 and 12 June 2014. [AMCo Senior Employee 4] indicated that Auden had been *'chasing [AMCo Senior Employee 1] for it'*, indicating there had been further contact between [AMCo Senior Employee 1] and [Auden Senior Employee 1] on 12 June 2014.

⁸⁶⁵ The stock was to be delivered to Waymade (see section 10.B.II.a.ii). The purchase order reflected the new volumes under the not yet finalised Second Written Agreement, but the old price of £1 per pack (as per the First Written Agreement). [Auden Senior Employee 3] of Auden later clarified that it was *'[i]nvoiced originally at £1.00 – this was credited and re-invoiced at £1.78'* – see Document 00178A, email from [Auden Senior Employee 3] to [Auden Senior Employee 4] dated 8 July 2014.

⁸⁶⁶ Document 200120, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Senior Employee 2] dated 13 June 2014.

⁸⁶⁷ Document 200120, email from [AMCo Senior Employee 4] to [AMCo Senior Employee 6], [AMCo Senior Employee 8], [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 13 June 2014, after [AMCo Senior Employee 6] had queried: *'would we be fine with "monthly volume needs to be at least 10,200 and any shortfall needs to be made up in the following month".'*

⁸⁶⁸ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 15 June 2014. See also Document 202647, emails between [AMCo Senior Employee 1], [AMCo Senior Employee 5] and [AMCo Senior Employee 4] dated 17-22 April 2014.

3.570. [AMCo Senior Employee 1] then discussed the start date, saying that it should be June. Referring to a conversation he had with [Auden Senior Employee 1], [AMCo Senior Employee 1] said:

*'I told him [Auden Senior Employee 1] that if not we will launch our own.'*⁸⁶⁹

3.571. On 16 June 2014, [AMCo Senior Employee 1] wrote to [Waymade Senior Employee 1] stating that AMCo was *'trying to finalise a longer term formal supply agreement on this (or indeed launch our own product) I'll get back to you this week with some news (hopefully good news!).'*⁸⁷⁰

3.572. On the same day, [AMCo Senior Employee 8] sent a *'further draft'* of the supply agreement to Auden's lawyer.⁸⁷¹ In the draft supply agreement, [AMCo Senior Employee 8] commented that *'the agreement is that AMCo will not sell a product which competes with the Auden product'* and that *'Auden is [...] protected by the restriction on selling competing product'*.⁸⁷²

3.573. The supply deal was subject to further negotiation during the days that followed.⁸⁷³ On 18 June 2014, [AMCo Senior Employee 8] outlined two outstanding points to [AMCo Senior Employee 1]:

- a. The first point concerned the supply price: *'[t]hey are suggesting that the price be a fixed £1.78 per pack. This is a lot simpler than a rebate system, so are you happy to agree that? I believe that is around the Aesica cost of goods?'*
- b. The second point concerned the 'non-compete' clause: *'[t]hey are trying to be very cute around the non-compete and, I suspect, trying to tie up our ability to compete, to acquire other competing products or to give 3 months' notice and sell our own Aesica version (albeit with the OD issues). I really don't like this, nor trust them.'* Instead of the *'overly-complicated (and therefore risky to us) wording'* suggested by Auden, [AMCo Senior Employee 8] suggested to *'go with a simple clear English summary of what the non-compete should say'*. His proposal

⁸⁶⁹ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 15 June 2014.

⁸⁷⁰ Document 202680, email from [AMCo Senior Employee 1] to [Waymade Senior Employee 1] dated 16 June 2014.

⁸⁷¹ Document 00161, email from [AMCo Senior Employee 8] to [X] dated 16 June 2014. The outstanding points included the start date of June, a proposal for how to deal with shortfalls in supplies, and the definition of 'Product' in the agreement.

⁸⁷² Document 00162, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden McKenzie (Pharma Division) Limited and Amdipharm Limited, pages 5 and 6.

⁸⁷³ [AMCo Senior Employee 1] and [Auden Senior Employee 1] spoke on the phone on 17 June 2014. Document 202681, [AMCo Senior Employee 1]'s calendar entry for 17 June 2014: *'Call with [Auden Senior Employee 1]'*. Document 200123, email from [X] to [AMCo Senior Employee 8] dated 17 June 2014.

replaced reference in the provision to '*the Product*', which had been broadly defined in Auden's proposal,⁸⁷⁴ with '*any hydrocortisone product(s) in tablet formulation*'.⁸⁷⁵

- 3.574. [AMCo Senior Employee 1] agreed with [AMCo Senior Employee 8]'s proposed wording of the clause. With respect to the supply price, [AMCo Senior Employee 1] noted that '*[t]he CoGs [cost of goods] are higher than Aesica (£1-£4) per pack) though to be honest it is hardly worth fussing over especially as the price is going up in the market and it is over £50 now*'.⁸⁷⁶
- 3.575. [AMCo Senior Employee 8] therefore proposed his revised version of the clause to Auden's lawyer later that day. He proposed that the clause was '*changed to a simple clear English summary of the agreed position, which is that AMCo shall not sell other hydrocortisone tablets without giving 3 months [sic] notice (which would allow Auden to terminate on 3 months [sic] notice)*'.⁸⁷⁷ Auden's lawyer agreed.⁸⁷⁸
- 3.576. On 25 June 2014 the agreed terms of supply were formalised in an agreement for the supply of 10mg hydrocortisone tablets. It is hereafter referred to as the '**Second Written Agreement**'.⁸⁷⁹

i. Terms of the Second Written Agreement

- 3.577. The Second Written Agreement had an effective date of 25 June 2014 and a duration of two years.
- 3.578. AMCo agreed to:

'procure all its requirements in the Territory [the UK] for hydrocortisone product(s) in tablet and capsule formulation from Auden on an exclusive basis and shall not, directly or indirectly, distribute, supply or sell, in the Territory any other hydrocortisone product(s) in tablet or

⁸⁷⁴ Which Auden had sought to define as 'any medicinal product containing hydrocortisone as the active ingredient or one or more Similar Active Substance as those contained in the Auden Mckenzie hydrocortisone Tablet formulation' – see Document 200242, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden Mckenzie (Pharma Division) Limited and Amdipharm Limited, clause 1.

⁸⁷⁵ Document 200123, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 1] dated 18 June 2014.

⁸⁷⁶ Document 200123, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] dated 19 June 2014. [AMCo Senior Employee 1]'s '*main concern at the moment is that we get the first order this month*'.

⁸⁷⁷ Document 200252, email from [AMCo Senior Employee 8] to [X] dated 19 June 2014.

⁸⁷⁸ Document 200252, emails between [X] and [AMCo Senior Employee 8] dated 19 June 2014.

⁸⁷⁹ Document 00446, "Own Label" Product Supply Agreement (for Hydrocortisone 10mg tablets) by and between Auden Mckenzie (Pharma Division) Limited and Amdipharm Limited, effective date 25 June 2014. [AMCo Senior Employee 8] sent Pinsent Masons the draft supply agreement which had been agreed '*in principle*' by [X] and [AMCo Senior Employee 8] on 25 June 2014. [AMCo Senior Employee 8] asked [X] to check and confirm that she was '*fine with this being the final version*' (Document 201099, email from [AMCo Senior Employee 8] to [X] dated 25 June 2014), and chased her on 28 June 2014 to confirm as '*[w]e urgently need to sign*' (Document 201099, email from [AMCo Senior Employee 8] to [X] dated 28 June 2014). Pinsent Masons confirmed: '*Good to go*' (Document 201099, email from [X] to [AMCo Senior Employee 8] dated 28 June 2014).

*capsule formulation. However, for the avoidance of doubt, nothing in this Agreement prevents Amdipharm and/or its Affiliates from applying at any time for a marketing authorisation from the MHRA in relation to a hydrocortisone product (whether in tablet, capsule or other formulation) and/or manufacturing (either itself or through a contract manufacturer) and supplying in the Territory hydrocortisone product(s) under a licence granted to it or any of its Affiliates provided that Amdipharm shall not and shall procure that none of its Affiliates shall do so directly or indirectly without giving give [sic] Auden at least three (3) months' written notice of its intention to do so.*⁸⁸⁰

- 3.579. If AMCo notified Auden *'of its intention to commence supply of its own version of the Product in the Territory, Auden shall have the option to terminate this Agreement on three (3) months' written notice'* to AMCo.⁸⁸¹
- 3.580. The meaning of these two clauses together was therefore that if AMCo intended to supply its own hydrocortisone tablets in the market it was required to give Auden three months' written notice, which triggered a right for Auden to terminate the supply arrangement on the same notice period.
- 3.581. The Second Written Agreement could also be terminated immediately in case of a breach of any of its terms and failure to remedy that breach within 30 days; and by either party *'without cause on four (4) months written notice to the other.'*⁸⁸²
- 3.582. Under the Second Written Agreement, Auden agreed to supply AMCo with a *'Minimum Volume'* of 12,000 packs of 10mg hydrocortisone tablets per month (ie double the volume that Auden had been supplying AMCo under the First Written Agreement) for the price of £1.78 per pack.⁸⁸³ Auden's average price to the rest of the market at the time was £55 per pack. AMCo therefore continued to obtain a 97% discount to Auden's other customers.
- 3.583. AMCo and Auden agreed that Auden would supply a fixed volume of 12,000 packs per month for the first three months of the Second Written Agreement. For any subsequent orders, it was agreed that *'Auden shall use reasonable endeavours to accept all orders but is only obliged to accept orders representing the Minimum Volume [ie 12,000 packs] for each calendar month.'*⁸⁸⁴

⁸⁸⁰ Second Written Agreement, page 5, clause 2.2.

⁸⁸¹ Second Written Agreement, page 18, clause 17.2.

⁸⁸² Second Written Agreement, page 18, clauses 17.1.(a) and 17.4.

⁸⁸³ Second Written Agreement, page 22, Schedule A.

⁸⁸⁴ Second Written Agreement, page 8, clauses 5.1 and 5.2.

3.584. Auden was therefore only obliged to accept orders for up to 12,000 packs per month. In fact, although the Second Written Agreement stated that AMCo's '*Minimum Volume*' would be 12,000 packs, this was the maximum volume of 10mg hydrocortisone tablets available to AMCo at the £1.78 price during the term of the Second Written Agreement. This is demonstrated by data provided by the parties⁸⁸⁵ and by contemporaneous documentary evidence, set out in table 3.28 below.

Table 3.28: volumes supplied to AMCo under the Second Written Agreement

Document	Evidence
202758, emails between AMCo staff dated 16 January 2015	<i>'As far as I am aware monthly we are getting 12000 packs of Hydrocortisone tabs and the total of all these orders are coming up to 13500 packs.'</i> <i>'Please take 750 packs off each of the biggest orders.'</i>
200141, email from [AMCo Senior Employee 3] to AMCo staff dated 24 July 2015	<i>'Very stable market with set supply quantities each month of 12k units. Timing issues can see small monthly fluctuations but annual quantity is concrete'</i>
02331, email from [Auden Senior Employee 4] to [Actavis Senior Employee 2] of Accord-UK dated 6 August 2015	<i>'Amco ... Product supplied Hydrocortisone 10mg tablets: max 12,000 packs per month'</i>
200201, email from [AMCo Senior Employee 1] to AMCo staff dated 7 August 2015	<i>'the 12K packs that we get from Auden are sold to specific customers every month and we do not have any spare – I am sure we would struggle to get more'</i>
202817, 202818 and 202827, emails between [AMCo Employee] and [AMCo Employee] dated 7, 10 and 11 August 2015	[AMCo Employee]: <i>'Can we procure additional order (16667 packs) from Auden over and above the monthly ordering of 12000 packs?'</i> [AMCo Employee]: <i>'I have had to send an enquiry to our supplier for additional volumes as per this enquiry, we have an agreement for a regular volume per month so I will have to get their approval before I respond'</i> The following day, [X] asked: <i>'When will we have the product from aesica delivered?'</i> and suggested fulfilling the order <i>'on our own ma'</i> , indicating that AMCo would not use Auden product
200151, draft responses to questions relating to Cinven's sale of the AMCo group prepared by [AMCo Senior Employee 3] dated 18 August 2015	Question: <i>'Could you comment on the factor limiting supply to AMCo of 10mg tablets? For example, is it limited availability of the API, or limited supply by Auden McKenzie of the finished product?'</i> Answer: <i>'Limited supply to AMCo of the finished product'</i>

⁸⁸⁵ Document 00674, data supplied by Auden on its sales of hydrocortisone tablets to Waymade and AMCo. AMCo received 12,200 packs in December 2014; however, only the 12,000 packs were supplied at the £1.78 price. See also Document 00448, data supplied by AMCo on its purchases of 10mg hydrocortisone tablets.

Document	Evidence
202884, LEK Consulting presentation dated 21 August 2015, slides 83 and 86	<i>'AMCo's current supply of hydrocortisone tablets is sourced from Auden, and it has been limited in its ability to meet demand by lack of supply.'</i>
200034 and 200153, AMCo commercial reports dated August 2015	<i>'Very stable market share c 15% as fixed monthly supply volume of 12k (market is 80k/mth) ... Some small monthly discrepancies due to month end ordering but yrlly [sic] volumes fixed.'</i> <i>'Fixed supply volumes at ~15% of market'</i>
02311, emails between [Actavis Senior Employee 2] and [Actavis Senior Employee 1] of Accord-UK dated 4 September 2015	<i>'AmCo pay £1.78 for Hydrocortisone – you OK to continue selling at this price?'</i> <i>'This is the contracted price so OK. NB 12,000 packs per month is the contracted quantity.'</i>
02329, emails between [X] and [Actavis Senior Employee 2] of Accord-UK dated 4 and 7 September 2015	<i>'I see that AMCo pay £1.78 for the Hydrocortisone Tabs, this seems very low. Are we happy with this?'</i> <i>'Price is fine as it is contracted – vols should be 12k per month (one to keep an eye on)'</i>
200203, email from [AMCo Senior Employee 8] to AMCo staff dated 23 September 2015	<i>'AMCo currently sells hydrocortisone in the UK which is sources [sic] from Auden McKenzie ... There is a volume cap in this OLS agreement.'</i>
02312, email from [Actavis Senior Employee 4] of Accord-UK to Accord-UK staff dated 28 September 2015	<i>'the AMCO supply we have a contract to supply Uk pack on the 10mg at a certain price ... it's a set volume at a set price'</i>
02335, email from [X] to [Actavis Senior Employee 1] of Accord-UK dated 24 February 2016	<i>'Please see Amdipharm forecast as requested'</i> <i>I make sure that they have just the 1 order a month for 12,000 packs'</i>
200452, note of state of play meeting with AMCo dated 18 May 2016, paragraph 29	<i>'AMCo had pushed for – and had wanted – more volume but as far as he [AMCo Senior Employee 8] was aware AMCo had only ever got a volume of 12,000 packs, and AMCo at times had to push hard to even get supply at that volume. The reference to a "minimum" volume was at AMCo's request because AMCo wanted to make sure that it would definitely get at least 12,000 packs per month and that Auden would be in breach of the agreement if they did not supply this minimum amount.'</i>
202960, email from [X] to [AMCo Senior Employee 5] dated 21 June 2016	<i>'On Hydrocortisone with Auden, we generally release order for the forward 3months, each month 12000packs'</i>

ii. The status of AMCo's Aesica product by the time of the Second Written Agreement

- 3.585. As explained in paragraph 3.529.b, on the day the parties entered into the First Written Agreement (25 February 2014), AMCo expected that its own 10mg product '*will hopefully be available in April or May*'.⁸⁸⁶
- 3.586. During the subsequent negotiations that led to the Second Written Agreement, AMCo experienced some delays that caused it to adjust its expectations for the timeframe of launching its product. These delays did not, however, lead AMCo to question the viability of its product or to anticipate a materially longer lead time for its launch: by 23 June 2014, two days before entering into the Second Written Agreement, AMCo expected its product to be available for launch during the following month, July 2014.⁸⁸⁷
- 3.587. The delays AMCo experienced to the development of its Aesica product during this period were:
- Minor delays in March 2014 to the order of the API and sign-off on the foil and artwork for the batches it had ordered from Aesica. This meant that these items were approved in March instead of February as planned.⁸⁸⁸
 - Aesica's insistence in April 2014 that its packaging process using the new automated blister feeder be validated on three consecutive batches (rather than its original plan to validate initially using only the October 2013 bulk batch). This meant that '*the supply of Hydrocortisone from Aesica is now expected at the end of May*'.⁸⁸⁹
 - Aesica's uncertainty in late April 2014 as to whether it would require further API to complete manufacture of the third of the batches ordered on 30 January 2014. This did not affect the timeline for supply of the

⁸⁸⁶ Document 200511, minutes of MPGL Management meeting on 18 February 2014, page 2.

⁸⁸⁷ Document 202686, email from [Aesica Employee] to [AMCo Employee] dated 23 June 2014. See also Document 202684, email from [AMCo Employee] to [AMCo Employee] dated 23 June 2014.

⁸⁸⁸ AMCo approved the order for '*15kg API*' to be used for the manufacture of three additional batches on 19 March 2014, instead of the initially planned '*End February*' (Document 202987, email from [AMCo Employee] to [X] and [X] dated 19 March 2014; compare with Document 201829, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 21 February 2014). AMCo signed off on the foil artwork on 20 March 2014 and on the Carton & PIL artwork on 21 March 2014, instead of the second week of February (see Document 201853, email from [X] to [X] dated 20 March 2014; and Document 201856, email from [X] to [X] dated 21 March 2014; compare with Document 202947, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 7 February 2014).

⁸⁸⁹ Document 201862, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 10 April 2014. See also Document 201860, email from [AMCo Employee] to [Aesica Employee] dated 4 April 2014; Document 201865, email from [Aesica Employee] to [AMCo Employee] dated 1 May 2014.

other batches.⁸⁹⁰ Aesica ultimately asked AMCo on 22 May 2014 to order an additional 1kg of API for this batch.⁸⁹¹ AMCo agreed to purchase 11kg of API instead to cover the needs of the third batch and *'the next few batches'*.⁸⁹²

- d. The unsuccessful commissioning of the blister feeder at Aesica in May 2014, which meant the feeder was returned to the manufacturer *'for modification'*. Aesica and AMCo agreed to use expired stock for further testing to avoid delays.⁸⁹³ This meant that the launch batches could not be supplied at the end of May after all. AMCo considered the possibility of manually packing the tablets while the blister feeder was unavailable and whether this would be *'acceptable for commercial use'*. It was noted that AMCo needed the *'batches available for End May but [...] it looks like its [sic] not feasible.'*⁸⁹⁴ (Aesica ultimately confirmed that the issues with the blister feeder were resolved on 2 July 2014.⁸⁹⁵)

3.588. Notwithstanding these delays, AMCo's product development continued to progress towards launch:

- a. In April 2014 AMCo confirmed that instead of a Type 1B variation, it would be able to address its high assay results through a simpler Type 1A variation (known as *'do and tell'*), where the MA holder should implement the change before notifying the MHRA.⁸⁹⁶ This variation was submitted on 3 April.⁸⁹⁷ It was approved by the MHRA on 1 May 2014.⁸⁹⁸ The new licensed assay method had no impact on the quality

⁸⁹⁰ Document 201865, email from [Aesica Employee] to [AMCo Employee] dated 1 May 2014.

⁸⁹¹ Document 202686, email from [Aesica Employee] to [AMCo Employee] dated 22 May 2014.

⁸⁹² Document 201891, email from [AMCo Employee] to [AMCo Employee]s dated 22 May 2014. See also Document 202702, email from [Aesica Employee] to [AMCo Employee] and [§] dated 8 July 2014.

⁸⁹³ Document 201876, email from [Aesica Employee] to [AMCo Employee] dated 7 May 2014; and email from [AMCo Employee] to [Aesica Employee] dated 8 May 2014. See also Document 200189, Strategic Development – Monthly Report, May 2014, page 8.

⁸⁹⁴ Document 201868, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 5] and [AMCo Employee] dated 7 May 2014.

⁸⁹⁵ Document 202705, email from [Aesica Employee] to [AMCo Senior Employee 7] dated 2 July 2014.

⁸⁹⁶ Type 1A changes have little or no impact on the quality, safety or efficacy of the product, for example administrative modifications such as the manufacturer's name, a minor change to a control method or details of where the product is packaged. In Type 1A procedures, classed as *'do-and-tell'*, the MA holder should implement the change before notifying the MHRA, ensuring that where relevant (non-immediate notification) it submits the application within 12 months. The MHRA takes up to 30 days to process a type 1A application. Instead, if the change is more significant than a 1A change but is not a type II change or an extension, it is considered a type 1B change. MHRA must approve type 1B changes before they are made to the product. See Medicines: apply for a variation to your marketing authorisation - GOV.UK (www.gov.uk).

⁸⁹⁷ Document 201862, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Employee] and others dated 10 April 2014.

⁸⁹⁸ Document 201871, letter from the MHRA to AMCo dated 1 May 2014. See also Document 200189, Strategic Development – Monthly Report, May 2014, page 8; Document 202944, email from [§] to [AMCo Senior Employee 5], [§] and [§] dated 28 September 2016.

or stability of the product, other than to ensure accurate results for assay were reported.⁸⁹⁹

- b. On 16 April 2014, AMCo held an internal meeting where it agreed that *'[a]ll activities must be placed on priority to ensure we have product release at the end of May.'*⁹⁰⁰ At this stage, AMCo expected to *'have increased volume once we have our own product in June and the price has gone up.'*⁹⁰¹
 - c. A strategic development report for May 2014, presented to Cinven and prepared on 27 May, stated in relation to *'Hydrocortisone Tablets': 'UK Launch in June 2014.'*⁹⁰²
 - d. An AMCo management meeting on 29 May 2014 noted: *'we are having further problems with our own product [...]. It is now due in July.'*⁹⁰³
 - e. Between 30 May and 10 June 2014, Aesica and AMCo further discussed the status of the blister feeder. Ultimately no modifications to the equipment/tooling were needed.⁹⁰⁴
 - f. On 10 June 2014 Aesica informed AMCo that the October 2013 bulk batch had passed testing and was *'ready for packaging'*, and that the other batches were now being tested.⁹⁰⁵
- 3.589. On 23 June 2014, two days before entering into the Second Written Agreement with Auden, AMCo was preparing to pick up the 10mg stock from Aesica in early July 2014.⁹⁰⁶
- 3.590. On the same day, Aesica confirmed to AMCo that it was *'targeting first shipment during the week commencing 14 Jul 2014'* (though it emphasised that this was *'a very aggressive timeline'*) and that the third of the batches ordered in January 2014 (referred to as *'Batch 4'* as the first of AMCo's

⁸⁹⁹ Document 200302, Aesica's response to the CMA's notice of 25 August 2016, response to question 4.

⁹⁰⁰ Document 202654, Meeting minutes: Hydrocortisone Aesica 10mg tab dated 16 April 2014. See also Document 202644, calendar invite from [AMCo Employee] to [X], [X], [AMCo Employee] and others for 16 April 2014, where [AMCo Employee] set out that *'I will have an update on launch batch manufacturing and packaging plans and we can start coordinating launch activities (May / June).'*

⁹⁰¹ Document 202645, email from [AMCo Senior Employee 4] to [X] dated 17 April 2014 commenting on email from [X] to [AMCo Senior Employee 4] and [X] dated 16 April 2014.

⁹⁰² Document 202667, AMCo strategic development strategic projects PPRM presentation May 2014, slide 3, attached to document 202666, email from [AMCo Senior Employee 7] to AMCo staff including [AMCo Senior Employee 2], who noted *'I am pulling together a presentation for Cinven next week of the Strategic Development group'*.

⁹⁰³ Document 200161, minutes of MPGL Management meeting on 29 May 2014, page 3.

⁹⁰⁴ Document 202686, emails between [Aesica Employee] and [AMCo Employee] dated 30 May – 10 June 2014.

⁹⁰⁵ Document 202686, email from [Aesica Employee] to [AMCo Employee] dated 10 June 2014.

⁹⁰⁶ Document 202684, email from [AMCo Employee] to [AMCo Employee] dated 23 June 2014.

commercial batches derived from its October 2013 bulk stock) was scheduled to be manufactured in August 2014.⁹⁰⁷

k. AMCo suspends its Aesica development on the same day as entering into the Second Written Agreement

3.591. In summary:

- a. On the day it entered into the Second Written Agreement, AMCo resolved to suspend its Aesica development and cancel outstanding orders and any future orders of its own product.
- b. Once it was delivered from Aesica on 8 August 2014, AMCo kept its product in 'quarantine' and explored selling it overseas.

3.592. On the day AMCo and Auden entered into the Second Written Agreement, 25 June 2014, AMCo held a meeting. A summary of what was agreed at that meeting was circulated by [AMCo Senior Employee 5] to AMCo's most senior management and to the technical and product development staff involved in AMCo's Aesica project. The summary read:

'Summary of agreement from today's PPRM meeting

Why [original emphasis]

New supply agreement signed with Auden

Will not be able to sell our own product (produced at Aesica) in the UK

Aesica [original emphasis]

*We will advise Aesica that the project is now parked due to delays but may be restarted in the future (**we do not mention the Auden agreement**) [original emphasis]*

We will continue with the packing of the three available batches at Aesica to complete this phase of the project

We will cancel the order for the 4th batch and any other subsequent orders that have been placed with Aesica

⁹⁰⁷ Document 202686, email from [Aesica Employee] to [AMCo Employee] dated 23 June 2014.

We would like to ensure Aesica are fully compensated for their costs that are over and above supply of the three batches (e.g. surplus materials, people costs etc)

Request Aesica to advise these costs and include in invoice upon delivery of stock

Stock *[original emphasis]*

The packed product will be held in store as a contingency against failure to supply from Auden

We wish to hold this stock at UDG (not Waymade) in quarantine, probably on a different sku.

(there is, should we wish not to hold this in reserve, possibilities to sell in a to be identified export market)

I suggest that I will write to Aesica detailing these points (plus expressing apologies and regret...blah blah blah at the cancellation of the project)

I will write to Aesica on Friday so if you have any additional comments, please let me know before midday Friday.

I will also request that supply chain ([redacted]) raises this, in due course, with UDG.⁹⁰⁸

3.593. The summary records that AMCo would not be able to sell its Aesica product in the UK; and that AMCo had therefore decided that:

- a. It would suspend its Aesica development, cancelling the outstanding order for its fourth batch (the third of the batches ordered in January 2014) and any subsequent orders and offering to compensate Aesica for its costs; and
- b. It would complete the packing of the other three batches and hold them as a contingency against a breakdown in the supply arrangement, or alternatively to sell overseas.

3.594. On the same day, [AMCo Senior Employee 2] emailed [AMCo Senior Employee 1] to raise concerns about the morale of AMCo's development

⁹⁰⁸ Document 200124, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 2], [AMCo Senior Employee 7] and [AMCo Employee], copied to [AMCo Senior Employee 1], [AMCo Senior Employee 6], [AMCo Employee], [redacted] and [AMCo Employee], dated 25 June 2014.

team and asked [AMCo Senior Employee 1] to recognise and thank them for their efforts:

'... we're a little concerned that the Strategic Projects team may be very demotivated after hearing today at PPRM that all their efforts to get Hydrocortisone ready for launch have been "wasted" because we're now not planning to sell the product. Also, this has a real adverse impact on the "new product revenues" which the whole Strat Dev team is targeted on, and I think we need to somehow recognise that:

(a) all their hard work facilitated the AM deal, and the main commercial benefit is that we now have long-term supply secured of a product with the full range of indications. This wouldn't have been possible without being launch-ready with our own product (or words to that effect); and

(b) the Aesica product gives us an excellent back-up for a very valuable and important project, in line with our Ops Excellence BAP, in the event that our new supply agreement partner defaults on supply (hence we're going to pack our 3 batches and leave in quarantine); and

*to somehow think about a compensatory element for their New Product Revenues target, which has been massively impacted in 2014 by not launching this product which they worked so hard to secure.'*⁹⁰⁹

3.595. [AMCo Senior Employee 1] sent an email to this effect on 28 June 2014:

'I just wanted to drop you a note to thank you for all the effort that you put into bringing the Aesica Hydrocortisone product to a position where we were able to launch.

As you know we have subsequently signed a deal with Auden Mackenzie [sic] to source product from them and therefore our own product will not be launched in UK. The rationale for this arrangement is that their product has an indication, Adrenal Insufficiency, that our product does not and hence selling their product removes a competitive disadvantage.

What I would like to stress though is that the work that you did to provide certainty of launch of our product gave those of us who were negotiating with Auden Mackenzie confidence to achieve the best deal

⁹⁰⁹ Document 200125, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1], copied to [AMCo Senior Employee 4] and [AMCo Senior Employee 5], dated 25 June 2014. On the same day, [AMCo Senior Employee 1] replied 'Yes you are right...and I agree with everything you say'.

possible for AMCo and I am sure that, as a result, Auden Mackenzie felt that they should agree to our terms.

*We are certainly in a much better position as a result of your work so again may I reiterate my thanks to you.*⁹¹⁰

- 3.596. AMCo's June 2014 monthly report stated: *'Hydrocortisone 10mg batches manufactured and ready for sale ... however, these won't be sold due to a deal extension being signed with Auden McKenzie'*.⁹¹¹ AMCo staff described the project as: *'virtually complete. Currently no intention to launch.'*⁹¹²
- 3.597. On 27 June 2014, [AMCo Senior Employee 5] wrote to Aesica to inform it that AMCo's 10mg hydrocortisone tablets project would *'be suspended for the UK territory'* and asking, *'Please cancel your plans for the manufacture of further batches'*.⁹¹³ In a later email to Aesica on 14 July 2014 [AMCo Senior Employee 5] described this message as *'the notification of the cancellation of the UK project'*.⁹¹⁴
- 3.598. Further to notifying Aesica of the cancellation of the project for the UK, AMCo asked Aesica to provide a quotation to explore *'opportunities for this product [10mg hydrocortisone tablets] in Germany'* and specified that *'the formulation and packaging materials are the same as those for the UK product that you have recently produced for us.'*⁹¹⁵
- 3.599. AMCo considered exporting its Aesica product to Serbia. However, after discussion AMCo concluded that this was not worthwhile because of the risk of parallel importation back into the UK. [AMCo Senior Employee 1] stated: *'Their target price is very close to Aesica CoGs and we also would be in danger of the product coming back into the UK – which is bad enough in itself but could also put us in breach of the contract that we have here with AM.'*⁹¹⁶
- 3.600. AMCo proceeded with the packing and shipping of the three already manufactured batches at Aesica. On 2 July 2014, Aesica confirmed that the

⁹¹⁰ Document 200126, email from [AMCo Senior Employee 1] to AMCo staff dated 28 June 2014.

⁹¹¹ Document 200192, AMCo strategic development report for June 2014.

⁹¹² Document 202696, email from [AMCo Employee] to [AMCo] dated 1 July 2014. See also Document 202737, email from [AMCo] to [AMCo] and [AMCo] dated 21 October 2014.

⁹¹³ Document 200275, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 27 June 2014.

⁹¹⁴ Document 202717, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 14 July 2014. See also Document 202992, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 30 June 2014.

⁹¹⁵ Document 202717, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 27 June 2014. Aesica provided AMCo with a *'proposal covering the 3 pack formats of Hydrocortisone for Germany'* on 11 August 2014: see Document 202717, email from [Aesica Employee] to [AMCo Senior Employee 5] dated 11 August 2014.

⁹¹⁶ Document 203640, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 9], [AMCo Senior Employee 8] and others dated 30 June 2014.

issues with the blister feeder had been resolved and expected to *'still be okay for W/C 14 Jul for first shipment.'*⁹¹⁷

- 3.601. On 8 July 2014, Aesica suggested that it *'may be in a position to purchase'* the API which it assumed *'was to be used to fulfil the original commercial demand'* and which it believed *'will no longer be required for commercial use.'* AMCo sold the excess stock of hydrocortisone API to Aesica in December 2014.⁹¹⁸
- 3.602. On 9 July 2014, Aesica informed AMCo that it was *'still on track for batch release and shipping next week. I think we are nearly there! Champagne is ready to go on ice!'*,⁹¹⁹ and indicated the *'pick-up date of July 15th.'*⁹²⁰ [AMCo Senior Employee 7] congratulated [AMCo Employee]: *'[g]reat news if pick up is on the 15th! Regardless of the strategy you have made the batches available for sale as promised!'*⁹²¹
- 3.603. [AMCo Senior Employee 2] and [AMCo Senior Employee 1] discussed the implications of not launching the Aesica product for the team's financial targets and queried if they could consider it as a 'launch'.⁹²² [AMCo Senior Employee 2] suggested: *'[i]f we could get to somehow launch a few boxes into a segment that AM [Auden McKenzie] won't notice, it would count as a launch ... any chance? It seems a bit harsh to deny the team a "launch" having done all this work, especially as it has also dropped the New Product Revenues forecast.'*⁹²³ [AMCo Senior Employee 4] confirmed that this was not possible: *'[w]e can't legally due to the exclusive agreement we have.'*⁹²⁴
- 3.604. On 29-30 July 2014, AMCo considered this further.⁹²⁵ [AMCo Senior Employee 1] suggested that AMCo needed to have *'some creative finance thinking on this'*.⁹²⁶ However, although [AMCo Senior Employee 6] ([X]) agreed that AMCo staff should be recognised and *'get the credit'*, he explained that *'externally [...] classifying this as a new product launch will*

⁹¹⁷ Document 202705, email from [Aesica Employee] to [AMCo Senior Employee 7] dated 2 July 2014.

⁹¹⁸ Document 202702, email from [Aesica Employee] to [AMCo Employee] and [X] dated 8 July 2014; and Document 200386, email from [X] to [X] and [X] dated 23 April 2015.

⁹¹⁹ Document 202705, email from [Aesica Employee] to [AMCo Senior Employee 7] dated 9 July 2014.

⁹²⁰ Document 202705, email from [AMCo Employee] to [AMCo Senior Employee 7] and [Aesica Employee] dated 10 July 2014.

⁹²¹ Document 202705, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 10 July 2014.

⁹²² [AMCo Senior Employee 1] wondered *'whether we could call it a launch as it really is the start of a new deal?'* – see Document 202704, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] and [AMCo Senior Employee 6] dated 10 July 2014.

⁹²³ Document 203642, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 4] dated 10 July 2014.

⁹²⁴ Document 203642, email from [AMCo Senior Employee 4] to [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 10 July 2014.

⁹²⁵ Document 202712, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 29 July 2014.

⁹²⁶ Document 202712, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 30 July 2014.

*undermine our credibility and risk that potential buyers will see our story as 'fabricated'.*⁹²⁷ [AMCo Senior Employee 1] responded that he would get Cinven's ideas as *'they are good at this stuff'*.⁹²⁸

- 3.605. Between 11 and 16 July 2014, Aesica informed AMCo that *'due to the delays encountered at the start of the packaging run'* the dispatch date for the three batches was now set for 31 July 2014.⁹²⁹ The expiration date of batch 1 (taken from the bulk stock manufactured in October 2013) was 31 March 2015. The expiration date of batches 2 and 3 (from the orders placed in January 2014) was 31 October 2015.⁹³⁰
- 3.606. On 23 July 2014, in anticipation of receiving the Aesica product, [AMCo Senior Employee 2] emailed AMCo colleagues: *'[w]e have some UK packs of Hydrocortisone 10mg sitting in a warehouse, which won't be sold in the UK any time soon. Is there anywhere else that we could sell it (outside the EU)?'*⁹³¹
- 3.607. On 1 August 2014, AMCo commented internally that *'[t]he shipment would be collected on 4th Aug from Aesica' to be 'delivered at UDG'*.⁹³²
- 3.608. On 7 August 2014, [AMCo Senior Employee 7] instructed [AMCo Employee] to *'make sure the stock is kept under quarantine storage once released as we are not selling these batches for now.'* [AMCo Senior Employee 7] also requested to *'advise when the batches are "released" by the Quality dept even though we are keeping them in quarantine for now.'*⁹³³
- 3.609. During August 2014, AMCo began corresponding with Aesica to update the dossier for its 10mg tablets in order to sell them overseas.⁹³⁴

⁹²⁷ Document 202712, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 30 July 2014.

⁹²⁸ Document 202712, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 30 July 2014.

⁹²⁹ Document 201898, email from [X] to [AMCo Employee] dated 11 July 2014; Document 201903, email from [X] to [AMCo Employee] dated 15 July 2014; and Document 201904, email from [X] to [AMCo Employee] dated 16 July 2014. See also Document 202712, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 29 July 2014; and Document 201911, email from [X] to [AMCo Employee] dated 31 July 2014.

⁹³⁰ Document 202743, email from [AMCo Senior Employee 9] to AMCo staff dated 12 November 2014. See also Document 201912, Invoice issued by Aesica dated 31 July 2014.

⁹³¹ Document 202709, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 9] and [X] dated 23 July 2014. See also Document 202965, email from [AMCo Senior Employee 7] dated 28 July 2014; and Document 202713, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 2] dated 31 July 2014; and Document 202724, email from [AMCo Senior Employee 7] to [AMCo Employee] and others dated 18 August 2014; and Document 202725, email from [AMCo Employee] to [AMCo Senior Employee 7] dated 20 August 2014.

⁹³² Document 201913, email from [AMCo Employee] to [AMCo Employee] dated 1 August 2014.

⁹³³ Document 201914, emails from [AMCo Senior Employee 7] to [AMCo Employee] and [AMCo Employee] dated 7 and 8 August 2014.

⁹³⁴ Document 202727, emails between [X] and [AMCo Employee] dated 29 August 2014.

3.610. On 8 August 2014, AMCo received the three packed batches of 10mg hydrocortisone tablets from Aesica (the '**August 2014 Batches**'). [AMCo Employee] confirmed that the August 2014 Batches were '*booked in at UDG*' (AMCo's third party warehouse supplier).⁹³⁵

3.611. The August 2014 Batches remained in 'quarantine' in AMCo's warehouse. A quarantine measure means '*the warehouse would not be able to book it out of the system*' and sell the product.⁹³⁶ When AMCo staff queried the status of the Aesica product, they were informed:

'The batch manufactured at the end of last year is now packed but there is no intention to release it to the market due to contractual reasons.

*Two further batches have been manufactured since the above, but again these will not be marketed.*⁹³⁷

3.612. During August and September 2014, AMCo considered 'releasing' the August 2014 Batches from quarantine in order to make them available for sale – not in the UK but overseas. This required approval from AMCo's '[REDACTED]', [AMCo Employee]. [AMCo Employee] did not immediately understand why AMCo wished to release product developed and approved for sale in the UK for sale overseas. Other AMCo staff explained to her that this was because AMCo could not sell the product in the UK '*for contractual reasons*':

- a. On 14 August 2014 [AMCo Employee] explained that she had been asked to release the three batches for quality purposes (meaning that they could be sold if AMCo wished) but that she had been told '*that they are not going to sell this product. I wanted to make sure all checks are performed before I release the product from our system so requested PV [Process Validation] data. I have not been instructed that these batches are going to be rejected. So I hope the batches which we have received are oaky [sic] and can be approved.*'⁹³⁸ [AMCo Employee] replied: '*The batches won't ne [sic] sold because of contractual reasons (commercial). They are not rejected.*'⁹³⁹

⁹³⁵ Document 201914, email from [AMCo Employee] to [AMCo Senior Employee 7] and [AMCo Employee] dated 8 August 2014.

⁹³⁶ Document 201541, transcript of interview with [AMCo Senior Employee 7] dated 13 October 2017, track 2 page 6 lines 1-11.

⁹³⁷ Document 202723, email from [AMCo Employee]s to [REDACTED] dated 14 August 2014.

⁹³⁸ Document 202732, email from [AMCo Employee] to [REDACTED], [AMCo Employee], [REDACTED] and others dated 14 August 2014.

⁹³⁹ Document 202732, email from [AMCo Employee] to [AMCo Employee], [AMCo Employee], [REDACTED], [REDACTED] and others dated 14 August 2014.

- b. On 18 August 2014, [AMCo Employee] chased [AMCo Employee] requesting her to *'confirm that the batches are released / kept under quarantine at UDG'*.⁹⁴⁰ [AMCo Senior Employee 7] explained that *'Just for the record we won't be selling these batches in the UK but may do so somewhere else. If they are released and ready to be sold it would be very helpful.'*⁹⁴¹ [AMCo Employee] further explained: *'The original plan was to sell this product in the UK (UK MA, UK packaging). However, for contractual reasons, we cannot sell this product in the UK.'*⁹⁴² [AMCo Senior Employee 7] added: *'In summary we just need to know that the batches are released and ready to sell if we decide we have a customer. Please can you confirm this?'*⁹⁴³
- c. [AMCo Employee] responded that *'these batches are packed for UK market and will not get released to any other market without proper deviation in place. I do not understand why you want to release the product if you don't want to sell in UK? If you wish to sell this in any other market please raised [sic] it as a planned deviation.'*⁹⁴⁴
- d. [AMCo Senior Employee 7] explained: *'At present we do not know where we can sell these batches. However, we MAY want to. In this case a planned deviation will be raised.'*⁹⁴⁵
- e. In early September 2014, [AMCo Employee] chased [AMCo Employee] again: *'Can you confirm if these batches are ready to be released for sale should we be able to identify a market (not the UK) where they can be sold? If not, please explain what is required.'*⁹⁴⁶

3.613. In order to approve the release of the August 2014 Batches for overseas sale, [AMCo Employee] and other AMCo staff followed up internally with a series of questions relating to stability issues discussed in December 2013

⁹⁴⁰ Document 202732, email from [AMCo Employee] to [AMCo Employee] and [AMCo Employee] dated 18 August 2014.

⁹⁴¹ Document 202725, email from [AMCo Senior Employee 7] to [AMCo Employee] [AMCo Employee] and [AMCo Employee] dated 18 August 2014. See also Document 202732, emails between [AMCo Senior Employee 7], [AMCo Employee], [AMCo Employee] and [AMCo Employee] dated 20 August 2014: for example, [AMCo Senior Employee 7] explained: *'[I]n summary we just need to know that the batches are released and ready to sell if we decide we have a customer. Please can you confirm this?'*

⁹⁴² Document 202765, email from [AMCo Employee] to [AMCo Employee] dated 20 August 2014 (emphasis added).

⁹⁴³ Document 202765, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 20 August 2014.

⁹⁴⁴ Document 202732, email from [AMCo Employee] to [AMCo Senior Employee 7] dated 20 August 2014.

⁹⁴⁵ Document 202732, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 26 August 2014. See also: Document 202724, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 26 August 201, in which [AMCo Senior Employee 7] explained: *'I would just like confirmation that these batches are OK to be sold elsewhere from a quality point of view if we would like to'.*

⁹⁴⁶ Document 202732, email from [AMCo Employee] to [AMCo Senior Employee 7] and [AMCo Employee] dated 5 September 2014.

(see section 3.F.II.b.ii above),⁹⁴⁷ apparently unaware that these issues had already been resolved and that the MHRA had approved the variation for the new assay analytical method on 1 May 2014.

I. Aesica identifies an issue affecting the packaging of the August 2014 Batches

3.614. In summary:

- a. On 5 September 2014 Aesica notified AMCo that it had packed the August 2014 Batches in foil that was thinner than specified on AMCo's MA. The batches were already being held in quarantine.
- b. Over the following four months AMCo continued to explore selling its August 2014 Batches overseas. AMCo also explored applying to the MHRA to vary the terms of its MA to allow for the thinner foil. It did not, however, treat this as an operational priority.

3.615. On 4 September 2014, Aesica discovered that the August 2014 Batches had been packed in foil with the wrong thickness: whereas AMCo's 10mg MA provided for foil of 25 µm (microns), Aesica had used 20 µm. This meant that the blister packs used for the August 2014 Batches were 5 µm thinner than specified on the licence.

3.616. Aesica notified AMCo the following day. Aesica asked AMCo to confirm if the packs had been distributed as the issue *'could have potential to lead to a Recall'* although explained: *'[i]nitial review has been completed and we believe it is a compliance issue rather than [sic] a product safety issue. we are generating an impact assessment which will support our initial conclusion.'*⁹⁴⁸

3.617. [AMCo Employee] ordered the August 2014 Batches to be put *'on hold immediately'*.⁹⁴⁹ [AMCo Employee] confirmed that the August 2014 Batches had already been put on hold prior to Aesica notifying AMCo of the foil issue, because of the *'contractual reasons'* that prevented AMCo from selling them in the UK: *'Batches will not get released for sale as we are not going to market our product in UK as per our agreement with Auden Mckenzie. It's a*

⁹⁴⁷ Document 202725, email from [AMCo Employee] to [AMCo Senior Employee 7] dated 20 August 2014; Document 202722, email from [AMCo Employee] to [AMCo Senior Employee 7] dated 20 August 2014; Document 202723, emails between [§] and [AMCo Employee] dated 21 August 2014; Document 201915, email from [AMCo Employee] to [§] and [Aesica Employee] dated 2 September 2014; and Document 202732, email from [AMCo Employee] to [§] dated 5 September 2014.

⁹⁴⁸ Document 201067, email from [§] to [AMCo Employee] dated 5 September 2014. See also Document 202732, email from [AMCo Employee] to [§] and [AMCo Employee] dated 8 September 2014.

⁹⁴⁹ Document 201067, email from [AMCo Employee] to [§], [§], [§], [§] and [AMCo Employee] dated 5 September 2014. See also Document 202732, email from [AMCo Employee] to [§] and [AMCo Employee] dated 8 September 2014.

*management decision. But SBDG team wish to market this product in some other territories which they have not yet finalised [sic].*⁹⁵⁰ Much later, on 5 May 2017, [AMCo Employee] explained: *'I can recollect there was OOS in assay test for hydrocortisone 10mg Tablets, but that was not the only reason for putting batches on hold. Mainly batches were on hold for Uk [sic] due to contractual agreement with Auden Mackenzie [sic] and when we asked to release the batches for other markets that time we were informed about the OOS and thickness issue which turn lead to reject the batches.'*⁹⁵¹

- 3.618. On 8 September 2014, Aesica shared the draft investigation report with AMCo ahead of a meeting the following day.⁹⁵² The meeting notes recorded: *'[b]ased on the review AMCo and Aesica confirmed that they would conclude that there is no impact on product quality as a result of the event.'* In addition, *'AMCo have confirmed that all 3 batches are in quarantine and no product has been supplied to the market.'*⁹⁵³
- 3.619. Between September and December 2014, AMCo continued to explore whether the August 2014 Batches could be released for sale outside of the UK (or, if necessary, in the UK *'[i]f there are problems with the current supply'*).⁹⁵⁴
- a. Despite issues with the foil, on 30 September 2014 [AMCo Employee] requested an update *'to understand if these batches can be sold outside the UK.'* [AMCo Senior Employee 7] added: *'we may even sell these batches in the UK. If there are problems with the current supply we must be in a position to sell these batches at short notice'*.⁹⁵⁵
 - b. On 22 October 2014 [AMCo Senior Employee 2] asked colleagues: *'We have 3 batches of UK packs for this product, which is sitting in UDG but unlikely ever to be sold. Is there anywhere we think we could sell this product?'*⁹⁵⁶

⁹⁵⁰ Document 202732, email from [AMCo Employee] to [AMCo Employee] and [REDACTED] dated 8 September 2014.

⁹⁵¹ Document 202929, email from [AMCo Employee] to [AMCo Employee] dated 5 May 2017.

⁹⁵² Document 201068, email from [Aesica Employee] to [AMCo Employee], [REDACTED], [REDACTED] and others dated 8 September 2014.

⁹⁵³ Document 202734, Compliance Event Meeting (Hydrocortisone 10 mg Tablets) dated 9 September 2014. On 13 March 2014, Aesica had requested AMCo to sign off on the bill of materials and the specifications for the blister foil and blister film ahead of the packaging process and obtained sign-off on 20 March 2014 (see Document 201848, email from [Aesica Employee] to [AMCo Employee], [AMCo Employee] and [AMCo Senior Employee 7] dated 13 March 2014; and Document 201853, email from [REDACTED] to [REDACTED] dated 20 March 2014).

⁹⁵⁴ Document 201067, email from [AMCo Senior Employee 7] to [AMCo Employee] and [AMCo Employee] dated 30 September 2014.

⁹⁵⁵ Document 201067, email from [AMCo Senior Employee 7] to [AMCo Employee] and [AMCo Employee] dated 30 September 2014.

⁹⁵⁶ Document 202738, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 9], [REDACTED] dated 22 October 2014. See also Document 202740, emails between [AMCo Employee] and [AMCo Employee] dated 27 and 28 October 2014.

- c. On 12 November 2014, [AMCo Senior Employee 9] emailed AMCo staff indicating that *'[t]he UK has surplus stock of the attached with the below expiry dates which they will most likely not be able to sell. Where applicable (mkts that can take stock based on a UK license) can you please check with our partners if there is any interest in taking this'*.⁹⁵⁷ During November 2014 AMCo considered opportunities to submit to a tender in Serbia,⁹⁵⁸ and to export its Aesica-manufactured 10mg hydrocortisone stock to the *'Nordic region'*, specifically noting that the product *'won't find it's [sic] way back to the UK'*.⁹⁵⁹
- d. In December 2014, AMCo also considered exporting its product to an African market.⁹⁶⁰ (It finally decided against selling its August 2014 Batches in Sudan in August 2015.⁹⁶¹) On 18 December 2014, [AMCo Senior Employee 2] explained: *'[t]he packs have been produced for UK < but we can't now sell them because we have tied ourselves up with another supplier. Therefore the packs are available for export sale. We might as well make some money out of it.'*⁹⁶²

3.620. Between September and December 2014, AMCo also explored whether it should apply to vary its 10mg MA to add 20 micron foil:

- a. On 16 September 2014, [AMCo Employee] emailed Aesica to ask whether it would be worth *'submitting a variation to add 20 micron to the license'*.⁹⁶³
- b. On 30 September 2014, [AMCo Employee] stated that a variation to add the new foil thickness would require justification by comparing the two foil thicknesses, but added: *'It's not something that we can fix immediately and are not currently working on it due to other Operational priorities but if it is that significant we will have to re-prioritise'*.⁹⁶⁴

⁹⁵⁷ Document 202743, email from [AMCo Senior Employee 9] to AMCo staff dated 12 November 2014.

⁹⁵⁸ Document 202744, email from [§] to [§] dated 13 November 2014. In response, [AMCo Employee] noted again on 14 November 2014 that *'[t]he stock received from Aesica is under quality hold. These batches have been packed using Foil that has a thickness specification outside of the registered specification [...] Currently there are no plans of future procurement'* (see the same document).

⁹⁵⁹ Document 202745, email from [AMCo Employee] to [AMCo Employee] dated 20 November 2014. On 9 December 2014, [AMCo Employee] sent a project appraisal for hydrocortisone 10mg tablets, see Document 202751, email from [AMCo Employee] to [§] dated 9 December 2014.

⁹⁶⁰ Document 202755, email from [AMCo Senior Employee 2] to [§] and [§] dated 18 December 2014, and email from [§] to [§] and [§] dated 18 December 2014 (same document).

⁹⁶¹ Document 202819, email from [§] to [§] dated 10 August 2015. See also Document 200201, emails between [AMCo Senior Employee 8] and [§] dated 7 August 2015.

⁹⁶² Document 202755, email from [AMCo Senior Employee 2] to [§] and [§] dated 18 December 2014.

⁹⁶³ Document 201068, email from [AMCo Employee] to [Aesica Employee], [§], [§] and others dated 16 September 2014.

⁹⁶⁴ Document 201067, email from [AMCo Employee] to [AMCo Senior Employee 7], [AMCo Employee] and [AMCo Employee] dated 30 September 2014.

- c. On 16 October 2014, [Aesica Employee], confirmed that Aesica *'would be happy to support a strategy to submit a variation to the Hydrocortisone 10 mg Tablet dossier to add 20 micron foil. [...] I think we can put together a suitable justification to support why existing stability data is acceptable plus we have 2 batches on stability in 20 micron foil – so initial data points will be available from these studies to submit with.'*⁹⁶⁵
- d. At the PPRM on 22 October 2014, AMCo discussed *'the release of the Hydrocortisone batches manufactured by Aesica and how quickly/easily this could be done'*.⁹⁶⁶ [AMCo Senior Employee 5] relayed internally: *'[w]hile we do not currently intend to sell the stock, we would like to arrange to have it "released" so that we could sell if the need arises immediately'* and requested to *'take the necessary actions to have these batches released (but with UDG blocked from issuing is [sic])'*.⁹⁶⁷ [AMCo Employee] replied that Aesica would support the application to register the new foil thickness.⁹⁶⁸
- e. On 23 October 2014, Aesica confirmed that *'[s]amples [of the August 2014 Batches] have been placed on stability'* to support the application to vary the foil thickness.⁹⁶⁹
- f. On 28 November 2014, AMCo requested Aesica to provide *'documents to support the change request for foil thickness'*,⁹⁷⁰ and later chased, explaining that *'we would like to be able to sell them rather than write them off and we do need your support in order to be able to do this (especially for the first batch which was manufactured more than a year ago)'*.⁹⁷¹ Aesica provided the requested documentation on 8 December 2014.⁹⁷²
- g. On 2 December 2014, AMCo signed a deviation report form which set out that *'[t]he decision to register the 20µm foil for the product has been taken and Change Control [...] has been raised to document the*

⁹⁶⁵ Document 201068, email from [Aesica Employee] to [AMCo Employee] dated 16 October 2014.

⁹⁶⁶ Document 200383, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 22 October 2014. See also Document 201068, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 22 October 2014.

⁹⁶⁷ Document 202739, email from [AMCo Senior Employee 5] to [REDACTED] and [AMCo Employee] dated 22 October 2014.

⁹⁶⁸ Document 202739, email from [AMCo Employee] to [AMCo Senior Employee 5] and [REDACTED] dated 22 October 2014.

⁹⁶⁹ Document 201923, email from [AMCo Employee] to [AMCo Employee] dated 16 December 2014.

⁹⁷⁰ Document 201069, email from [REDACTED] to [Aesica Employee] dated 28 November 2014.

⁹⁷¹ Document 200278, email from [AMCo Employee] to [Aesica Employee] dated 3 December 2012. See also Document 201069, email from [REDACTED] to [Aesica Employee] dated 1 December 2014.

⁹⁷² Document 201069, email from [Aesica Employee] to [REDACTED] dated 8 December 2014.

*change and identify all [...] tasks required. The future release of the batches will depend upon the outcome of the change control.*⁹⁷³

3.621. Other than the potential variation to add 20 micron thickness foil, AMCo did not consider that there was any further work for Aesica to complete with regards to its 10mg hydrocortisone tablets. On 21 October 2014, AMCo commented that there was *'very little going on with this product at Aesica. There is nothing for project team to do that's for sure.'*⁹⁷⁴

3.622. By January 2015 AMCo had begun to consider whether instead of applying to vary the foil thickness on its MA, it should simply apply for batch specific variations to cover the 20 micron foil on the August 2014 Batches, allowing them to be sold, and have Aesica pack any future batches in 25 micron foil.⁹⁷⁵

m. Auden resumes Project Guardian in response to a new threat from Orion and Allergan's concerns about the security of its position

3.623. In summary:

- a. From September 2014 onwards Auden entered into negotiations with Allergan (then known as Actavis) for the sale of AM Pharma.
- b. In the course of those negotiations, both parties became aware that a new potential competitor had been granted a skinny label 10mg MA.
- c. In response to this development, Auden resumed Project Guardian. However, its approaches were once again rebuffed by authorities.
- d. It therefore became clear that Auden was unlikely to succeed in preventing off-label dispensing of competing skinny label hydrocortisone tablets. This resulted in Allergan agreeing a £220 million reduction in the purchase price of Auden, combined with an earn-out on sales of hydrocortisone tablets.

3.624. As explained in section 3.F.III.h above, Project Guardian was conceived in early 2014 as Auden's response to the threat posed specifically by AMCo's

⁹⁷³ The report set out that *'the thicker foil was unlikely to be required for product protection'* and that *'[t]he deviation is not believed to represent a significant risk to the patient; however, due to the compliance aspect the deviation is considered major'*. The report concluded that *'[t]he deviation had the potential to result in product not meeting registered specification being available in the market although the potential patient impact is considered to be negligible. [...] Batches associated with the deviation are quarantined and may only be considered for release if the packaging material (20 µm Foil) is registered for the product (or if a BSV is raised and approved)'*.

Document 202886, signed 'Deviation Report Form' dated 27 November 2014.

⁹⁷⁴ Document 202737, email from [X] to [X] and [X] dated 21 October 2014.

⁹⁷⁵ Document 201924, email from [AMCo Employee] to [Aesica Employee] and [X] dated 5 January 2015. See also Document 201926, email from [X] to [AMCo Employee] dated 5 January 2015.

skinny label hydrocortisone tablets, which Auden believed at that time to be on the verge of launching. After the parties entered into the Second Written Agreement on 25 June 2014, Auden took no further material steps on Project Guardian until a new potential competitor emerged in November 2014.⁹⁷⁶

- 3.625. In September 2014, Allergan (then known as Actavis: see paragraph 3.7 above) considered the possibility of acquiring AM Pharma through its subsidiary Actavis Holdings UK Limited. Due diligence materials noted that hydrocortisone tablets were a key product for Auden and the orphan designation for Plenadren effectively granted exclusivity to Auden until 2022.^{977,978}
- 3.626. Accord-UK commissioned a financial due diligence report from PwC on the proposed acquisition of AM Pharma. PwC concluded that AM Pharma was *'highly cash generative selling niche, high margin drugs'* and its *'product portfolio has historically been based on the hydrocortisone range'*.⁹⁷⁹ Further, it found that hydrocortisone tablets contributed 46% of the company's gross profit and *'generates the highest absolute gross margin'*.⁹⁸⁰ PwC also noted that *'[w]e understand that significant price increases have been achieved in Hydrocortisone largely due to the orphan status that it holds in the UK and the current lack of competition'*.⁹⁸¹

⁹⁷⁶ The only correspondence from Auden on Project Guardian between July and November 2014 on the CMA's file consists of: an email to the MHRA dated 8 July 2014, requesting a response to Auden's letter dated 14 April 2014 discussed at paragraph 3.544.a above (Document 00284, email from [X] to [X] dated 8 July 2014); and an exchange of emails with Rowlands Pharmacy between 18 and 21 July 2014 following Rowlands' request to see Auden's SmPC (Document 00179B, emails between [X] and [X] between 18 and 21 July 2014). These communications represent the tail end of Auden's approaches to stakeholders in February to June 2014.

⁹⁷⁷ Document 00705, Project Apple Presentation September 2014.

⁹⁷⁸ Allergan (at the time called Actavis) had itself previously considered entering the market with hydrocortisone tablets. In February 2014, Allergan approached ViroPharma SPRL (the owner of Plenadren at the time, which it had previously approached in 2013 for consent), to seek consent under the orphan designation rules for the grant of a MA for hydrocortisone tablets to include the adrenal insufficiency in adults indication. Allergan alleged that a refusal of consent would constitute breaches of Articles 101(1) and/or 102 TFEU (Document 200321, letter from Actavis Group to ViroPharma SPRL dated 26 February 2014). ViroPharma SPRL refused consent (Document 200323, letter from ViroPharma SPRL to Actavis Group dated 7 April 2014). Allergan took the first steps in seeking to develop hydrocortisone tablets in May 2014 (Document 00701, Merger Notification of anticipated acquisition of Auden McKenzie Holdings Limited dated 18 March 2015, footnote 44; Document 00702, Hydrocortisone Tablet UK 10mg, 20mg – New Development Project Kick Off Meeting dated 20 August 2014) and anticipated a launch in 2016 and forecasted sales in the range of €7.5 million (market share: 40%) for 2016 and €5.9 million (market share: 35%) for 2017 with price erosion in the market between 60-70% for this period (See Document 00703, 'Actavis Global Business Case: Hydrocortisone tablets'). Ultimately it took no further steps to launch its own product independently in the UK (Document 00704, paragraph 3.1, Response to CMA information request in the anticipated acquisition of Auden McKenzie Holdings Limited by Actavis Holdings UK Limited dated 21 April 2015).

⁹⁷⁹ Document 00681, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016, Annex 11, page 7: Project Apple due diligence report dated 11 December 2014.

⁹⁸⁰ Document 00681, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016, Annex 11, pages 7 and 22: Project Apple due diligence report dated 11 December 2014.

⁹⁸¹ Document 00681, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016, Annex 11, page 17: Project Apple due diligence report dated 11 December 2014.

- 3.627. Materials for the acquisition noted that *'Hydrocortisone tablets comprise 40% of sales today...due a unique orphan drug exclusivity - expected to erode in the near term'* and *'[n]ear term cash cow with the remainder of the business growing with a significant pipeline'*.⁹⁸²
- 3.628. However, on 20 November 2014, Allergan raised concerns with Auden about the protection the orphan designation gave to its hydrocortisone tablets. According to an email from [Auden Senior Employee 1] summarising the November discussions, Allergan's IP specialist noted the fact that an orphan designation holder can give consent to any other company to develop products with the same indication, and therefore *'established the point to all present in the meeting that Auden's product did actually not have complete protection'*.⁹⁸³
- 3.629. On 25 November 2014, the MHRA granted an MA for 10mg hydrocortisone tablets to Orion Corporation (**'Orion'**).⁹⁸⁴ As a result of the orphan designation, this MA did not include the indication for adrenal insufficiency in adults.
- 3.630. According to [Auden Senior Employee 1]'s email, *'[t]he grant of this [Orion] license was of concern to Actavis...[t]he new Hydrocortisone license [sic] grant resulted in the Executive board of Actavis raising concerns over the proposed deal to acquire Auden and negotiations stopped around mid-December. [✂] went as far as to say that Actavis were no longer excited about the deal and we should find a new acquirer, as Actavis were seriously concerned about the new Orion license [sic] been [sic] used 'Off label' and the impact this would have on their investment if they acquired Auden'*.⁹⁸⁵
- 3.631. In response to these developments, Auden resumed Project Guardian.
- 3.632. On 28 November 2014 Auden approached the MHRA again to highlight the differences between its MAs and Orion's MA. Auden's letter expressed concerns about the possibility of the prescription and dispensing of Orion's hydrocortisone tablets off-label, specifically saying that it felt the SmPC and Product Information Leaflet (**'PIL'**) to be *'misleading'* or could be *'misinterpreted'*. It stated: *'We feel this will have a material effect both on our product and healthcare professional's [sic] liability in terms of dispensing the product to patients with an unlicensed indication.'* Auden requested that the

⁹⁸² Document 00706, Project Apple Presentation January 2015, Executive Summary and Hydrocortisone Background.

⁹⁸³ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

⁹⁸⁴ PL 27925/0078.

⁹⁸⁵ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

MHRA require Orion to make amendments to its SPC and PIL *'to ensure that healthcare professionals do not dispense the product with the unlicensed indication'*.⁹⁸⁶

- 3.633. On 1 December 2014, Auden complained to the [X] and the [X] at Orion. In its letters, Auden alleged that Orion's SmPC and labelling *'is misleading and will cause confusion to patients and healthcare professionals when prescribing and dispensing the product'* and stated that *'steps need to be put in place to amend the packaging [...] to ensure that healthcare professionals do not dispense the product with the unlicensed indication.'* The letters said that Auden had *'notified the MHRA of this issue and will be monitoring the dispensing of your product to determine if it is being dispensed for an unlicensed indication and will inform the authorities and professional associations representing dispensing pharmacists accordingly'*.⁹⁸⁷
- 3.634. Auden wrote to the MHRA again on 4 December 2014, reiterating its concerns. In this email it noted that the MHRA had not responded to its approaches in April 2014 (in the first phase of Project Guardian). Auden noted that its *'Initial query was based on the Amdipharm product, however recently the MHRA have approved a marketing authorisation to Orion'*, and that it was therefore raising its concerns about off-label dispensing again and requesting a response to its original enquiries..⁹⁸⁸
- 3.635. However, Auden's approaches were once again rebuffed.
- 3.636. On 17 December 2014 Orion responded to Auden, disputing the allegations and explaining that it did not see any grounds for Auden or the MHRA objecting to its approved packaging, PIL and SmPC. Orion's letter stated that *'[h]ealthcare professionals in the UK have a wide discretion when prescribing medicinal products, a discretion that pharmaceutical companies should not interfere with unless specific safety issues have arisen'*.⁹⁸⁹
- 3.637. On 19 December 2014, the MHRA responded to Auden's letter and email of April 2014.
- 3.638. In relation to Auden's proposal for the labelling of hydrocortisone tablets to indicate whether they were full or skinny label, the MHRA noted that *'current labelling legislation [...] does not require the outer packaging for prescription only medicines to include the indicated use(s) of the medicine'*.

⁹⁸⁶ Document 00235, email from [X] (Auden Mckenzie) to [X] (MHRA) dated 28 November 2014.

⁹⁸⁷ Document 00239, letter from [X] to [X], dated 1 December 2014. See also Document 00243, letter from [X] to [X], dated 1 December 2014.

⁹⁸⁸ Document 00282, email from [X] (Auden Mckenzie) to [X] (MHRA) dated 4 December 2014.

⁹⁸⁹ Document 00265, letter from [X] (Orion) to [X], copying MHRA dated 17 December 2014.

- 3.639. In relation to Auden's arguments about '*Liability for prescribing and dispensing*' off label, the MHRA wrote:

*'As you are aware Auden McKenzie raised this matter previously in a letter dated 14 April to [Chief Pharmaceutical Officer for NHS England], to which you received a reply. From the public health perspective, there are no material differences between the available generic immediate release hydrocortisone tablets; these are all bioequivalent to the brand leader. The indications stated in the Summary of Product Characteristics (SmPC) and the patient information leaflet of the more recently authorised products differ from the older products due to the orphan legislation'*⁹⁹⁰

- 3.640. The MHRA suggested exploring with '*the MAHs [MA holders] of the recently granted hydrocortisone tablet products*' the possibility of including a voluntary statement in their product information to the effect that hydrocortisone may also be authorised to treat other conditions not mentioned in their SmPCs.⁹⁹¹
- 3.641. On 23 December 2014, Auden emailed [redacted] at the MHRA reiterating Auden's concerns and requesting that the labels on Orion's and AMCo's products be amended to specify the '*age range that the product can be prescribed for*'. The email stated: '*we are still very concerned that any other products launched which do not have the indication of adrenal insufficiency in adults would still cause confusion amongst health care professional[s]. [...] We believe this to be a legal and ethical issue*'. The email went on to say: '*by unknowingly prescribing or dispensing the unlicensed indicated product the prescriber and dispensing pharmacist are open for litigation.*'⁹⁹²
- 3.642. On 23 February 2015, and again on 30 March 2015, Auden wrote to the MHRA requesting a response to Auden's emails of 28 November and 23 December 2014. These emails noted that Auden had also raised concerns relating to the Orion product literature to the equivalent Swedish Authority.⁹⁹³
- 3.643. However, the MHRA responded to Auden on 21 April 2015 that '*we do not intend to formally require a change to the SmPC, outer packaging, inner packaging or patient information leaflet of the other hydrocortisone products*' of Orion or AMCo.⁹⁹⁴

⁹⁹⁰ Document 00288, letter from to [redacted] to [redacted] dated 19 December 2014.

⁹⁹¹ Document 00288, letter from to [redacted] to [redacted] dated 19 December 2014.

⁹⁹² Document 00278, email from [redacted] to [redacted] dated 23 December 2014.

⁹⁹³ Document 00277, email from [redacted] to [redacted] dated 30 March 2015.

⁹⁹⁴ Document 00628, letter from the [redacted] to [redacted] dated 21 April 2015.

- 3.644. On 9 January 2015, [Auden's External Consultant] advised Auden that *'[i]nadvertent off-label use is [...] as likely with this [Orion] product as with any product that does not carry the extensive indications as the originator product'* and that *'[t]his is becoming increasingly an issue as more products come to market with limited indications.'* [Auden's External Consultant] recommended that Auden continue to attempt to differentiate its product from any competitor product, noting, however, that *'Superintendents would be unlikely to be too exercised about the introduction of the Orion product on to the market. This may change if there is a bioavailability issue that surfaces or if an adverse event arises'*.⁹⁹⁵
- 3.645. It therefore became clear that Auden was unlikely to succeed in preventing off-label dispensing of competing skinny label hydrocortisone tablets.
- 3.646. In a January 2015 presentation, Allergan anticipated that Auden's market share would erode by 60% and that prices would erode by 90% over a three-year period, on the expectation that competitors would enter in 2015 *'without indication for adrenal insufficiency and being launched and dispensed off label'*.⁹⁹⁶
- 3.647. Allergan and AM Pharma discussed various options to address these concerns in December 2014 and January 2015, with a view to *'de risking the Hydrocortisone product element for Actavis to continue its interest in Auden'*. The parties ultimately agreed a deal where the purchase price was substantially reduced from £520 million to £300 million plus an earn-out for hydrocortisone tablets. It was noted that the deal *'represents a total and complete de risking of Hydrocortisone for Actavis and only an earnout depending on their success to market Hydrocortisone tablets'*.⁹⁹⁷
- 3.648. On 5 March 2015, Auden sent another letter to the PSNC noting that it remained *'concerned that this issue continues to cause confusion amongst all stakeholders and perhaps most importantly amongst patients'* and seeking support in communicating with the DHSC and the NHS to issue guidance about off-label supply of medicines. Auden argued that the differences in indications between full and skinny label hydrocortisone tablets were analogous to the recent case of Pregabalin, in which a High

⁹⁹⁵ Document 00254, email from [Auden's External Consultant] to [Auden Senior Employee 4] dated 9 January 2015.

⁹⁹⁶ Document 00706, Project Apple Presentation January 2015, Hydrocortisone Background.

⁹⁹⁷ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

Court judgment prompted NHS England and the PSNC to issue guidance to practitioners on prescribing for patented indications.⁹⁹⁸

3.649. The PSNC also rebuffed Auden's approach. It responded that:

'The status of hydrocortisone is not comparable to the situation with Lyrica / pregabalin. The guidance from NHS England, issued following a Judgment of the High Court, and the guidance we have given was issued in order to alert contractors of the risk of litigation for breach of patent law.'

*As per our letter in April 2014, we raised the issues relating to differences in licensed indications between manufacturers in the past, and the Department of Health was not willing to intervene. We note your intention to approach the Department of Health and NHS England on this matter. PSNC does not believe that the patent case will provide the justification to make a further approach to the Department, and so we are unable to offer support.'*⁹⁹⁹

n. Allergan's acquisition of AM Pharma prompts AMCo to resume its Aesica 10mg development for the UK market

3.650. In summary:

- a. The news that AM Pharma was to be acquired by Allergan made AMCo concerned that the new owners would terminate the 10mg supply arrangement. This prompted AMCo once more to re-engage with its Aesica development, submitting its application to vary its MA for the thinner foil and ordering further batches.
- b. AMCo ultimately withdrew its application to vary its MA and instead instructed Aesica to continue packing in 25 micron foil. The August 2014 Batches were destroyed.

3.651. On 26 January 2015 Allergan announced its acquisition of AM Pharma. That day, [Auden Senior Employee 1] tried to call [AMCo Senior Employee 1].¹⁰⁰⁰

3.652. As a result of the sale of AM Pharma, AMCo again became concerned about the continuity of its supply from Auden. AMCo's concern that Auden's new owners might terminate the 10mg supply arrangement prompted AMCo to

⁹⁹⁸ Document 00432, letter from [Auden Senior Employee 4] to [X] (PSNC) dated 5 March 2015.

⁹⁹⁹ Document 00433, letter from [X] (PSNC) to [Auden Senior Employee 4] dated 6 March 2015.

¹⁰⁰⁰ Document 200136, emails between [Cinven Senior Employee 1] and [AMCo Senior Employee 1] dated 26 January 2015.

re-engage in earnest with its Aesica product and intensify its efforts to make the August 2014 Batches available for sale in the UK:

- a. On 27 January 2015, the day after the Allergan acquisition was announced, [AMCo Senior Employee 2] asked AMCo staff to check whether Auden had *'amended their labelling re: indication?'*. [AMCo Senior Employee 1] replied: *'Given the Auden Mck news please could we have a session on our Hydrocortisone products – either at PPRM or some other time soon?'*¹⁰⁰¹
- b. On the same day, [AMCo Senior Employee 2] wrote to [AMCo Senior Employee 1]: *'Main issue now is whether Actavis will continue to supply. We should get ready to sell our own product, just in case'*. [AMCo Senior Employee 1] replied *'Agreed! If I remember thought [sic] there is still some work to do to get it ready'*, to which [AMCo Senior Employee 2] responded: *'[n]ot a lot though'*.¹⁰⁰²
- c. AMCo's PPRM to discuss hydrocortisone was scheduled for 28 January 2015. That day, internal AMCo instructions were to ensure that the Aesica manufactured 10mg hydrocortisone tablets could be sold in the UK if required. [AMCo Senior Employee 5] explained to a colleague: *'We may ... may ... bring back our own Hydrocortisone manufactured at Aesica as we are concerned that Actavis may pull the Auden product from us. We are to push forward with getting the variation done to sort out the current batches packed with the wrong thickness foil as well'*.¹⁰⁰³
- d. On 29 January 2015, [AMCo Employee] explained to AMCo staff: *'Following the acquisition of Orden [sic] (our source of Hydrocortisone), there is now an urgent request from the management that we do everything possible to make sure these batches can be released ASAP.'*¹⁰⁰⁴

3.653. AMCo therefore increased its efforts to get the August 2014 Batches released by making a variation application to the MHRA – which, as explained in paragraph 3.620.b above, had not previously been considered

¹⁰⁰¹ Document 202761, emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 27 January 2015.

¹⁰⁰² Document 202762, emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 27 January 2015. [AMCo Senior Employee 2] also noted that Auden McKenzie's MA was *'still alive and kicking'*. See more generally on the issue of Allergan acquiring Auden McKenzie: Document 202761, emails between [AMCo Senior Employee 2], [REDACTED] and [AMCo Senior Employee 1] dated 27 January 2015; and Document 200136, emails between [Cinven Senior Employee 1] and [AMCo Senior Employee 1] dated 26 January 2015.

¹⁰⁰³ Document 202763, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 28 January 2015 (emphasis in original).

¹⁰⁰⁴ Document 202764, email from [AMCo Employee] to AMCo staff dated 29 January 2015.

an operational priority¹⁰⁰⁵ – and subsequently ordered new batches from Aesica packed in the originally registered 25 micron thickness foil.

- 3.654. On 3 February 2015, [AMCo Employee] emailed [AMCo Employee]: *'Regulatory Affairs is now preparing to submit a variation to add the Foil thickness of 20microns to the License.'* On 5 February, she asked: *'Please can you let me know if the Hydrocortisone 10mg tablets manufactured at Aesica will be releasable once the variation is approved?'*¹⁰⁰⁶
- 3.655. [AMCo Employee] responded on 6 February 2015 confirming that the August 2014 Batches would be released *'once approval is received.'* She noted, however: *'I understand we are not going to market this product in to [sic] UK market'*.¹⁰⁰⁷ [AMCo Employee] replied *'[t]here is now a chance that we may need to sell these batches in the UK.'*¹⁰⁰⁸
- 3.656. On the same day, AMCo asked Aesica again to confirm whether *'the packaging line for Hydrocortisone 10mg tablets could still accommodate 25 micron blister foil without modification.'*¹⁰⁰⁹ Aesica confirmed that this was possible *'[i]n principal [sic]'* but suggested running a trial.¹⁰¹⁰
- 3.657. On 12 February 2015, AMCo held an internal meeting to discuss *'how we decide to source Hydrocortisone 10mg tablets (which we currently source from Auden McKenzie, who are in the process of being bought by Actavis) for the UK in the long-term, and any decisions we might need to make now to support that plan'*. The meeting considered the remaining shelf life on the current batches and possible opportunities to sell these, the variation application and possible future orders from Aesica. In relation to the variation application, [AMCo Employee] explained that *'[t]he batches will be available for sale once the variation to add their foil thickness to the license has been approved. The variation is being submitted this week and will be approved in 30 days if we do not receive any RFI.'*¹⁰¹¹
- 3.658. According to notes circulated by [AMCo Senior Employee 7], at the 12 February meeting AMCo decided to:

¹⁰⁰⁵ Document 201067, email from [AMCo Employee] to [AMCo Senior Employee 7], [AMCo Employee] and [AMCo Employee] dated 30 September 2014.

¹⁰⁰⁶ Document 202765, emails from [AMCo Employee] to [AMCo Employee] and [AMCo Employee] dated 3 and 5 February 2015.

¹⁰⁰⁷ Document 202765, email from [AMCo Employee] to [AMCo Employee] and [AMCo Employee] dated 6 February 2015.

¹⁰⁰⁸ Document 202765, email from [AMCo Employee] to [AMCo Employee] and [AMCo Employee] dated 6 February 2015.

¹⁰⁰⁹ Document 201929, email from [X] to [X] dated 6 February 2015.

¹⁰¹⁰ Document 201929, email from [Aesica Employee] to [X] and [X] dated 10 February 2015.

¹⁰¹¹ Document 202948, email from [AMCo Employee] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [X] and others dated 3 February 2015.

- a. Destroy its first batch of 10mg tablets (*'Batch Number 6045100'*¹⁰¹²) *'due to the limited shelf life and the fact the batch will not be released until Mid – End March 15;'*
- b. Release its second and third batches (*'Batches 6046079 and 6080'*¹⁰¹³) as soon as possible, while following up with International Health Partners to confirm . *'if they would like to take the 2 batches';*
- c. Submit its application for a Type 1B variation to change the foil thickness on the 10mg MA. This would take place on 13 February; and
- d. Discuss the manufacture of additional new batches with Aesica: *'we will discuss manufacturing an additional **2 batches** for availability ASAP.'*¹⁰¹⁴

3.659. [AMCo Employee] replied to [AMCo Senior Employee 7], asking: *'So are we definitely going to sell hydrocortisone ex Aesica?'* [AMCo Senior Employee 7] replied:

*'It is all still in the air! The additional batches are an insurance policy and I can elaborate tomorrow when we meet. We will only use them if required.'*¹⁰¹⁵

3.660. In light of its concerns about continuity of supply from Auden following its acquisition by Allergan, AMCo had therefore resolved to take steps to make its existing stock of Aesica hydrocortisone tablets available for sale (where this was not precluded by their shelf life) and to manufacture further batches. However, this was only *'an insurance policy'*, to be actioned if required. ([AMCo Employee] later informed a colleague in relation to these new batches: *'The deal with Auden McKenzie has fallen through and we now wish to resurrect our original plan and market our product in the UK.'*¹⁰¹⁶ [AMCo Senior Employee 7] later wrote that the launch of Aesica-manufactured 10mg hydrocortisone tablets was still uncertain: *'As of April's*

¹⁰¹² Batch 6045100 (15,867 packs) was one of the three batches manufactured and packed by Aesica. Its expiry date was 31 March 2015. See Document 202970, email from [AMCo Employee] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [REDACTED], [AMCo Senior Employee 2], [AMCo Employee], [REDACTED], [AMCo Senior Employee 5], [AMCo Senior Employee 7] and [AMCo Employee] dated 3 February 2015; and Document 202770, email from [REDACTED] to [AMCo Senior Employee 5] dated 16 February 2015.

¹⁰¹³ Batches 6046079 (12,816 packs) and 6046080 (15,891 packs) were two of the three batches manufactured and packed by Aesica. Their expiry date was 31 October 2015. See Document 202970, email from [AMCo Employee] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [REDACTED], [AMCo Senior Employee 2], [AMCo Employee], [REDACTED], [AMCo Senior Employee 5], [AMCo Senior Employee 7] and [AMCo Employee] dated 3 February 2015; and Document 202770, email from [REDACTED] to [AMCo Senior Employee 5] dated 16 February 2015.

¹⁰¹⁴ Document 202948, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 1], [REDACTED], [AMCo Senior Employee 2] and others dated 12 February 2015 (emphasis in the original).

¹⁰¹⁵ Document 202948, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 12 February 2015.

¹⁰¹⁶ Document 202783, email from [AMCo Employee] to [REDACTED] dated 14 April 2015.

PPRM the launches for 2015 were: [...] Hydrocortisone 10mg Tablets (Aesica; only if we have to launch this)'.¹⁰¹⁷

- 3.661. On 18 February 2015, [AMCo Senior Employee 1] approved the purchase of '2 year's worth' of hydrocortisone API.¹⁰¹⁸ On the same day, AMCo issued a purchase order to Aesica for 30,000 packs of 10mg hydrocortisone tablets, to be delivered on 10 June 2015.¹⁰¹⁹
- 3.662. AMCo ultimately withdrew its application to vary its MA to allow for the 20 micron foil in May 2015, having concluded that it was unnecessary and that it would instead simply continue to order further batches from Aesica in 25 micron foil:
- a. On 9 March 2015, AMCo received an RFI from the MHRA in relation to its application, which required AMCo to provide, amongst other things, *'[s]tability data using the proposed packaging material'*.¹⁰²⁰
 - b. However, on 7 April 2015 AMCo concluded that it did not have *'the required data to answer the RFI'*.¹⁰²¹ In addition, on 10 April 2015, AMCo became aware that there was potentially an issue affecting the API that had been used in the manufacture of the August 2014 Batches that had been packed in the wrong foil.¹⁰²² AMCo therefore considered that it will *'potentially not have to bother [with the Type 1B variation] as the batches may need to be scrapped'*.¹⁰²³
 - c. On 15 April 2015, AMCo informed Aesica that it had *'taken the decision to proceed with packing the next order of hydrocortisone tablets using the 25gsm [micron] material instead of 20gsm [micron] as previously advised [...] please pack with the 25 micron foil on this product until further notice'*.¹⁰²⁴

¹⁰¹⁷ Document 202793, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 2] and [AMCo Employee] dated 27 April 2015.

¹⁰¹⁸ Document 201070, email from [AMCo Senior Employee 1] to [AMCo Employee], [AMCo Senior Employee 4], [AMCo Senior Employee 2], [AMCo Senior Employee 5] and [AMCo Senior Employee 7] dated 18 February 2015.

¹⁰¹⁹ Document 201932, purchase order 4500009470 issued by AMCo to Aesica on 18 February 2015.

¹⁰²⁰ Document 201933, email from [X] to [AMCo Employee] dated 9 March 2015. In late March 2015, AMCo sought Aesica's assistance in preparing a response to the MHRA's RFI: Document 201935, email from [AMCo Employee] to [Aesica Employee] dated 25 March 2015; email from [AMCo Employee] to [Aesica Employee] dated 26 March 2015; email from [AMCo Employee] to [Aesica Employee] dated 31 March 2015.

¹⁰²¹ Document 201936, email from [AMCo Employee] to [AMCo Employee], [X], [X] and others dated 7 April 2015.

¹⁰²² Document 201937, email from [X] to [AMCo Employee] dated 10 April 2015.

¹⁰²³ Document 202783, email from [X] to [AMCo Employee] dated 13 April 2015.

¹⁰²⁴ Document 201938, email from [X] to [Aesica Employee] and [X] dated 15 April 2015.

- 3.663. On 5 May 2015, AMCo held an internal meeting. [AMCo Senior Employee 7]'s notes of that meeting recorded that:
- a. AMCo had withdrawn its application to change the foil thickness and would not be pursuing the option of adding 20 micron foil to the licence. *'All were in agreement that this is not required as Aesica can supply us FP [final product] packed using 25µm foil with no issues. We would also prefer not to commence an additional stability study which is non critical (both in terms of time and cost).'*
 - b. The two additional 'FP' (finished product) batches would be packed using 25 micron foil. They were scheduled for manufacture in July 2015.¹⁰²⁵
- 3.664. On 19 May 2015, AMCo and Aesica entered into a manufacturing and supply agreement for the manufacture of *'a minimum of three batches of 15,000 packs (i.e. 45,000 packs) [of 10mg hydrocortisone tablets] per year (1 August 2015 – 31 July 2016)'* at a price of **[£1-£4]** per pack, packed in blisters.¹⁰²⁶
- 3.665. On 22 May 2015, AMCo confirmed to Aesica that it would not be varying its licence and that *'we will be only using 25 micron foil for this product'*.¹⁰²⁷
- 3.666. On 27 May 2015, AMCo ordered the August 2014 Batches to be destroyed, on the basis that *'there is no realistic way in which they might be used'* given they had been packed in the wrong foil.¹⁰²⁸
- 3.667. On 5 June 2015, AMCo and Aesica discussed a delay in the delivery of the 10mg hydrocortisone tablets ordered in February 2015 (see paragraph 6.755 above) from June 2015 to September 2015 due to an *'issue with Calcium Stearate'* (an excipient material required for the production of 10mg hydrocortisone tablets) which meant Aesica required *'a new delivery'* of this material.¹⁰²⁹ On 28 July 2015, Aesica informed AMCo that it had received the material and that *'current delivery date for this will be Oct 13th'*.¹⁰³⁰

¹⁰²⁵ Document 201941, email from [AMCo Senior Employee 7] to [AMCo Employee], [X], [X] and others dated 5 May 2015. See also Document 202016, [AMCo Senior Employee 7]'s handwritten notes dated 5 May 2015.

¹⁰²⁶ Document 200292, paragraph 11.1, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

¹⁰²⁷ Document 202802, email from [X] to [Aesica Employee], [AMCo Employee], [AMCo Employee] and others dated 22 May 2015.

¹⁰²⁸ Document 202802, email from [X] to [AMCo Employee] and [X] dated 27 May 2015; and email from [AMCo Employee] to [X], [AMCo Employee] and [X] dated 27 May 2015; and Document 202802, email from [X] to [X] dated 22 May 2015.

¹⁰²⁹ Document 201991, email from [X] to [AMCo Employee] dated 5 June 2015, referring to purchase order 4500009470, which is the order of February 2015.

¹⁰³⁰ Document 201991, email from [X] to [AMCo Employee] dated 28 July 2015.

3.668. On 21 August 2015, AMCo issued a further purchase order to Aesica for 30,000 packs of 10mg hydrocortisone tablets to be delivered on 7 December 2015.¹⁰³¹

o. AMCo acquires another hydrocortisone tablets portfolio and makes plans to use it to negotiate further volumes from Auden/Actavis

3.669. On 1 October 2014, AMCo acquired Focus Pharmaceuticals Ltd. (**'Focus'**), a speciality pharmaceuticals business.¹⁰³² Focus' business included a pipeline project for hydrocortisone tablets developed with the assistance of a Greek CMO and developer called Lamda.¹⁰³³

3.670. On 5 August 2015, [Focus Senior Employee 2] circulated an outline proposal, explaining how the return from Focus' hydrocortisone tablets could be maximised. According to the proposal, the rights and licence for Focus' hydrocortisone tablets would be moved to a new company run by [Focus Senior Employee 2] and [Focus Senior Employee 1] that would pay a royalty to AMCo based on profit generated from sales of the product. AMCo would have the right to recall the licence. The new company was referred to as 'Roma'.¹⁰³⁴ The proposal considered two scenarios:

- a. *'Scenario 1: NEWCo agree a supply deal with Auden/Actavis to avoid the issue of the orphan indication. AMCo to be paid on a quarterly basis 75% of Gross Profit generated from the product'* (for this scenario the proposal forecasted a volume of 8,000 packs per month and AMCo's annual return of £2,671,200); or
- b. *'Scenario 2: NEWCo manufacture and supply from their own license. AMCo to be paid on a quarterly basis 70% of Gross Profit generated from the product'* (for this scenario the proposal forecasted a volume of 10,000 packs per month, and annual return of £2,310,000).¹⁰³⁵

3.671. In Scenario 1, AMCo intended for its Focus product to be used as leverage to obtain further supplies of 10mg hydrocortisone tablets from Auden/Actavis, as contemporaneous documents show. For example:

¹⁰³¹ Document 201958, Purchase Order issued by AMCo on 21 August 2015.

¹⁰³² Document 200170, Minutes of a Meeting of the Board of Directors of Amdipharm Mercury Limited on 5 November 2014, page 3.

¹⁰³³ Document 00444, paragraphs 1.21(b) and 3.3(a), AMCo's response to the CMA's section 26 notice dated 8 March 2016.

¹⁰³⁴ See, for example, Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.

¹⁰³⁵ Document 200144, email from [Focus Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 5 August 2015; and Document 200145, Hydrocortisone 10mg & 20mg tablet proposal.

- a. On 18 August 2015, [AMCo Senior Employee 3] stated: *'The new MA will give us the ability to negotiate a greater volume supply. Our expectations are a total supply of 24k units a month'*.¹⁰³⁶
 - b. AMCo's strategy consultants explained that *'AMCO indicate that its current supply is sourced from Auden, and it has been limited in its ability to meet demand due to lack of supply. the Focus acquisition (of 10mg and 20mg hydrocortisone) is anticipated to provide them a more competitive position to seek increasing supplies from Auden Mckenzie'*.¹⁰³⁷ The consultants described AMCo's *'management's strategy'* as *'to regain supply leveraging its new competitive position'*.¹⁰³⁸
 - c. On 1 September 2015, [AMCo Senior Employee 1] explained that: *'The most important job they [Focus management] have to do for us is negotiated [sic] with Actavis/Auden and get the highest level of monthly volume (and keep it there ongoing).'*¹⁰³⁹
 - d. On 23 November 2015, [AMCo Employee] proposed with respect to a *'Pipeline discussion with Concordia'* that [AMCo Senior Employee 3] *'explain the strategy to leverage our MA'*.¹⁰⁴⁰
- 3.672. On 27 November 2015, it was *'yet to be decided'* whether AMCo would pursue Scenario 1 or Scenario 2: *'We may sell this product ourselves directly (although it too does not have the orphan indication) or we may approach Auden for further stocks of their 10 and 20 mg. This is yet to be decided'*.¹⁰⁴¹
- 3.673. By December 2015, however, Scenario 1 was the favoured option:
- a. On 3 December, in response to a request to provide updated information on the potential launch date of *'Hydrocortisone (Focus)'*, [AMCo Senior Employee 3] stated:

'Hydro for May 16 is fine. We just need the MA so [AMCo Senior Employee 7] needs to check when this will be. This is the date

¹⁰³⁶ Document 200151, L.E.K. Questions for Management 17th August 2015, attachment to Document 200150, email from [AMCo Senior Employee 3] to [Cinven Senior Employee 1] and others dated 18 August 2015.

¹⁰³⁷ Document 202884, 'Project Harmony: AMCo opportunity assessment' presentation prepared by LEK Consulting dated 21 August 2015, slides 82 and 85.

¹⁰³⁸ Document 202793, 'Project Harmony' presentation prepared by LEK Consulting dated 21 August 2015, slide 85.

¹⁰³⁹ Document 202821, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 3] dated 1 September 2015.

¹⁰⁴⁰ Document 202828, email from [AMCo Employee] to [REDACTED] dated 20 November 2015.

¹⁰⁴¹ Document 202829, email from [AMCo Senior Employee 3] to [REDACTED] dated 27 November 2015.

*confirmed last time we spoke. We will develop some product in case but we just need the MA to secure a supply deal elsewhere.*¹⁰⁴²

- b. On 10 December [Focus Senior Employee 2] set out in an email to [AMCo Senior Employee 3]: *'As you are aware the only manufacturer with a product with the full list of indications is Actavis. Therefore our first choice would be to negotiate a supply agreement from them which would then allow us to sell the product to the entire market'*.¹⁰⁴³

- 3.674. On 12 January 2016, AMCo sent [Focus Senior Employee 2] and [Focus Senior Employee 1] a *'draft contract for the hydrocortisone product'*.¹⁰⁴⁴ [Focus Senior Employee 2] then communicated AMCo's proposed course of action to Lamda on 18 January 2016, setting out that: *'we have been discussing with some of the key customers and at present all of the National chains have the policy that they can only use a product with the full range of indications. Therefore to give us the largest market possible we are going to open negotiations with Actavis to see if they will supply a product to us with the full range of indications'*.¹⁰⁴⁵
- 3.675. However, in early March 2016 further market entry by other suppliers (as set out in section 3.E.V.b.i above) led AMCo to reconsider the prospective agreement with respect to the Focus product.¹⁰⁴⁶
- 3.676. On 10 March 2016, [AMCo Senior Employee 3] recommended to [AMCo Senior Employee 8]: *'In light of some major changes to the market that have come through from the sales team this week I think we need to ... not proceed with any agreement with Roma.'*¹⁰⁴⁷
- 3.677. On 14 March 2016, [AMCo Senior Employee 3] implemented his recommended approach and emailed [Focus Senior Employee 1] and [Focus Senior Employee 2] of Focus explaining: *'In short we are not in a position to move ahead. There have been some major movements in the*

¹⁰⁴² Document 202830, email from [AMCo Senior Employee 3] to [X] dated 3 December 2015.

¹⁰⁴³ Document 202835, email from [Focus Senior Employee 2] to [AMCo Senior Employee 3] dated 10 December 2015. [Focus Senior Employee 2] also noted that if Actavis UK was unwilling to supply, Focus would launch its own Lamda-produced product, but this would limit supply, as *'less than 30% of the market'* was willing to buy a skinny-label product, and *'[t]here is already a product being sold into this limited market'*.

¹⁰⁴⁴ Document 202949, email from [AMCo Senior Employee 3] to [Focus Senior Employee 2] and [Focus Senior Employee 1] dated 12 January 2016. On 25 January 2016, [Focus Senior Employee 2] and [Focus Senior Employee 1] provided AMCo with their comments on *'ROMA FPL – License and Supply Agreement'* and agreed that it *'covers the key points we have previously agreed'*, see Document 202949, email from [Focus Senior Employee 2] to [AMCo Senior Employee 3], and [AMCo Senior Employee 8] dated 25 January 2016.

¹⁰⁴⁵ Document 202836, email from [Focus Senior Employee 2] to [X] dated 18 January 2016.

¹⁰⁴⁶ Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.

¹⁰⁴⁷ Document 200156, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 8] dated 10 March 2016.

*market with Bristol, Lucis, Alissa etc launching as well as some other unforeseen complications’.*¹⁰⁴⁸

3.678. Instead of pursuing the Roma proposal, AMCo ultimately opted to launch its Focus hydrocortisone tablets, in light of its observation that *‘[t]he market has changed considerably’*.¹⁰⁴⁹

3.679. Similarly, AMCo also considered whether to use its skinny label tablet development with German CMO MIBE (an historic project begun by the Mercury Pharma group prior to Cinven’s acquisition of Amdipharm) to obtain further supplies of 10mg hydrocortisone tablets from Auden/Actavis. On 6 November 2015 AMCo considered the *‘project as incremental considering that we would get aprox. 4,000 boxes more a month from Auden’* once it obtained its MA in 2016. AMCo assumed that it could secure supply of 4,000 additional packs of the Auden product on the assumption that *‘we don’t have sales generated from MIBE’*.¹⁰⁵⁰ Ultimately, AMCo decided not to pursue the MIBE development in May 2016 since *‘the number of entrants reduces the need to utilise all our developments’*.¹⁰⁵¹

p. Alissa’s entry prompts Actavis to revisit Project Guardian and offer Alissa a 10mg supply deal using the Second Written Agreement as a template

3.680. In summary:

- a. Orion’s 10mg MA was transferred to another competitor, Alissa. Alissa entered with skinny label 10mg tablets in October 2015.
- b. Accord-UK took over sales of hydrocortisone tablets from AM Pharma in September 2015. In December 2015 Accord-UK made an offer to supply Aesica using the Second Written Agreement as a template: a specified volume of 10mg tablets per month at £1.78 per pack.
- c. Alissa rejected Accord-UK’s offer and further independent entry took place in early 2016. This prompted Accord-UK to initiate a

¹⁰⁴⁸ Document 202858, emails from [AMCo Senior Employee 3] to [Focus Senior Employee 1] and [Focus Senior Employee 2] dated 14 March 2016. See also Document 202994, email from [AMCo Senior Employee 3] to [AMCo Employee] dated 14 March 2016, reporting internally: *‘I have also told them it is a no on a hydro deal.’*

¹⁰⁴⁹ Document 202879, Launch Meeting Minutes dated 4 April 2016.

¹⁰⁵⁰ Document 202932, spreadsheet titled ‘Hydrocortisone TABLETS 10MG X 30 – JANILA’, see ‘Cover’ and ‘Incremental Auden #11’ tabs.

¹⁰⁵¹ Document 202910, email from [AMCo Employee] to [AMCo Employee], [AMCo Senior Employee 5] and [AMCo Senior Employee 3] dated 24 May 2016. See also Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016.

'communications plan' drawing on Auden's Project Guardian materials, seeking to preserve its market position.

- 3.681. On 5 December 2014, [Auden Senior Employee 1] forwarded to [Actavis Senior Employee 2] of Accord-UK (then Actavis UK Limited) Auden's correspondence with the MHRA and Orion discussed in paragraphs 3.632 to 3.634 above. This included Auden's email to the MHRA of the previous day, 4 December 2014. [Auden Senior Employee 1] wrote: *'As discussed'*.¹⁰⁵² [Auden Senior Employee 1] had therefore discussed Auden's concerns about the Orion product and its efforts to lobby the MHRA and Orion about its indications with Accord-UK while those efforts were ongoing.
- 3.682. On 30 April 2015, Orion's 10mg MA was transferred to Alissa Healthcare (**'Alissa'**).¹⁰⁵³
- 3.683. In May 2015, Allergan completed its acquisition of AM Pharma. On 20 May 2015 [AMCo Senior Employee 1] and [AMCo Senior Employee 2] of AMCo discussed the implications of the orphan designation. [AMCo Senior Employee 2] asked: *'Will Actavis be as smart at pursuing this as [Auden Senior Employee 1] was?'* [AMCo Senior Employee 1] replied:
- 'According to [Auden Senior Employee 1] Actavis will continue his strategy'*.¹⁰⁵⁴
- 3.684. Between 29 May 2015, when the acquisition of AM Pharma completed, and 31 August 2015, AM Pharma's trading activities, including the business of selling hydrocortisone tablets, were transferred intra-group to Accord-UK, an existing wholly-owned subsidiary of Allergan.¹⁰⁵⁵
- 3.685. From 1 September 2015 onwards, Accord-UK took over from AM Pharma the economic activity of selling hydrocortisone tablets, including supplying AMCo under the Second Written Agreement. From September 2015 AMCo issued its purchase orders for the 12,000 monthly packs of 10mg hydrocortisone tablets supplied under the Second Written Agreement to Accord-UK. A purchase order issued in September 2015 stated: *'Actavis has taken over Auden & all the future orders would be supplied by Actavis'*.¹⁰⁵⁶

¹⁰⁵² Document 00230, email from [X] to [Auden Senior Employee 1] dated 5 December 2014; and email from [Auden Senior Employee 1] to [Actavis Senior Employee 2] dated 5 December 2014.

¹⁰⁵³ Document 00623, MHRA's response to the CMA's section 26 notice dated 15 February 2016, Annex A: Hydrocortisone Tablets with Additional Data for CMA.

¹⁰⁵⁴ Document 202954, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2], [AMCo Senior Employee 6] and [AMCo Senior Employee 3] dated 20 May 2015.

¹⁰⁵⁵ Document 00686, response to question 12, AM Pharma's response to the CMA's section 26 notice of 24 August 2016. See also AM Pharma's accounts for the year ending 31 December 2015.

¹⁰⁵⁶ See, for example, purchase order numbers 4500010691 4500010692, and 4500010693 dated 3 September 2015; 4500010775 dated 11 September 2015; and 450001108 dated 4 November 2015.

- 3.686. In September 2015, Accord-UK's commercial staff investigated the Second Written Agreement that they had acquired from AM Pharma and, while noting the unusually low supply price, resolved to continue that agreement on the existing terms.¹⁰⁵⁷
- 3.687. Actavis continued to supply AMCo with 12,000 packs per month at £1.78 per pack while continuing to increase its ASPs to its other customers. Actavis also continued to increase monthly ASPs for 10mg hydrocortisone tablets from £66.76 in September 2015, peaking at £72.14 in March 2016.
- 3.688. On 15 October 2015, Alissa entered the market with skinny label 10mg hydrocortisone tablets manufactured by Orion.¹⁰⁵⁸
- 3.689. On the same day that Alissa entered the market, [Auden Senior Employee 4] of AM Pharma asked Auden staff to obtain the SPCs and PILs for the Orion and AMCo products '*as a matter of urgency*'. He then sent [Actavis Senior Employee 3] of Accord-UK some of Auden's Project Guardian materials, including its March 2015 correspondence with the PSNC on Orion discussed in section 3.F.III.m above and materials from the first phase of the project discussed in section 3.F.III.h above.¹⁰⁵⁹ [Actavis Senior Employee 3] replied: '*Excellent thanks. I'm briefing all the field teams today on the SPC and tablet differences so this is great to have.*'¹⁰⁶⁰
- 3.690. Actavis was therefore conscious that Alissa posed a threat to its position as sole supplier of hydrocortisone tablets.
- 3.691. On 11 November 2015, [Alissa Senior Employee] of Alissa approached [Actavis Senior Employee 1] of Actavis for a 10mg supply deal. [Alissa Senior Employee] stated that he was looking to '*source 40k packs of 30 tablets three times a year, maximum 120k packs for sale in the UK market. My current supply price is <[£1-£4] per pack.*'¹⁰⁶¹
- 3.692. [Actavis Senior Employee 1] forwarded [Alissa Senior Employee]'s email internally, attaching the Second Written Agreement with AMCo and noting:

¹⁰⁵⁷ See, for example, document 02311, emails between [Actavis Senior Employee 2] and [Actavis Senior Employee 1] dated 4 September 2015 ('*AmCo pay £1.78 for Hydrocortisone – you OK to continue selling at this price?*' '*This is the contracted price so OK*'); document 02329, emails between [Actavis Senior Employee 2] and [§] dated 4 and 7 September 2015.

¹⁰⁵⁸ Document 00512, paragraph 1, Alissa's response to the CMA's section 26 notice dated 15 June 2016. See also document 00438, email from [§] to [Actavis Senior Employee 3] dated 15 October 2015: '*Just to let you know Alissa have launched their Hydr 10mg today!!*'

¹⁰⁵⁹ Document 00431, email from [Auden Senior Employee 4] to [Actavis Senior Employee 3] dated 15 October 2015. See also document 00438, email from [Actavis Senior Employee 3] to Accord-UK staff dated 15 October 2015: '*Alissa launch. [§] says this is the Orion product and not the full indications.*'

¹⁰⁶⁰ Document 00439, email from [Actavis Senior Employee 3] to [Auden Senior Employee 4] dated 16 October 2015.

¹⁰⁶¹ Document 00696, email from [Alissa Senior Employee] to [Actavis Senior Employee 1] dated 11 November 2015.

'attached is the current supply agreement we have with Amco. From a commercial perspective we would like to proceed with discussion with Alissa [sic]'.¹⁰⁶²

- 3.693. [Actavis Senior Employee 1] responded to [Alissa Senior Employee] on 22 December 2015, offering a *'[s]upply of up to 8,000 packs per month over a two year period. Supply price of £1.78 per pack. This would be fixed for the initial 12 month supply period. Supply would be in Actavis/Auden Mckenzie livery.'*¹⁰⁶³
- 3.694. Actavis therefore made an offer to supply Alissa using the Second Written Agreement as a template: a specified volume of 10mg tablets per month at £1.78 per pack.
- 3.695. Ultimately, the supply deal did not go ahead and the offer was rejected by Alissa as being, amongst other things, *'vague'*.¹⁰⁶⁴
- 3.696. Actavis continued to monitor further entry by competitors in early 2016.¹⁰⁶⁵
- 3.697. On 13 January 2016, the minutes of Accord-UK's generics commercial meeting noted that:

'Bristol now have an MA.

Be sensitised to it and review when they launch.

Alissa and Bristol under 18s only indication

...

*Amco in market as well (our product).'*¹⁰⁶⁶

- 3.698. The minutes noted that Accord-UK had *'Decided'*:

'Can pull Amco supply now there are more players in the market'.

¹⁰⁶² Document 00696, email from [Actavis Senior Employee 1] to [X] dated 25 November 2015.

¹⁰⁶³ See Document 00508, email from [Alissa Senior Employee] to [Actavis Senior Employee 1] dated 11 November 2015; and email from [Actavis Senior Employee 1] to [Alissa Senior Employee] dated 22 December 2015.

¹⁰⁶⁴ Document 00699, Signed witness statement of [Alissa Senior Employee] from Alissa dated 30 September 2016, paragraph 1.18.

¹⁰⁶⁵ See, for example, Document 02341, Key Product Summaries dated February 2016, page 3; Document 02342, Key Product Summaries dated May 2016, page 3.

¹⁰⁶⁶ Document 02811, GCM minutes dated 13 January 2016, page 5.

- 3.699. Despite this statement, Accord-UK in fact continued to supply AMCo with 10mg hydrocortisone tablets until the expiry of the Second Written Agreement.¹⁰⁶⁷
- 3.700. The minutes of the meeting also noted, however, that Accord-UK was '*planning a campaign*' in relation to hydrocortisone tablets.¹⁰⁶⁸
- 3.701. In March and April 2016, Actavis prepared models seeking to predict market conditions after the expiry of the Second Written Agreement in June 2016, both of which predicted price erosion as a result of entry.¹⁰⁶⁹
- 3.702. In anticipation of further entry, Actavis initiated a '*communications plan*'.¹⁰⁷⁰ This involved sending materials drawing on Auden's Project Guardian to industry stakeholders to promote its hydrocortisone tablets on the basis that they: (i) were '*[t]he **only** immediate release hydrocortisone tablet to be licensed for use in adults with primary, secondary or acute adrenal insufficiency*'; (ii) were '*[l]icensed for use in children in chronic adrenocortical insufficiency*'; and (iii) '*can be halved and quartered for ease of dose adjustment*'.¹⁰⁷¹
- 3.703. Accord-UK's '*Key Product Summaries*' for February 2016 recorded the action planned in light of competitive entry (among other items):

'Highlights

[...] Pituitary Foundation sent out comms to all members highlighting licence differences between Auden and Alissa products, comms urged patients to request Auden product [...]

GRC approved 2016 sponsorship requests for two key patient groups – Pituitary Foundation and Addison's Disease Self Help Group [...]

Strategies/Goals

[...] Review penetration from Alissa and Amco in >18 market sector

¹⁰⁶⁷ Document 00674, Annex 4 to AM Pharma's response to the CMA's section 26 notice dated 23 June 2016.

¹⁰⁶⁸ Document 02811, GCM minutes dated 13 January 2016, page 5.

¹⁰⁶⁹ Document 02327, email from [Actavis Senior Employee 3] to [X] and others dated 18 March 2016; and Document 02332, email from [Actavis Senior Employee 3] to [X] dated 1 April 2016.

¹⁰⁷⁰ Document 00656, paragraph 14.10, AM Pharma's response to the CMA's section 26 notice dated 23 May 2016.

¹⁰⁷¹ Document 00659, draft marketing letter for industry stakeholders (emphasis in original). See also Document 03474. See also Document 00665, Hydrocortisone Tablets, April 2016, Key Messages for Actavis Hydrocortisone Tablets, slide 16; see also slide 17 setting out the '*multi pronged approach*' with a '*leave piece, wholesaler support, trade media advertising, telemarketing script/Q&A, mailing*'.

Continue communication to pharmacy decision makers on dispensing guidance due to different licence indications [...]

Wholesale support for defence campaign agreed with AAH, Alliance, Phoenix, Mawdsleys & DE [...]

Priorities/Next steps

Review other own label as defence strategy

[...] core messaging being trained into teams end of March'.¹⁰⁷²

- 3.704. By May 2016, Accord-UK's 'Key Product Summaries' recorded that the full campaign was now in use and that it was 'seeing some early wins' as well as receiving campaign support from a number of wholesalers. As one of its goals, the document recorded '*[c]ontinue to use campaign to reinforce benefits of Actavis/Auden Hydrocortisone*'. Actavis UK would also 'review defence strategy options in light of Alissa and Bristol launch'.¹⁰⁷³

q. Independent entry prompts AMCo to launch its Aesica product

3.705. In summary:

- a. Having monitored other potential competitors preparing to enter the market from November 2014 onwards, AMCo received further stock from Aesica in November 2015.
- b. AMCo continued to monitor the market. In March 2016 its management reached the view that the scale of independent entry and the erosion of prices it was creating made it unavoidable that it would have to launch its own product rather than continue to sell the Auden/Actavis product it obtained under the Second Written Agreement.
- c. In May 2016, AMCo entered the market with its Aesica product.

3.706. From November 2014 onwards, AMCo also started to observe a number of new suppliers being granted MAs for skinny label 10mg hydrocortisone tablets¹⁰⁷⁴ and entering the market. This prompted AMCo to reconsider its

¹⁰⁷² Document 02341, Key Product Summaries dated February 2016, page 3.

¹⁰⁷³ Document 02342, Key Product Summaries dated May 2016, page 3.

¹⁰⁷⁴ AMCo was monitoring the market and on 13 November 2014, [AMCo Senior Employee 4] requested an 'urgent RAMA check' with respect to 10mg hydrocortisone tablets, having found out that 'Dexcel are selling this product in the market to groups.' AMCo wanted to find out whether Dexcel had a MA, whether their product was full or skinny label, whether they could be taking supply from Auden and whether there were any termination and volume reduction provisions in the Second Written Agreement in the event of competitive entry (see Document 200133, email exchange between [AMCo Senior Employee 6], [AMCo Senior Employee 2], [AMCo Senior Employee 8], [AMCo Senior Employee 4], [REDACTED] and [AMCo Senior Employee 1] dated 13-15 November 2014).

own strategy with respect to its Aesica-manufactured 10mg product and ultimately enter the market in May 2016.

3.707. AMCo became aware of Orion's MA on 25 November 2014. [AMCo Senior Employee 1] emphasised that it was '*important*' to '*look into the Orion [...] licence*' '*because there are rumours of competition on this*'¹⁰⁷⁵ and that this would '*very likely [...] have an impact on next year's performance*'.¹⁰⁷⁶ On 2 December 2014, [AMCo Senior Employee 4] confirmed that Orion chose to distribute their product through Alissa.¹⁰⁷⁷

3.708. On 27 January 2015, [AMCo Senior Employee 1] reported to Cinven that '*[t]here are three MAs granted for hydrocortisone: *our product (the old Amdipharm MA that we chose not to commercialise), *the Orion product – we have no evidence of them launching (yet) *the Auden McKenzie product*'.¹⁰⁷⁸

3.709. In anticipation of Alissa's launch, AMCo started experiencing difficulties in implementing price increases for the Auden/Actavis product it was selling. On 17 March 2015, [AMCo Employee] noted:

*'we do need to bear in mind that Alissa will be launching the Orion product very soon (possibly next month). [...] Implementing a price rise is difficult when everyone knows that competition is around the corner, and Auden are continuing to supply at the old costs. For the sake of a few quid per pack I think we should be looking to develop customer relations rather than push ahead with a price rise that is likely to be short-lived.'*¹⁰⁷⁹

3.710. On 20 March 2015, [AMCo Employee] updated [AMCo Senior Employee 1]: '*I have heard that Alissa Healthcare are likely to negotiate a supply deal with Auden/Actavis rather than launch the Orion stock due to the licence indication issue.*' [AMCo Senior Employee 1] commented: '*[g]ood news that*

¹⁰⁷⁵ Document 202747, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [REDACTED], [AMCo Senior Employee 2] and [AMCo Senior Employee 5] dated 2 December 2014; and Document 202749, email from [REDACTED] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 2] and others dated 2 December 2014.

¹⁰⁷⁶ Document 202952, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8], [AMCo Senior Employee 4], [REDACTED] and others dated 2 December 2014.

¹⁰⁷⁷ Document 200135, email from [AMCo Senior Employee 4] to [Focus Senior Employee 1] and [Focus Senior Employee 2] dated 2 December 2014. See also Document 202748, email from [AMCo Senior Employee 4] to [REDACTED] dated 2 December 2014.

¹⁰⁷⁸ Document 200138, email from [AMCo Senior Employee 1] to [Cinven Senior Employee 1] dated 27 January 2015.

¹⁰⁷⁹ Document 202792, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 17 March 2015. See also Document 202780, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 6] dated 18 March 2015, where [AMCo Senior Employee 1] referred to Orion's anticipated launch as one of the '*potential threats to us*' and requested to hold off with implementing price increases to customers '*just in case we are faced with competition*'.

Alissa are doing this. It makes sense as their product also doesn't have the full indications that the Auden product has. In which case I hope that we will see Cat M [ie the drug tariff] increase in due course'.¹⁰⁸⁰ AMCo therefore anticipated that rather than launching its own product, Alissa would strike a supply arrangement with Auden similar to its own, and that this would give Auden the opportunity to continue to increase its prices.

- 3.711. On 22 April 2015, AMCo confirmed that its *'patience has paid off'* as prices were moving upwards on hydrocortisone tablets again.¹⁰⁸¹ [AMCo Senior Employee 1] was pleased and hoped that the upward trend *'continues'*.¹⁰⁸²
- 3.712. AMCo continued to monitor the developments around Alissa's entry,¹⁰⁸³ and by May 2015, Alissa had still not launched its 10mg product. [AMCo Senior Employee 2] stated: *'he [Alissa Senior Employee] has either done a deal to get supply from AM [Auden] for the product with the complete indication and is just supplying it to a handful of small customers, or he is selling his own product to those same small customers, but not competing in the high volume market, or he has done a deal with AM to stay off the market, which would be unadvisable given recent legislation re: Servier and Lundbeck.'*¹⁰⁸⁴ As described in section 3.F.III.p above, Alissa approached Accord-UK in November 2015 in relation to a potential supply deal.
- 3.713. By 19 October 2015, AMCo understood that Alissa had not entered into a supply arrangement with Accord-UK and would therefore enter the market, anticipating an impact on price. [AMCo Employee] reported: *'Actavis are informing customers that Alissa are launching their hydrocortisone i.e. they have not done a deal. [...] The only way Alissa can sell is by dropping the price.'*¹⁰⁸⁵
- 3.714. Having been asked to *'do some digging'* by [AMCo Senior Employee 3], [Focus Senior Employee 1] clarified:

¹⁰⁸⁰ Document 202781, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 20 March 2015 and [AMCo Senior Employee 1]'s email response dated 22 March 2015.

¹⁰⁸¹ Document 202792, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 22 April 2015.

¹⁰⁸² Document 202792, email from [AMCo Senior Employee 1] to [AMCo Employee] dated 23 April 2015.

¹⁰⁸³ On 23 April 2015, [AMCo Senior Employee 3] looked for an update *'on the rumour about Alissa sourcing product from Auden instead of launching the Orion product'*. [AMCo Employee] responded that there were no further news, but noted: *'I would imagine that negotiations have become far more complicated with Actavis in the mix'* – see Document 202792, emails between [AMCo Senior Employee 3], [AMCo Employee] and [AMCo Senior Employee 1] dated 23 April 2015.

¹⁰⁸⁴ Document 202952, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1], [AMCo Senior Employee 3], [X] and [AMCo Senior Employee 6] dated 26 May 2015.

¹⁰⁸⁵ Document 202826, email from [AMCo Employee] to [AMCo Senior Employee 3] dated 19 October 2015.

'Yes Alissa are planning to launch their own product, ie they as yet have not done a deal'.¹⁰⁸⁶

- 3.715. In response, [AMCo Senior Employee 3] informed [AMCo Senior Employee 1] that *'the Hydro market is going to change a little.'*¹⁰⁸⁷
- 3.716. On 2 November 2015, Aesica delivered the 31,036 packs of 10mg hydrocortisone tablets that AMCo had ordered on 18 February 2015 (see paragraph 3.661 above).¹⁰⁸⁸
- 3.717. In light of the changing market conditions, AMCo started considering entering the market with its own Aesica-manufactured 10mg hydrocortisone tablets.
- 3.718. On 29 February 2016 [AMCo Employee] emailed [AMCo Senior Employee 3]: *'Bristol are apparently due to launch in a couple of weeks ... At the moment this brings the price down to around £63-65. Sandoz will apparently also be launching this year, although their timeframe is less imminent'.* [AMCo Senior Employee 3] forwarded her email to [AMCo Employee], commenting: *'It looks like my suspicions on where this market might go are coming true and we may need to act April-June with volumes.'*¹⁰⁸⁹ [AMCo Senior Employee 3] separately forwarded [AMCo Employee]'s email to [AMCo Senior Employee 1], noting: *'[s]ome decisions are imminent'.*¹⁰⁹⁰
- 3.719. On 1 March 2016, [AMCo Senior Employee 3] asked for an update on the status of AMCo's own Aesica-manufactured 10mg stock and how quickly it could be obtained. [AMCo Senior Employee 3] commented:

*'I think we have 30k packs and another 30k packs arriving this month. Is that right? Could we get more soon after? I think we have another 30k packs in June but I am thinking something like 60k packs in April. It looks like my suspicions on where this market might go are coming true and we may need to act April-June with volumes.'*¹⁰⁹¹

¹⁰⁸⁶ Document 202826, email from [Focus Senior Employee 1] to [AMCo Senior Employee 3] dated 20 October 2015.

¹⁰⁸⁷ Document 202826, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 20 October 2015.

¹⁰⁸⁸ Aesica's invoice records that delivery was on 29 October 2015. AMCo's internal records record 2 November 2015. Document 201959, Invoice issued by Aesica on 29 October 2015. See also Document 202827, email from [AMCo Employee] to [X], [AMCo Employee] and [X] dated 4 November 2015.

¹⁰⁸⁹ Document 202846, emails between [AMCo Senior Employee 3], [AMCo Employee] and [AMCo Employee] dated 1 March 2016.

¹⁰⁹⁰ Document 202844, email from [AMCo Senior Employee 3] to [AMCo Employee] and [AMCo Senior Employee 1] dated 29 February 2016.

¹⁰⁹¹ Document 202845, email from [AMCo Senior Employee 3] to [AMCo Employee] and [AMCo Senior Employee 5] dated 1 March 2016.

3.720. On the same day, [AMCo Senior Employee 3] emailed [AMCo Employee] and [AMCo Employee]:

*'we may see a huge change in the market stability. We do not know how important or key the orphan indication will be if Bristol, Alissa and Sandos launch but I have now got 60k packs ready by the end of this month to react with. I am also trying to get a further 60k packs in by May/June. It could be an opportunity for us to severe [sic] the deal with Actavis and go to market.'*¹⁰⁹²

3.721. [AMCo Senior Employee 3] therefore anticipated that in light of further market entry, AMCo might need to launch its product in the coming months and end the Second Written Agreement.

3.722. Later that day, AMCo confirmed internally that *'[t]he order planned for delivery in March is now ready for collection'*.¹⁰⁹³ It was *'released for sale'* on 17 February 2016¹⁰⁹⁴ and was kept *'separate from the Actavis stock'*.¹⁰⁹⁵

3.723. The order referred to was placed by AMCo on 21 August 2015 (see above) and *'released for sale'* on 17 February 2016, two months after its planned delivery date.

3.724. On the following day, 2 March 2016, [AMCo Senior Employee 3] emailed [AMCo Employee]: *'[t]he market is changing day by day so can we ensure we release this product [10mg hydrocortisone tablets] in March and April as fast as possible please.'* [AMCo Employee] responded that *'[AMCo Senior Employee 5] has suggested that maybe we should review everything but not release until you tell us to do so while we are still selling Auden product.'*¹⁰⁹⁶

3.725. There followed further internal AMCo discussions as to whether it was still selling the Auden tablets or if it could sell its own Aesica product. On 3 March 2016, in a conversation with [AMCo Senior Employee 5], [AMCo Employee] queried whether AMCo was selling Auden's or its own Aesica-manufactured 10mg hydrocortisone tablets, noting that [AMCo Senior Employee 3] had asked him to *'fast track future release'*. Further to [AMCo Senior Employee 5]'s confirmation that it was *'[s]till Auden'*, [AMCo

¹⁰⁹² Document 202847, email from [AMCo Senior Employee 3] to [AMCo Employee] and [AMCo Employee] dated 1 March 2016.

¹⁰⁹³ Document 202845, email from [AMCo Employee] to [AMCo Employee] dated 1 March 2016. See also Document 201961, Invoice issued by Aesica on 29 February 2016 for 31,898 packs of 10mg hydrocortisone tablets.

¹⁰⁹⁴ Document 202861, email from [X] to Alloga UK dated 17 March 2016.

¹⁰⁹⁵ Document 202893, email from [AMCo Employee] to [X] dated 26 April 2016. It was confirmed that *'the deliveries in No 15 and Mar 16 were packed with the correct 25 micron foil'* and had been released, see Document 202868, online conversation between [X] and [X] dated 21 March 2016.

¹⁰⁹⁶ Document 202851, email from [AMCo Senior Employee 3] to [AMCo Employee] dated 2 March 2016; and email from [AMCo Employee] to [AMCo Senior Employee 3] dated 3 March 2016.

Employee] asked whether there was *'any restriction or deal agreed [...] thought we may have said not to release ours while still selling Auden stock??? something from the past'*. [AMCo Senior Employee 5] confirmed that this was correct and explained that:

'Ours has always been merely a back up until now. [...] It may change if Auden do not renew the agreement which seems likely and is why we are stocking up on our own MA. Think we need to be careful that ours does not go out to patients without [AMCo Senior Employee 3]'s, say so....maybe that means not releasing it but making sure we can at a moments [sic] notice'.¹⁰⁹⁷

- 3.726. On the same day, in a further conversation with [AMCo Employee], [AMCo Employee] asked if AMCo could be in a position to release its Aesica product quickly. [AMCo Employee] noted: *'we have received Licence product but not sure if we can release this now. I understand there was some agreement with Auden Mckenzi [sic]. That we will not release licence product'*.¹⁰⁹⁸
- 3.727. Having checked with [AMCo Senior Employee 5], [AMCo Employee] later confirmed that *'we need to have reviewed everything so we can release but not actually release [sic] [...] we just need to be ready to release at a moments [sic] notice in case we have issues with Auden [sic]'*.¹⁰⁹⁹
- 3.728. On 8 March 2016, following the market entry by Resolution Chemicals, [AMCo Employee] reported internally: *'[w]ith the market as fluid as it is at the moment I would like to avoid any unnecessary delay in placing our stock.'*¹¹⁰⁰
- 3.729. On 9 March 2016 [AMCo Employee] forwarded to [AMCo Senior Employee 3] further information on competitors entering the market (*'Bristol are now on the market ... There are rumours that Milpharm will also be launching in the next couple of months'*). [AMCo Employee] stated that AMCo's customers *'have both declined to buy any stock from me this month as they are very nervous about the price dropping quickly ... I do think we need to have a backup strategy re: pricing for next month.'* [AMCo Senior Employee 3] forwarded this to [AMCo Senior Employee 1], noting: *'Further power to the bow of launching in my view'*; and to [AMCo Senior Employee 8], noting: *'In light of some major changes to the market that have come through from the*

¹⁰⁹⁷ Document 202850, conversation between [AMCo Employee] and [AMCo Senior Employee 5] dated 3 March 2016.

¹⁰⁹⁸ Document 202849, conversation between [AMCo Employee] and [AMCo Employee] on 3 March 2016.

¹⁰⁹⁹ Document 202852, conversation between [AMCo Employee] and [AMCo Employee] dated 3 March 2016.

¹¹⁰⁰ Document 202856, email from [AMCo Employee] to [AMCo Senior Employee 3] dated 8 March 2016.

*sales team this week I think we need to ... explore launching our own product onto the market.'*¹¹⁰¹

- 3.730. On the same day, [AMCo Senior Employee 3] separately emailed [AMCo Senior Employee 1], stating:

'The imperfect storm is brewing and the digging I have done with various industry types and through [AMCo Employee] and [AMCo Employee] this week is strengthening my views and recommended approach.

*We cannot delay any longer as we [...] have more arrivals entering the market, have our own agreement up for renewal in the summer, are starting to find it a little tougher to sell [...].'*¹¹⁰²

- 3.731. By March 2016 AMCo had therefore reached the view that it could delay the launch of its Aesica product no longer, because of factors including: the arrival of further genuine competition to the market (*'more arrivals entering the market'*); the erosion of the very high prices AMCo had been able to charge for the 10mg tablets it obtained from Accord-UK as a result (*'starting to find it a little tougher to sell'*); and the uncertainty as to whether the 10mg supply deal would be renewed (*'our own agreement up for renewal in the summer'*).
- 3.732. On 6 April 2016, [AMCo Employee] suggested to *'look again at whether to launch ours'* and queried whether there was *'a clause in the Actavis agreement which precludes us from marketing ours whilst we have supply from them'*, noting that she *'would be surprised if there wasn't'*.¹¹⁰³
- 3.733. On 26 April 2016, AMCo noted that *'[w]e have 60k packs released and 30k packs expected in July16'*, and wanted to order an additional 60,000 packs for delivery in August 2016.¹¹⁰⁴ Due to the *'unforecasted'* nature of the order, Aesica informed AMCo that it could deliver 45,000 packs and 15,000 packs in November and December 2016, respectively.¹¹⁰⁵
- 3.734. In May 2016, AMCo entered the market¹¹⁰⁶ with its skinny label 10mg hydrocortisone tablets manufactured by Aesica, which it sold to a

¹¹⁰¹ Document 200156, emails between [AMCo Employee], [AMCo Senior Employee 3], [AMCo Senior Employee 1] and [AMCo Senior Employee 8] dated 9-10 March 2016.

¹¹⁰² Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.

¹¹⁰³ Document 202877, email from [AMCo Employee] to [AMCo Employee] dated 6 April 2016.

¹¹⁰⁴ Document 202894, emails between [X] and [AMCo Employee] dated 26 April 2016.

¹¹⁰⁵ Document 202897, email from [AMCo Employee] to [X] dated 28 April 2016.

¹¹⁰⁶ The sales were first recorded in the month of May 2016 in the data submitted to the CMA (Document 201045,

wholesaler, Depharma,¹¹⁰⁷ recognising that *'[c]ompetition has arrived on Hydrocortisone and the skinny label product is unexpectedly taking volume share'*.¹¹⁰⁸

3.735. From mid-May 2016, AMCo observed erosion in prices and market shares as a result of competition. For example:

- a. On 17 May 2016, [AMCo Employee] reported that the price was *'now down to £51 due to Bristol, Resolution, Alissa and us chasing market share. [...] The buyers are very nervous of taking any quantity of stock as the prices are falling so quickly.'*¹¹⁰⁹
- b. On 21 July 2016, [AMCo Employee] further reported: *'Alissa pricing confirmed at £40. The only way is down....'*¹¹¹⁰

3.736. The July 2016 Concordia Commercial UK and Ireland report set out that *'July month missed forecast due to Hydrocortisone competition effects'*, noting that the forecast had been prepared on the assumption that AMCo would continue selling the Accord-UK product throughout 2016 (*'12k units at an ASP £68'*) and ASPs would have remained stable *'throughout the whole year given no additional competition'*.¹¹¹¹

3.737. The report further set out the following factors contributing to *'The Perfect Storm'* in relation to the hydrocortisone market, which meant the July forecast had been missed:

- a. *'In January 2016 Actavis served notice¹¹¹² that they would terminate supply to CRx [Concordia] of the Full Label product and the agreement came to an end in June 2016.'*
- b. *'Delays in the Lamda SKU launch resulted in CRx taking the decision to launch the Skinny label SKU [Aesica-manufactured 10mg*

Sales by Customer – Aesica Queenborough Ltd livery tab). At a meeting on 26 April 2016, AMCo confirmed it would supply a customer with its Aesica 10mg product, and subsequently in May 2016, it accepted orders and supplied various customers (Document 200451 and Document 200452, note of State of Play meeting between the CMA and AMCo dated 18 May 2016, paragraphs 35 and 45, Document 200453, paragraph 4.8, Follow up to the State of Play meeting between the CMA and AMCo on 18 May 2016, Document 200288, Chronology of *'Amdipharm's Development of Reduced Indication 10mg Hydrocortisone'*, submitted on a voluntary basis by AMCo on 14 October 2016).

¹¹⁰⁷ Document 201353, Notes of oral hearing with Concordia dated 20 July 2017.

¹¹⁰⁸ Document 200208, UK Commercial Monthly Report – March 2016, page 2.

¹¹⁰⁹ Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016.

¹¹¹⁰ Document 202915, email from [AMCo Employee] to [AMCo Employee] dated 21 July 2016.

¹¹¹¹ Document 202917, 'Concordia Commercial UK and Ireland Jul 2016' slide pack, slides 3, 13.

¹¹¹² This may have been the understanding of certain AMCo staff but does not appear to have been the case. Accord-UK did not in fact write to AMCo to state that the Second Written Agreement had terminated until 30 June 2016: Document 02787, letter from [Actavis Senior Employee 2] to [AMCo Senior Employee 8] dated 30 June 2016. As explained below, [AMCo Senior Employee 8] replied to Accord-UK to emphasise that *'The Agreement has not been terminated, it has expired'*.

hydrocortisone tablets] *to ensure continuity of presence in the market.*¹¹¹³

- c. *'By Q2 '16 it was clear there was going to be additional competition entering the market from Bristol, Resolution, Teva, Alissa. Price and market share has therefore been impacted.'*¹¹¹⁴

3.738. The report further noted that *'Hydrocortisone 10mg is moving towards a commodity market with many players, particularly in the Skinny label market.'*¹¹¹⁵

r. The 10mg supply deal between Auden/Actavis and AMCo ends

3.739. AMCo entered the market without notifying Actavis that it was intending to enter (and seemingly, therefore, unbeknown to Actavis), contrary to the requirement to do so under the terms of the Second Written Agreement, and anticipated that Actavis would stop supplying it shortly.¹¹¹⁶

3.740. AMCo continued to place orders for 10mg hydrocortisone tablets with Actavis on the terms of the Second Written Agreement, including for delivery after the Second Written Agreement expired.¹¹¹⁷

3.741. However, the Second Written Agreement expired on 24 June 2016. On 30 June 2016, Actavis sent a letter to AMCo confirming its termination.¹¹¹⁸ It was not renewed and Actavis did not fulfil orders after this date. AMCo

¹¹¹³ On 10 October 2016, the MHRA granted skinny label MAs for both the 10mg and 20mg Lamda-manufactured hydrocortisone tablets (see the MHRA's approved SmPC for Focus' Hydrocortisone Tablets at [Microsoft Word - 2958052151657664792_spc-doc.doc \(windows.net\)](#) and [Microsoft Word - 2515053291655195867_spc-doc.doc \(windows.net\)](#)). Focus entered the market with 20mg and 10mg hydrocortisone tablets manufactured by Lamda on 11 August and 18 September 2017, respectively (Document 02662, response to question 1, AMCo's response to the CMA's section 26 notice dated 25 January 2018).

¹¹¹⁴ Document 202917, 'Concordia Commercial UK and Ireland Jul 2016' slide pack, slide 14.

¹¹¹⁵ Document 202917, 'Concordia Commercial UK and Ireland Jul 2016' slide pack, slide 15.

¹¹¹⁶ See Document 202898, email from [AMCo Employee] to [AMCo Employee] dated 28 April 2016; and Document 202900, email from [AMCo Senior Employee 3] to [AMCo] and others dated 6 May 2016.

¹¹¹⁷ See, for example, Document 202943, letter from [AMCo Senior Employee 8] to [Actavis Senior Employee 2] dated 6 July 2016: *'you are refusing to honor two of our purchase orders which, as you say, are currently outstanding and have been for some time ... which are due for delivery on July 16 and August 16 respectively ... The Agreement has not been terminated, it has expired. Accordingly, we consider that you are under a contractual obligation to fulfil orders that are outstanding at the date of expiration of the Agreement.'* See also Document 202960, email from [AMCo] to [AMCo Senior Employee 5] dated 21 June 2016; Document 02783, email from [AMCo] to [AMCo] dated 22 July 2016; Document 02785, email from [Actavis Senior Employee 1] to [AMCo] dated 22 July 2016; Document 202995, conversation between [AMCo] and [AMCo Senior Employee 5] dated 2 August 2016; Document 02790, email from [AMCo] to [Actavis Senior Employee 2] dated 15 August 2016; and Document 202942, email from [AMCo Senior Employee 8] to [Actavis Senior Employee 2] dated 16 August 2016.

¹¹¹⁸ Document 02787, letter from [Actavis Senior Employee 2] to [AMCo Senior Employee 8], dated 30 June 2016; Document 02816, email from [Actavis Senior Employee 2] to [AMCo] dated 29 June 2016. Also see Document 02786, email from [Actavis Senior Employee 2] to [AMCo], in which [Actavis Senior Employee 2] shared the letter with [AMCo], and Document 02789, email exchange between [AMCo] and [AMCo] dated 13 July 2016.

received no further supplies of 10mg hydrocortisone tablets from Actavis after the expiry of the Second Written Agreement.¹¹¹⁹

¹¹¹⁹ Document 200258, paragraph 9, AMCo's response to the CMA's section 26 notice dated 23 August 2016.

4. MARKET DEFINITION AND DOMINANCE

4.1. This section sets out:

- a. an overview of the CMA's key market definition and dominance findings (section 4.A);
- b. the CMA's assessment of the relevant market(s) for the purposes of this Decision (section 4.B); and
- c. the CMA's assessment of whether Auden/Actavis held a dominant position in the relevant market(s) (section 4.C).

A. Overview of key market definition and dominance findings

I. The CMA's findings

4.2. This section considers the definition of the relevant market(s) for the purposes of the Infringements and whether Auden/Actavis held a dominant position in those relevant market(s).

4.3. Market definition is a tool to identify and define the boundaries of competition between firms, the main purpose of which is to identify in a systematic way the competitive constraints that the undertakings involved face. It is a key step in identifying whether an undertaking is dominant but is not an end in itself.

4.4. Dominance is defined as the ability to behave to an appreciable extent independently of competitors, customers and ultimately of consumers¹¹²⁰ and can be thought of as the ability profitably to sustain prices above competitive levels or restrict output or quality below competitive levels.¹¹²¹

4.5. The CMA has concluded that the relevant markets are the supply of hydrocortisone tablets (including both full and skinny label tablets) in the UK. The evidence demonstrates that there were separate 10mg and 20mg hydrocortisone tablet markets following the entry of competing suppliers and also suggests that there was a combined market for 10mg and 20mg strengths prior to the entry of competing suppliers.¹¹²² The CMA has concluded that Auden/Actavis was dominant in those markets throughout the

¹¹²⁰ *United Brands v Commission* C-27/76, EU:C:1978:22 ('*United Brands*'), paragraph 65.

¹¹²¹ OFT415 *Assessment of market power* (December 2005), adopted by the CMA, paragraph 1.4 and Communication from the Commission: Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C 45/7, 24.2.2009, ('*Enforcement Priorities Guidance*'), paragraph 11.

¹¹²² See section 4.B.II.c.iii for the CMA's analysis of whether 10mg and 20mg tablets formed part of the same or separate relevant markets.

Unfair Pricing Abuses.¹¹²³ However, the CMA's conclusion that Auden/Actavis was dominant prior to the entry of competing suppliers holds regardless of whether there was a single combined market for both tablet strengths or separate markets for each tablet strength.

- 4.6. The CMA sets out its formal assessment of the relevant markets and dominance below, which includes a detailed discussion of the points included in this overview. While simultaneously holding very high market shares and profitably maintaining very high prices for a prolonged period of time together constitute proof that Auden/Actavis held a dominant position, the CMA has also considered the competitive conditions for the supply and demand of 10mg and 20mg hydrocortisone tablets in drawing its conclusions on market definition and dominance in this case.
- 4.7. That full and skinny label hydrocortisone tablets form the relevant markets¹¹²⁴ and that Auden/Actavis was dominant in those relevant markets is, in particular, demonstrated by the facts that:
- a. For around seven years (from 2008 until 2015), Auden/Actavis was a monopolist supplier,¹¹²⁵ profitably imposing significant price increases for hydrocortisone tablets. Other potential treatments did not sufficiently constrain hydrocortisone tablets to warrant inclusion in the relevant product market.¹¹²⁶
 - b. Subsequently, Auden/Actavis did face competition, following independent entry by skinny label tablet suppliers. This led to falls in both Auden/Actavis's prices and volumes and also skinny label tablet prices, demonstrating that skinny label tablets form part of the relevant market.
 - c. For 10mg tablets (which account for 96% of the total volumes of hydrocortisone tablets dispensed), however, Auden/Actavis retained an assured base of full label customers (amounting to approximately 50% of total volumes of hydrocortisone tablets), which enabled it to charge a

¹¹²³ The Unfair Pricing Abuse is from 1 October 2008 until 31 July 2018 for 10mg hydrocortisone tablets, and from 1 October 2008 until 8 January 2017 for 20mg hydrocortisone tablets. The CMA has made no finding in relation to whether Auden/Actavis held a dominant position for 10mg or 20mg hydrocortisone tablets outside of those periods.

¹¹²⁴ Combined 10mg and 20mg market pre-entry and 10mg and 20mg separate markets post-entry.

¹¹²⁵ Between 2011 and 2016 Auden/Actavis supplied Waymade and AMCo with limited volumes of its hydrocortisone tablets at a substantial discount to the price it supplied other customers at (87% and 97% respectively). Waymade and AMCo then sold those volumes in the market for a profit. The CMA has found that these supply arrangements were payment in return for AMCo's and Waymade's agreement not to enter the market independently. See section 6 below.

¹¹²⁶ This is supported by prescribing evidence that 95% of patients with adrenal insufficiency take hydrocortisone tablets as they are the best option therapeutically.

substantial premium given its position as the only supplier of 10mg full label tablets.

- d. For 20mg tablets, Auden/Actavis faced competition from one 20mg full label tablets supplier (Waymade) and from skinny label tablet suppliers. Despite this, Auden/Actavis retained a market share by value in excess of 60% of 20mg hydrocortisone tablets and the ability to charge a substantial premium above prices of competing 20mg tablet suppliers.

4.8. These points are demonstrated in figures 4.1 and 4.2 below, which show that:

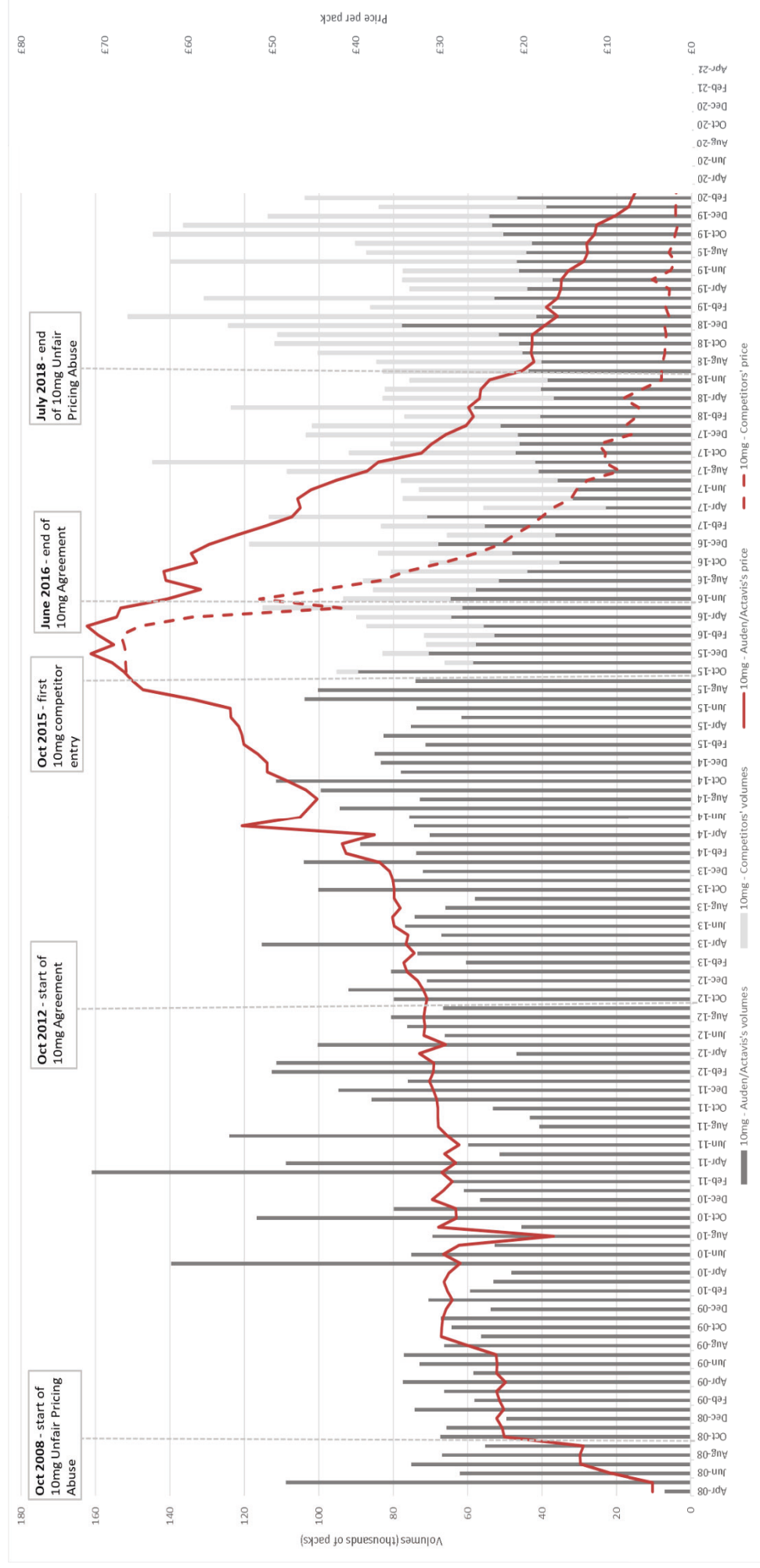
- a. Prior to independent entry, Auden/Actavis repeatedly and substantially raised prices (an overall increase of 200% and 171% for 10mg and 20mg tablets respectively),¹¹²⁷ without any discernible impact on hydrocortisone tablet volume trends, which were steadily growing throughout.¹¹²⁸
- b. Following independent entry, there was substantial switching from full to skinny label tablets¹¹²⁹ and accompanying falls in both full and skinny label tablet prices.
- c. Following independent entry, Auden/Actavis continued to charge prices significantly in excess of those charged by its competitors while maintaining significant market shares.

¹¹²⁷ For 10mg tablets: an increase from £22.28 in October 2008 (the month the 10mg Unfair Pricing Abuse started) to £66.76 in September 2015 (the month before independent entry commenced for 10mg tablets). For 20mg tablets: an increase from £23.74 in October 2008 (the month the 20mg Unfair Pricing Abuse started) to £64.26 in June 2015 (the month before independent entry commenced for 20mg tablets).

¹¹²⁸ That the volume trend remained unchanged following independent entry when prices were declining further demonstrates the lack of substitutability between hydrocortisone tablets and other medicines in the treatment area.

¹¹²⁹ Consistently with this, the evidence demonstrates that there was expected to be demand for skinny label tablets prior to independent entry taking place from October 2015 (see section 3.E.IV.a above), though the level of that demand was uncertain.

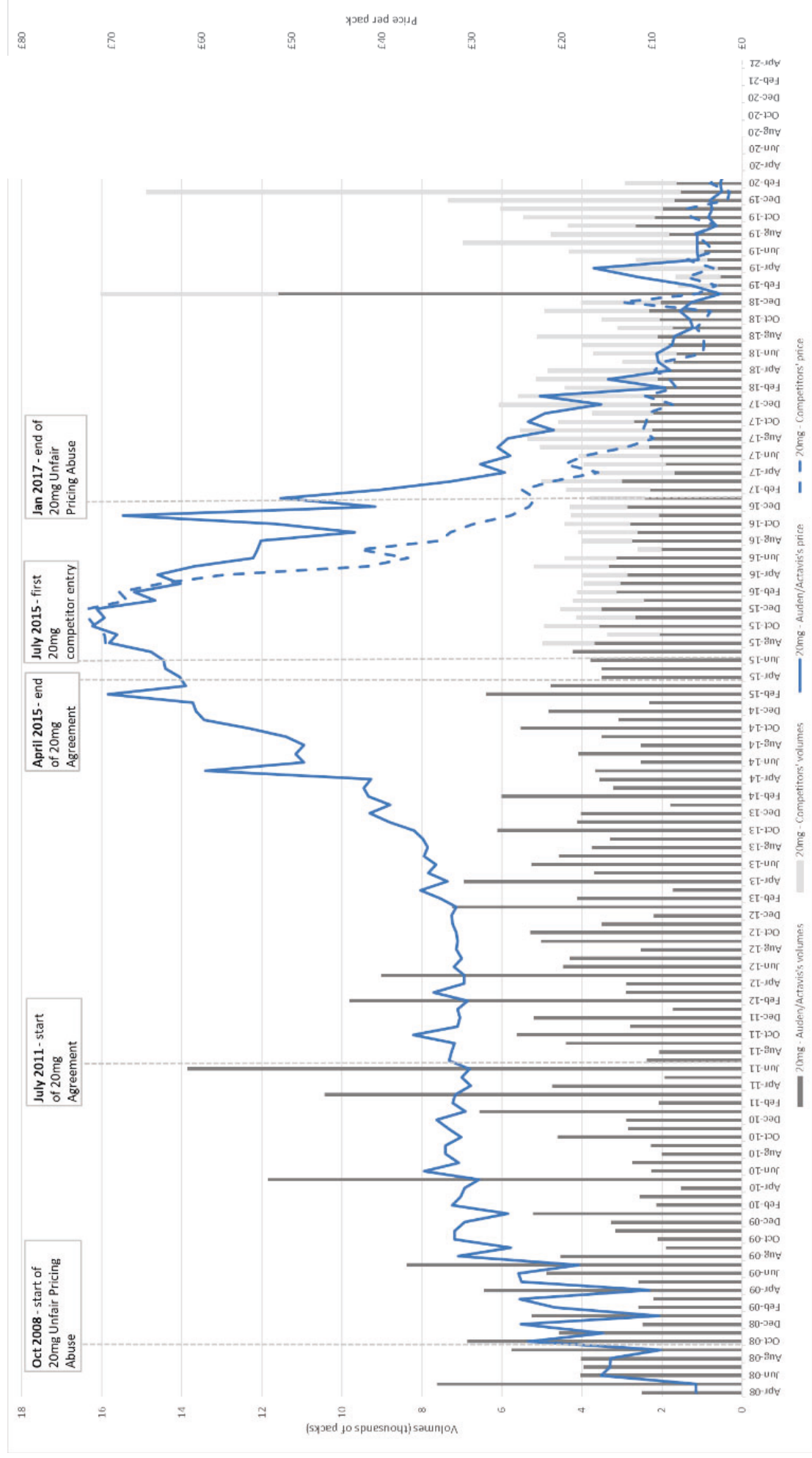
Figure 4.1: Auden/Actavis's and competitors' 10mg hydrocortisone tablet prices and volumes¹¹³⁰



Source: CMA analysis based on data submitted by relevant parties.

¹¹³⁰ After 2015 (following independent entry), the volumes in figures 4.1 and 4.2 are stacked bars to show the proportions of Auden/Actavis's volumes and competitors' volumes. The dark grey bars are Auden/Actavis's volumes, the light grey bars are its competitors' volumes, and the combination of the dark and light grey bars are total volumes.

Figure 4.2: Auden/Actavis's and competitors' 20mg hydrocortisone tablet prices and volumes



Source: CMA analysis based on data submitted by relevant parties.

- 4.9. Being able to observe the impact of skinny label tablet entry on Auden/Actavis's prices and volumes provides a natural event to assess the constraints that Auden/Actavis was facing both before and after that entry. Figures 4.1 and 4.2 provide a clear picture that: (i) despite significant changes in hydrocortisone tablet prices, total volumes trends were unchanged, (ii) it was entry of skinny label tablet suppliers that precipitated the falls in prices of both full and skinny label tablets, and (iii) Auden/Actavis retained a large share of supply and the ability to price at a premium to competitors following independent entry during the Unfair Pricing Abuses. This demonstrates that the relevant markets include both full and skinny label hydrocortisone tablets but are no wider (ie the relevant markets do not include any other treatments). It also demonstrates that Auden/Actavis retained the ability to behave to an appreciable extent independently of its competitors, customers and ultimately of end consumers such that it retained a dominant position within those markets throughout the period of the Unfair Pricing Abuses.
- 4.10. Hydrocortisone tablets were in the third stage of the drug life cycle, during which entry by suppliers of the same generic medicine would usually be expected to erode prices and volumes of the incumbent supplier and keep prices low, providing a significant competitive constraint because they are supplying homogenous products (see section 3.B.III above). Entry did not take place for a long time during which Auden/Actavis continued raising prices as a sole supplier,¹¹³¹ and when entry belatedly happened, the constraint from entry did not materialise to the same degree for hydrocortisone tablets and Auden/Actavis.
- 4.11. This was a result of the barrier to expansion created by the orphan designation, which created differentiated versions of hydrocortisone tablets - full and skinny label versions. Despite being bioequivalent and therefore interchangeable from a therapeutic perspective and with off-label dispensing expected prior to skinny label entry, full and skinny label tablets were not substitutes for all customers (as some customers had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets, see section 3.E.IV.c.i above). As a result, this differentiation provided Auden/Actavis with an assured base, which gave rise to substantial market power as it enabled Auden/Actavis to charge its captive customers a significant price premium compared to its competitors' prices.

¹¹³¹ See also section 4.C.II.b.iii for an explanation of how Auden's Agreements with AMCo and Waymade enabled it to prolong its dominant position.

- 4.12. Taken together, the evidence demonstrates that Auden/Actavis clearly faced competitive constraints from skinny label suppliers, with the entry of skinny label tablet suppliers precipitating falls in prices, effectively halting and then starting to reverse the unchecked price rises of the previous seven years when Auden/Actavis was a monopolist and resulting in substantial switching away from Auden/Actavis's tablets. While those competitive constraints from skinny label tablets were sufficiently strong to warrant including skinny label tablets in the same relevant market as full label tablets, they were not significant enough to prevent Auden/Actavis from retaining substantial market power arising from its assured base of customers that had no choice but to purchase its tablets and as such, to prevent Auden/Actavis from being dominant.

II. Representations on consistency between market definition and dominance

- 4.13. AMCo, Cinven, Intas/Accord-UK and Waymade submitted that the CMA's approach to market definition – which recognises that skinny label hydrocortisone tablets posed a sufficient competitive constraint on full label tablets to be included in the same relevant market – was inconsistent with its provisional finding that Auden/Actavis held a dominant position during the Unfair Pricing Abuses.¹¹³²
- 4.14. As explained above and in this section, the CMA's findings on market definition are not inconsistent with its findings on dominance:
- a. The test for market definition is whether a product imposes a **sufficient constraint** on the focal product to be considered part of the same relevant market.¹¹³³ Skinny label tablets imposed such a constraint on full label tablets. Following independent entry, around 50% of the market by volume switched to skinny label tablets and prices fell across the market.
 - b. The test for dominance is that an undertaking is able to act **to an appreciable extent** independently of its competitors, customers and ultimately consumers.¹¹³⁴ Auden/Actavis met that test throughout the Unfair Pricing Abuses. In particular, Auden/Actavis was able to

¹¹³² Document 204922, AMCo's RSSO paragraphs 4.62, 4.72 and 4.86, Document 204967, Cinven's RSSO paragraphs 5.14-5.16 and 5.46-5.48, Document 204969, Cinven's CRA analysis, paragraph 53, Document 205212, Intas/Accord-UK's RSSO, paragraphs 31-33, Document 204903, Waymade's RSSO, paragraph 8.128.

¹¹³³ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97 (emphasis added). See also *GlaxoSmithKline plc and others v Competition and Markets Authority* [2018] CAT 4, paragraph 401: '[t]he critical question, as stated in *Aberdeen Journals*, is to identify what other products provided a competitive constraint to the conduct of the potentially dominant firm'.

¹¹³⁴ *Case 27/76 United Brands v Commission*, EU:C:1978:22, paragraph 65 (emphasis added).

maintain a significant price premium relative to skinny label tablets¹¹³⁵ because of its assured base of customers (around 50% of the market by volume that had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets), thereby sustaining Auden/Actavis's market power.

- 4.15. These tests are not mutually exclusive. An entrant's product may sufficiently compete with an incumbent's to be included within the same relevant market, but not to the extent that it deprives the incumbent of the ability to behave to an appreciable extent independently. If this were not the case, dominance would only be possible in single-product markets.¹¹³⁶ That is clearly wrong.
- 4.16. It is uncontroversial to have differentiated products in the same relevant market as one another: there is a distinction between identifying substitutability between products that are differentiated and finding the ability to hold market power over those differentiated products. What matters is the degree of the competitive constraint and whether the degree of constraint is sufficient to prevent an undertaking acting appreciably independently of its competitors, customers and consumers.
- 4.17. The evidence demonstrates that skinny label tablet suppliers imposed a sufficient competitive constraint on full label tablets such that full and skinny label tablets were part of the same product market, most clearly shown by the entry of skinny label tablets being the event that caused Auden/Actavis to start to lose market share (both value and volume shares) and halt and start to reverse Auden/Actavis's continual price increases. However, the constraint exerted by skinny label tablets was not significant enough to prevent Auden/Actavis from being able to act independently of competitors, customers and consumers to an appreciable extent during the Unfair Pricing Abuses, most clearly shown by Auden/Actavis being able to charge a premium as compared to its competitors while retaining significant market shares (by both value and volume). Accordingly, Auden/Actavis continued to be dominant in the relevant markets during the post-entry period.

B. Market definition

I. Legal framework for market definition

- 4.18. In order to determine whether an undertaking holds a dominant position, and to assess the potential harm to competition from agreements between

¹¹³⁵ And relative to competitor's prices (including Waymade's full label tablets) on 20mg tablets.

¹¹³⁶ It is well-established that an undertaking does not need to be a monopolist in order to be dominant. See, for example, Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 113 to 121 and 196.

undertakings, it is first necessary to define the relevant market in which the relevant undertakings operate.¹¹³⁷

- 4.19. Market definition is a key step in identifying the constraints acting on a supplier of a given product and in identifying whether an undertaking is dominant. Market definition is a tool to identify and define the boundaries of competition between undertakings. It is not an end in itself.¹¹³⁸ The purpose of defining the relevant market is *'to determine the competitive constraints on the product on the basis of which the market is defined'*.¹¹³⁹
- 4.20. The definition of the relevant market should therefore not be an abstract exercise detached from the question of whether there has been an infringement of the competition rules.¹¹⁴⁰ Definition of the relevant market is carried out, in the context of the Chapter II prohibition, *'in order to define the boundaries within which it must be assessed whether a given undertaking is able to behave, to an appreciable extent, independently of its competitors, its customers and, ultimately, consumers'*.¹¹⁴¹ In the context of the Chapter I prohibition, definition of the relevant market is carried out *'to determine whether the agreement in question is capable of affecting trade ... and has the object or effect of preventing, restricting or distorting competition'*.¹¹⁴²
- 4.21. There are normally two dimensions to the definition of the relevant market: (i) a product dimension; and (ii) a geographic dimension. A further possible dimension to market definition is time.¹¹⁴³ A firm may find itself exposed to competitive constraints at one point in time but may be free from them at another.¹¹⁴⁴
- 4.22. According to the European General Court:

¹¹³⁷ C-6/72 *Europemballage Corporation and Continental Can Company v Commission*, EU:C:1973:22, paragraph 32. See also C-27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 10; C-85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 21; and *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 88.

¹¹³⁸ See, for example, *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 36, paragraph 90; and *European Commission Notice on the definition of the relevant market for the purposes of Community competition law*, OJ C 372, 9.12.1997, p. 5 to 13. See also *OFT403 Market definition*, paragraph 2.1; *GSK v CMA* [2018] CAT 4, paragraph 397.

¹¹³⁹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 174.

¹¹⁴⁰ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 101.

¹¹⁴¹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 30, citing C-322/81 *Michelin I*, paragraph 37.

¹¹⁴² C-179/16 *Hoffmann-La Roche v AGCM*, paragraph 49 and the caselaw cited.

¹¹⁴³ See *OFT403 Market definition*, paragraph 5.1.

¹¹⁴⁴ For example, in *GlaxoSmithKline plc and others v Competition and Markets Authority* [2018] CAT 4, paragraph 402, the CAT recognised that *'it is not illogical to find that as a pharmaceutical product approaches the stage when generic entry becomes a realistic possibility, the generic product is then taken into account in ... market definition, although years beforehand when there was no realistic prospect of a challenge to the patent on the active pharmaceutical ingredient, generic companies would not be regarded as relevant to market definition'*. This was endorsed by the Court of Justice: see *GSK v CMA* [2021] CAT 9, paragraphs 86-87.

*'the relevant product market includes products or services which are substitutable or sufficiently interchangeable with the product or service in question, not only in terms of their objective characteristics, by virtue of which they are particularly suitable for satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question'.*¹¹⁴⁵

- 4.23. The relevant product market *'is to be defined by reference to the facts in any given case, taking into account the whole economic context'*. The economic context may include, but is not limited to: (i) the objective characteristics of the products; (ii) the degree of substitutability or interchangeability between the products, having regard to their relative prices and intended use; (iii) the competitive conditions; (iv) the structure of supply and demand; and (v) the attitudes of consumers and users.¹¹⁴⁶
- 4.24. These factors are not, however, fixed or exhaustive. The factors to be taken into account will depend on the individual facts of each case. The products concerned must be *'close enough'* substitutes to be regarded as being in the same market.¹¹⁴⁷ The concept of the relevant market *'presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned'*.¹¹⁴⁸
- 4.25. In C-179/16 *Hoffmann-La Roche*, the European Court of Justice held that the fact that a medicine is only interchangeable with the focal product by virtue of being used 'off-label' to treat the same conditions is no bar to finding that they are in the same relevant product market. Such off-label use in fact *'reveals the existence of a specific relationship of substitutability'* between the two products.¹¹⁴⁹
- 4.26. However, functional interchangeability or similarity of characteristics will not, in themselves, provide sufficient criteria to determine whether two products are demand substitutes because the responsiveness of customers to relative changes in price may be determined by other considerations as well.¹¹⁵⁰ For example, in *AstraZeneca*, the European Commission noted that:

'In determining the functional substitutability of medicines it is not enough, for the purposes of product market definition, to state that

¹¹⁴⁵ T-504/93 *Tiercé Ladbroke v Commission* EU:T:1997:84, paragraph 81.

¹¹⁴⁶ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 96.

¹¹⁴⁷ OFT403 *Market definition*, paragraph 2.5. See also *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97.

¹¹⁴⁸ C-85/76 *Hoffman-La Roche v Commission*, EU:C:1979:36, paragraph 28.

¹¹⁴⁹ C-179/16 *Hoffmann-La Roche v Commission*, paragraphs 61 and 64-67.

¹¹⁵⁰ Commission Notice on Market Definition, paragraph 36.

*different medicines are prescribed for the same general illness or disease’.*¹¹⁵¹

- 4.27. The General Court and Court of Justice upheld the Commission’s approach.¹¹⁵²
- 4.28. The key consideration is the extent to which different product types are capable of constraining an undertaking’s conduct in practice. As the CAT has explained, the question is whether the products ‘*sufficiently compete with each other to be sensibly regarded as being in the same market*’:

*‘Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned sufficiently compete with each other to be sensibly regarded as being in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?’*¹¹⁵³

- 4.29. There is no set ‘*hierarchy*’ of evidence in EU or UK law on issues such as market definition¹¹⁵⁴ and it is a matter for the authority to determine what evidence it chooses to rely on to establish a relevant market.¹¹⁵⁵
- 4.30. Where available, evidence of actual substitution arising from past events or shocks will normally be ‘*fundamental for market definition*’, including reactions to changes in relative prices and to the launch of new products.¹¹⁵⁶ In a number of cases in the pharmaceutical sector, market definition has therefore been approached on the basis of assessing the effects of price increases and the impact of entry on substitution patterns.¹¹⁵⁷ For example, in *AstraZeneca*,¹¹⁵⁸ the European Commission used price data and price developments to assess whether other products constrained the price of a pharmaceutical product. The General Court, on appeal, rejected an argument that ‘*price-related indicators are inappropriate for competition*

¹¹⁵¹ Commission decision of 15 June 2005 in Case 37507, *AstraZeneca*, paragraph 381.

¹¹⁵² T-321/05 *AstraZeneca v Commission*, paragraph 71, upheld in C-457/10 P *AstraZeneca v Commission*.

¹¹⁵³ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97 (emphasis added). See also *GlaxoSmithKline plc and others v Competition and Markets Authority* [2018] CAT 4, paragraph 401: ‘[t]he critical question, as stated in *Aberdeen Journals*, is to identify what other products provided a competitive constraint to the conduct of the potentially dominant firm’.

¹¹⁵⁴ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 127.

¹¹⁵⁵ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 128.

¹¹⁵⁶ Commission Notice on Market Definition, paragraph 38.

¹¹⁵⁷ See, for example, Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011; Commission Decision of 9 July 2014, *Perindopril (Servier)*, Case AT.39612; Case CE/9742-13, *Phenytoin* (CMA Decision dated 7 December 2016); Case CE-9531/11 *Paroxetine* (CMA Decision dated 12 February 2016).

¹¹⁵⁸ COMP/A 37.507/F3, *AstraZeneca*: see, for example, paragraphs 423 and 428-431.

analysis purposes where competition on the market is not based on price,¹¹⁵⁹ holding that ‘... *the specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context*’.¹¹⁶⁰ The General Court adopted the same approach in *Servier*, in which it emphasised that price and volume analysis does have a role to play in the assessment of competitive constraints and market definition in the pharmaceutical sector. Those constraints must however be assessed in their full context.¹¹⁶¹

- 4.31. The CAT has also held that evidence of how the undertakings in question see the market is likely to be ‘*particularly significant*’, and that evidence as to how the allegedly dominant undertaking views its competitors, and vice versa, may, depending on the particular circumstances, be of ‘*decisive importance*’.¹¹⁶²

II. The CMA's assessment of market definition

a. Summary of the relevant market(s)

- 4.32. The CMA has defined the relevant market in this Decision by reference to the specific facts of this case. In accordance with the legal framework set out in section 4.B.I above, the CMA has assessed a range of qualitative evidence on non-price and price parameters of competition as well as quantitative evidence on actual consumption patterns in response to price changes and the entry of other hydrocortisone tablet suppliers.¹¹⁶³
- 4.33. Consistent with the case law and guidance set out in section 4.B.I above, the CMA has reviewed evidence on the effects of Auden/Actavis’s actual price increases over the relevant period and the impact of the entry of other hydrocortisone tablet suppliers to assess whether other products competed

¹¹⁵⁹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 112.

¹¹⁶⁰ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 183.

¹¹⁶¹ T-691/14 *Servier v Commission*, paragraphs 1385 and 1571.

¹¹⁶² *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraphs 103-104.

¹¹⁶³ AMCo submitted that the CMA took an inconsistent approach as compared to market definition in *Phenytoin*, as upheld by the CAT, stating that ‘*The CMA has misapplied Phenytoin which involved substantially similar factual circumstances and market characteristics*.’ Document 204922, AMCo’s RSSO, paragraph 4.7.1. Cinven also stated the CMA’s approach to market definition and dominance contrasted with the position adopted in *Phenytoin* where the CMA had explicitly relied on Pfizer/Flynn’s ability to charge inflated prices as a reason to define a narrow product market (Document 204967, Cinven’s RSSO, paragraphs 5.47-5.48), and that its reliance on bioequivalence was in stark contrast to the CMA’s approach in other cases, including *Phenytoin* (Document 206665, Cinven’s RLOF, paragraph 3.18). The CMA rejects these submissions on the basis that market definition is fact-specific and each case will depend on its own fact pattern (*Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97). There is no obligation to follow any particular analytical approach when defining the relevant market.

sufficiently with full label hydrocortisone tablets to warrant inclusion within the relevant product market.

- 4.34. The CMA has also considered the representations it received from the parties on the SSO. In this respect, it has taken account of the submissions made by each of AMCo, Cinven and Waymade that full and skinny label hydrocortisone tablets do not form part of the same product market¹¹⁶⁴ and the contrasting submissions of Auden/Actavis and Intas/Accord-UK which submitted that skinny label hydrocortisone tablets compete with full label tablets.¹¹⁶⁵
- 4.35. Following a thorough assessment of all the relevant evidence and representations, the CMA has concluded that the relevant product market for the purposes of this Decision is the supply of 10mg and 20mg hydrocortisone tablets (including both full label and skinny label 10mg and 20mg hydrocortisone tablets) in the UK,¹¹⁶⁶ with a combined market for 10mg and 20mg strengths prior to the entry of competing suppliers, and separate 10mg and 20mg hydrocortisone tablet markets following the entry of competing suppliers:
- a. There are few alternatives therapeutically so almost all patients for adrenal insufficiency are treated with hydrocortisone tablets as the first line treatment of choice. Consistent with this, there is little evidence of switching away from hydrocortisone tablets despite significant price rises, or switching to hydrocortisone tablets when prices were falling,

¹¹⁶⁴ Document 204922, AMCo's RSSO, paragraphs 4.93-4.97, Document 204967, Cinven's RSSO, paragraph 5.60, Document 204903, Waymade's RSSO, paragraphs 8.4(d) and 8.118-8.129. See also Document 206665, Cinven's RLOF, paragraphs 3.2-3.32 and Document 206670, AMCo's RLOF, paragraphs 4.6-4.13.

¹¹⁶⁵ Auden/Actavis considered that it was apparent only on an *ex post* basis that skinny label tablets compete with full label tablets, Document 205217, Auden/Actavis's RSSO, paragraph 3.19. See also Document 205212, Intas/Accord-UK's RSSO, paragraphs 26 to 30 and Document 206676, Intas/Accord-UK's RLOF, paragraph 5 and page 5.

¹¹⁶⁶ For the avoidance of doubt, even if skinny label tablets did not exert a sufficient constraint on full label tablets to form part of the relevant market, that would not change the CMA's conclusions in this Decision. As the sole supplier of 10mg full label tablets (ie 100% market share of full label tablets) and one of only two suppliers of 20mg full label tablets (with market shares by value around 80% of full label tablets), Auden/Actavis would still be dominant on a market definition separating skinny and full label tablets. Changing the market definition such that skinny label tablets were not in the same relevant market as full label tablets would also not change the CMA's conclusions that AMCo and Waymade were potential competitors to Auden/Actavis when they entered into the 10mg Agreement (see sections 6.C.II.b.iii and 6.C.II.b.iv below) (Waymade had a full-label 20mg product so the distinction is not relevant to the 20mg Agreement) and that the 10mg Agreement had as its object the prevention, restriction or distortion of competition (see section 6.D.III below). Significant volumes switched from full to skinny label tablets (see section 4.B.II.c.ii below) and skinny-label suppliers therefore competed for a significant part of the volumes that were first supplied exclusively by Auden, regardless of the market definition which is adopted. It is not necessary for an undertaking to be in the same relevant market in order for it to be a potential competitor, and nor can it be said with certainty whether they will be at the time a market exclusion agreement is concluded. By definition a potential competitor has not yet entered the market and therefore the competitive process that would follow that entry has not yet taken place. In the present case it has been possible to observe what happened after skinny-label entry *did* occur, and it is clear that this led to Auden/Actavis losing significant volumes to those entrants and to prices falling. That process was delayed by the 10mg Agreement.

indicating that the constraints from other medicines were not sufficient to warrant their inclusion in the same relevant market.

- b. Full and skinny label hydrocortisone tablets are bioequivalent products, both dispensed against prescriptions for hydrocortisone tablets (see section 3.D.I above). Once skinny label hydrocortisone tablets became available, there was significant switching to them away from full label hydrocortisone tablets, and prices of full label tablets fell steadily. Consistent with this, the evidence shows that prior to entry it was expected that skinny label hydrocortisone tablets would be interchangeable with full label hydrocortisone tablets and that skinny label tablets would be dispensed off-label (see section 3.E.IV.a above).
- 4.36. Although the evidence shows that there were separate 10mg and 20mg hydrocortisone tablets markets following the independent entry of competing suppliers of hydrocortisone tablets,¹¹⁶⁷ the evidence also suggests that there was a combined market for 10mg and 20mg hydrocortisone tablets prior to independent entry. Accordingly, the CMA has concluded that there was a combined market for 10mg and 20mg hydrocortisone tablets prior to independent entry. However, whether 10mg and 20mg tablets were in the same or separate markets does not make a difference to the CMA's analysis of and conclusion on whether Auden/Actavis held a dominant position prior to independent entry given that Auden/Actavis's market share was 100%¹¹⁶⁸ even when the market is given its widest possible definition.
- 4.37. The following sections are set out as follows:
- a. First, the CMA identifies the focal product (section 4.B.II.b).
 - b. Next, the CMA defines the relevant product market (section 4.B.II.c). In doing so, the CMA considers:
 - i. Qualitative and quantitative evidence relating to hydrocortisone tablets and other potential substitutes and concludes that the market is no wider than 10mg and 20mg hydrocortisone tablets (section 4.B.II.c.i).
 - ii. Qualitative and quantitative evidence relating to full and skinny label hydrocortisone tablets and concludes that 10mg and 20mg

¹¹⁶⁷ From July 2015 (for 20mg hydrocortisone tablets) and October 2015 (for 10mg hydrocortisone tablets).

¹¹⁶⁸ Although Waymade and AMCo supplied Auden/Actavis's hydrocortisone tablets pursuant to their supply agreements with Auden/Actavis, this did not represent independent competition to Auden/Actavis.

skinny label hydrocortisone tablets are within the relevant product market (section 4.B.II.c.ii).

- iii. Whether 10mg and 20mg hydrocortisone tablets are within the same or separate product markets (section 4.B.II.c.iii) and concludes that although the evidence suggests initially the different strengths of hydrocortisone tablets may have been in the same product market, there were separate markets for each tablet strength following independent entry.

- c. Finally, the CMA assesses the relevant geographic market (section 4.A.III.d) and concludes that it is no wider than the UK.

4.38. In the following sections, references to the relevant market(s) therefore refer to:

- a. a combined product market including both 10mg and 20mg full and skinny label hydrocortisone tablets during the period before independent entry (1 October 2008 to 30 June 2015); and
- b. separate product markets for 10mg and 20mg hydrocortisone tablets (both full and skinny label) during the period after independent entry (from 1 July 2015 until 31 July 2018 for 10mg tablets and from 1 July 2015 to 8 January 2017 for 20mg tablets).

b. The focal product

4.39. The focal products for the purposes of this Decision are 10mg and 20mg full label hydrocortisone tablets.¹¹⁶⁹ This is because Auden/Actavis supplied only full label hydrocortisone tablets throughout the Infringements.

4.40. The CMA has identified the following products as the most likely substitutes for the focal product, beginning with the closest potential substitutes, and has assessed the extent to which substitution from the focal product to any (or all) of these products would be sufficient to warrant widening the relevant product market beyond the focal product in the sections that follow:

- a. skinny label hydrocortisone tablets – for the period after 3 November 2011;¹¹⁷⁰

¹¹⁶⁹ Consistent with past decisions (Case CE-9531/11 *Paroxetine* (CMA Decision dated 12 February 2016)); the CMA has treated the focal product as including hydrocortisone tablets distributed by parallel importers ('Parallel Imports') as these products are identical and there are no clinical issues with switching patients between different sources of hydrocortisone tablets.

¹¹⁷⁰ That is, the date Plenadren was granted its MA and the orphan designation status commenced.

- b. Plenadren – for the period after 3 November 2011;
- c. other forms of hydrocortisone medicine – throughout the Infringements; and
- d. other corticosteroids – throughout the Infringements.

c. The relevant product market

i. Whether other medicines in the relevant treatment area form part of the relevant product market

Qualitative evidence

- 4.41. The CMA has reviewed a range of qualitative evidence on non-price and price parameters of competition to inform its assessment of whether other medicines in the relevant treatment area¹¹⁷¹ form part of the relevant product market. This includes examining whether other products were perceived by prescribers to be substitutable with full label hydrocortisone tablets from a therapeutic perspective.
- 4.42. The review of qualitative evidence below is structured as follows:
- a. the ATC classification; and
 - b. prescribing: product characteristics and medical recommendations.

ATC classification

- 4.43. The Commission,¹¹⁷² the General Court¹¹⁷³ and the CMA¹¹⁷⁴ have noted in previous cases that a starting point for defining the relevant product market in the case of pharmaceutical products is the Anatomical Therapeutic Chemical ('ATC') classification system. The purpose of the ATC

¹¹⁷¹ In this section, the CMA uses the term 'medicines in the relevant treatment area' to refer to medicines that can be used to treat adrenal insufficiency.

¹¹⁷² Commission Decision of 28 February 1995, *Glaxo/Wellcome*, Case IV/M.555; Commission Decision of 10 March 1995, *Behringwerke AG/Armour Pharmaceutical Co*, Case IV/M.495; Commission Decision of 10 January 1996, *Adalat*, Case IV/34.279/F3; Commission Decision of 29 July 1997, *Ciba-Geigy/Sandoz*, Case IV/M.737; Commission Decision of 4 February 1998, *Hoffmann-La Roche/Boehringer Mannheim*, Case IV/M.950; Commission Decision of 26 February 1999, *Astra/Zeneca*, Case IV/M.1403; Commission Decision of 22 May 2000, Case IV/M.1878 *Pfizer/Warner-Lambert*; Commission Decision of 28 February 2001, *Abbott/Basf*, Case IV/M2312.

¹¹⁷³ Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, ECR, EU:T:2010:266, paragraphs 154–156, upheld by the CJEU in Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770.

¹¹⁷⁴ Decision No. CA98/02/2011, *Reckitt Benckiser*, 12 April 2011; Decision No. CA98/2/2001, *Napp Pharmaceutical Holdings Limited*, 30 March 2001; and Decision No. CA98/3/2003, *Genzyme Limited*, 27 March 2003.

classification system is to serve as a tool for drug utilisation monitoring and research in order to improve the quality of drug use.¹¹⁷⁵

- 4.44. The ATC classification system groups active substances in a hierarchy of five different levels. At the first level, the system divides drugs into 14 main groups based on the physiological organ or system on which they act. At the second level, the system groups active substances according to either pharmacological or therapeutic groups. The third and fourth levels identify further sub-categories according to chemical, pharmacological or therapeutic subgroups and the fifth level is the chemical substance (hydrocortisone in this case).
- 4.45. As the ATC classification system groups substances according to their therapeutic use (as well as other factors), it can be used as a starting point for market definition. However, which particular level of the ATC classification system is an appropriate starting point will depend on whether medicines in a certain class have the same therapeutic indications such that using level three or level four as a starting point may be appropriate in different circumstances. In this case, the classification system indicates that hydrocortisone tablets belong to the third level category '*Corticosteroids for systemic use, plain*'. The fourth-level class '*Glucocorticoids*' includes a set of 16 medicines including Hydrocortisone, Prednisolone, Dexamethasone and various other corticosteroids.¹¹⁷⁶
- 4.46. Other forms of hydrocortisone, Plenadren, and other corticosteroids¹¹⁷⁷ are considered in further detail below to determine whether any of the alternatives determined by the ATC classification system have the potential to be competitive constraints on full label hydrocortisone tablets.

¹¹⁷⁵ The ATC classification system is recognised and used by the European Pharmaceutical Market Research Association, and the corresponding system maintained by the World Health Organization. See [WHO Collaborating Centre for Drug Statistics Methodology ATC/DDD Index](#): 'Purpose of the ATC/DDD system'.

¹¹⁷⁶ [WHO Collaborating Centre for Drug Statistics Methodology ATC/DDD Index](#): 'Systemic hormonal preparations, excl. sex hormones and insulins'. https://www.whocc.no/atc_ddd_index/

¹¹⁷⁷ Auden/Actavis submitted that the CMA should place weight on ATC classifications as a starting point and analyse differences (such as side effects and effectiveness) between hydrocortisone and other products at ATC level 4 (Document 205217, Auden/Actavis's RSSO paragraphs 3.8 to 3.9). The CMA has considered ATC classifications as a starting point. However, each market definition will depend on its own facts, and there is no obligation to follow any particular analytical approach (*Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97). The CMA's quantitative analysis implicitly takes account of all other medicines in the treatment area because to the extent that there was switching away from hydrocortisone tablets in response to Auden/Actavis's price increases, this would be evident in the volume data (see paragraphs 4.57 to 4.73). Moreover, as set out at paragraphs 4.53 to 4.55, other medicines are not recommended as a first line treatment for adrenal insufficiency in adults, and as such, are unlikely to be therapeutic substitutes for hydrocortisone tablets.

Prescribing considerations

- 4.47. Any decision to substitute between hydrocortisone tablets and other potential medicines in the treatment area (such as Plenadren or other corticosteroids) would be made by prescribers (this would typically be a specialist, with follow-up prescriptions being written by GPs). Before taking such a decision, the prescriber will take account of a range of factors including therapeutic substitutability and individual patient response to treatments.
- 4.48. This section discusses the product characteristics and medical recommendations for when the following medicines might be appropriate for use:
- a. hydrocortisone tablets;
 - b. Plenadren;
 - c. other forms of hydrocortisone; and
 - d. other corticosteroids.
- 4.49. Reviewing the product characteristics including chemical composition and mode of action of different medicines may inform market definition as differences can suggest that the medicines are not readily substitutable. Similarly, clinical practice guidelines and recommendations provide advice on the prescribing of the focal product and alternative products and are therefore useful in informing product market definition.
- 4.50. As set out in section 3.C.II above, hydrocortisone tablets are an immediate-release preparation of hydrocortisone, for oral use, available in two tablet strengths: 10mg and 20mg. As explained in section 3.C.I above, hydrocortisone tablets are considered the first line treatment of choice for patients with primary or secondary adrenal insufficiency.^{1178, 1179} A decision to switch a patient with adrenal insufficiency away from hydrocortisone tablets (or commence treatment with a medicine other than hydrocortisone tablets) would need to be made by an endocrinologist and would only be done in rare instances when a patient is not able to tolerate hydrocortisone tablets.¹¹⁸⁰

¹¹⁷⁸ Document 00603, response to question 1, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹¹⁷⁹ As the vast majority of use of hydrocortisone tablets is for treating adrenal insufficiency, and hydrocortisone tablets are rarely used for treating other conditions, the CMA has only considered substitute treatments for adrenal insufficiency in this analysis.

¹¹⁸⁰ Document 02046.B, note of call between CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 7.b, page 5.

- 4.51. Unlike hydrocortisone tablets which are immediate-release drugs, Plenadren is a modified-release version of hydrocortisone. This means that rather than having to take multiple doses in a day, a patient only needs to remember to take the medicine once and it will be slowly released, which can help improve patient compliance. Plenadren, like full label hydrocortisone tablets, can be used to treat adrenal insufficiency in adults.¹¹⁸¹
- 4.52. Plenadren is not routinely or commonly prescribed as it is not NICE recommended or recommended by the specialist CRG for endocrinology.¹¹⁸² Instead, prescribing restrictions are imposed locally by individual CCGs. Plenadren is much more expensive than hydrocortisone tablets (see section 3.C.III above). The combination of high prices for Plenadren¹¹⁸³ and the lack of data on its efficacy¹¹⁸⁴ has led many CCGs not to recommend Plenadren for the treatment of adults with adrenal insufficiency,¹¹⁸⁵ which explains the very low volumes of Plenadren being prescribed and dispensed in the UK (see section 3.C.IV above). This indicates that CCGs do not consider hydrocortisone tablets and Plenadren to be interchangeable and, by not including it in their formularies, they are limiting further interchangeability between the two products for prescribers using those formularies.¹¹⁸⁶
- 4.53. Other forms of hydrocortisone medicine,¹¹⁸⁷ such as injections, are not generally used as routine cortisol replacement therapy. These differ in that although the underlying chemical is the same, the method of ingestion is different. Such medicines are recommended for use in only very limited circumstances and in different settings: medical groups informed the CMA

¹¹⁸¹ Auden/Actavis submitted that Plenadren and hydrocortisone tablets have an identical ATC drug classification, suggesting that they fall in the same relevant market (Document 205217, Auden/Actavis's RSSO paragraph 3.11). As set out at paragraph 4.43 above, an ATC classification is a starting point for identifying medicines that may be substitutes, but is not, in itself, determinative.

¹¹⁸² The specialist clinical reference group for endocrinology. Document 00603, response to question 7, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹¹⁸³ Shire also explained to the CMA that '*Given that Plenadren was a relatively low priority product, a decision was taken at Shire not to develop other active pricing or promotion strategies. We serve orders that are made but we do not proactively market or promote Plenadren.*' (Document 206381, Shire's response to question 2 of the CMA's section 26 notice dated 9 March 2021).

¹¹⁸⁴ Document 02046.B, Note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to questions 4.a and 4.b, page 4.

¹¹⁸⁵ See section 3.C.III above. Shire also explained to the CMA that '*Plenadren faces severe market access restrictions, primarily due to not (yet) being included in primary and secondary care formularies*' (see Document 200320, Shire's response to question 6 of the CMA's section 26 notice dated 20 June 2016). More recently, Shire explained that '*Shire has made no further efforts to obtain formulary status and as a result it [Plenadren] is not to our knowledge included in any formularies*' (Document 206381, Shire's response to question 2 of the CMA's section 26 notice dated 9 March 2021).

¹¹⁸⁶ The CMA therefore rejects Auden/Actavis's submission that '*The CMA's rationale for excluding the drug Plenadren from the relevant product market, is solely the price differential*' (Document 205217, Auden/Actavis's RSSO, paragraph 3.12). The price differential is a factor contributing to the limited switching between hydrocortisone tablets and Plenadren.

¹¹⁸⁷ Soluble hydrocortisone tablets are not considered in this section because they were not available during the Infringements (see Section 3.C.IV above).

that these forms of hydrocortisone medicine are only used rarely, for example, in emergency situations (see section 3.C.IV above).¹¹⁸⁸

- 4.54. Other corticosteroids such as prednisolone and dexamethasone are not generally viewed as clinical substitutes for hydrocortisone tablets as they are more potent than hydrocortisone and can remain active in the bodily system over a much longer time. The usage of synthetic corticosteroids cannot be monitored accurately and may also increase the likelihood of adverse metabolic side effects.¹¹⁸⁹
- 4.55. Unlike hydrocortisone tablets, other corticosteroids are only recommended as a second line treatment for adrenal insufficiency in exceptional circumstances when hydrocortisone tablets are not well tolerated by patients (see section 3.C.V above).¹¹⁹⁰ The Society for Endocrinology estimates that only a small proportion of patients with adrenal insufficiency use other corticosteroids, compared with an estimated 95% of adult patients using hydrocortisone tablets.¹¹⁹¹ This shows that other corticosteroids are not substitutes for hydrocortisone tablets, but are instead prescribed sequentially and only in limited circumstances.¹¹⁹²
- 4.56. Taken together, the analysis of the prescribing considerations indicates that other medicines in the treatment area are unlikely to exert a sufficient constraint on hydrocortisone tablets. This is because they differ substantially in either characteristics or prescribed uses, with hydrocortisone tablets being the clearly preferred first-line treatment for adrenal insufficiency.

Quantitative evidence

- 4.57. As explained in section 4.B.I above, when assessing whether different products are in the same product market, it is not sufficient to state that

¹¹⁸⁸ Document 00603 and Document 00599, response to question 8, responses to the CMA's section 26 notice dated 20 June 2016 from the Society for Endocrinology and Royal College of Physicians and Document 00893B, response to question 1, supplementary response from the Society for Endocrinology to the CMA dated 20 July 2016.

¹¹⁸⁹ See section 3.C above.

¹¹⁹⁰ For example, when a patient is intolerant or allergic to hydrocortisone or when, due to medical reasons, an alternative glucocorticoid regime is required. Document 00603 and Document 00599, responses to questions 2, 3 and 9, Society for Endocrinology and the Royal College of Physicians responses to the CMA's section 26 notice dated 20 June 2016; and Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to questions 5 and 7, pages 3–5.

¹¹⁹¹ Document 00603, response to question 2, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹¹⁹² Auden/Actavis submitted that the CMA should look not only at the proportions of patients using certain drugs at the current time, but also at what proportion of patients requiring cortisol replacement therapy are not able to use any product other than hydrocortisone tablets. (Document 205217, Auden/Actavis's RSSO, paragraph 3.10). As hydrocortisone tablets are recommended as a first-line treatment for adrenal insufficiency, whereas other medicines such as corticosteroids are only used in exceptional circumstances, such as when hydrocortisone tablets are not well tolerated, the CMA is satisfied that there are no other options but hydrocortisone tablets for many patients

products have similar characteristics and are generally prescribed to treat the same conditions. This is because prescribers may value different characteristics differently or pharmacies may differentiate between products that appear to have similar characteristics.

- 4.58. The purpose of market definition is to identify the products that are capable of exerting a sufficient competitive constraint on the focal product such that they should be included in the relevant market.
- 4.59. Accordingly, the key consideration when determining whether to include a product in a relevant market is not whether the products have similar characteristics and are functional substitutes **in theory**. Instead, it is necessary to consider whether customers view a product as closely substitutable with the focal product by reason of the different products' characteristics, their prices and their intended use,¹¹⁹³ so that, **in practice**, they would substitute between products to an extent that would prevent a monopolist supplier of hydrocortisone tablets from sustaining a small but significant and non-transitory increase in price ('**SSNIP**').
- 4.60. This sub-section considers the quantitative evidence relevant to full label hydrocortisone tablets, and the extent to which other medicines used to treat adrenal insufficiency (Plenadren, other forms of hydrocortisone and other corticosteroids) were in practice regarded as demand-side substitutes.
- 4.61. Alongside a detailed review of qualitative evidence on non-price and price parameters of competition, the CMA has considered actual consumption patterns¹¹⁹⁴ to determine whether other products in the treatment area were capable of exerting a sufficient competitive constraint on full label hydrocortisone tablets.¹¹⁹⁵
- 4.62. The SSNIP test provides a methodology for carrying out a quantitative analysis. The test asks whether it would be profitable for a hypothetical monopolist of the focal product, which operates in the geographic area under investigation where the focal product is sold, to increase the price of the focal product by a small but significant amount (for example, 5 to 10%) above competitive levels for a sustained period of time.¹¹⁹⁶ If such an increase in the price of the focal product would be profitable, the test is

¹¹⁹³ Case T-321/05 *AstraZeneca v Commission* EU:T:2010:266, paragraph 31. See also C-85/76 *Hoffmann-La Roche v Commission* EU:C:1979:36, paragraph 28.

¹¹⁹⁴ The European Commission's *Notice on the definition of relevant market for the purposes of Community competition law* (97/C 372/03) (the '**Commission Notice on Market Definition**'), paragraph 38, explains that evidence of actual substitution would be fundamental to defining markets where this evidence is available.

¹¹⁹⁵ This section does not discuss competition through other parameters such as marketing spending. As hydrocortisone tablets are a generic medicine and the patent expired at the latest in the 1970s, competition through marketing spending is not relevant.

¹¹⁹⁶ This increase is usually referred to as a small but significant non-transitory increase in price or SSNIP.

complete and the focal product sold by the hypothetical monopolist is (usually) the relevant market.¹¹⁹⁷

- 4.63. In this case, the CMA does not need to hypothesise that there is a single supplier (monopolist) of the focal product as Auden/Actavis was the only supplier of full label hydrocortisone tablets in the UK during the Infringements up until the independent entry of other hydrocortisone tablet suppliers from July 2015. In addition, given the repeated and significant price rises for Auden/Actavis's hydrocortisone tablets during the Infringements, the CMA has not needed to conduct a hypothetical SSNIP test as it can observe as an empirical matter how much switching has actually occurred in practice in response to actual price increases.
- 4.64. The quantitative evidence shows that the market should not be widened beyond hydrocortisone tablets. The quantitative evidence clearly demonstrates that Auden/Actavis profitably implemented numerous significant price increases without experiencing a discernible impact on its volumes. Auden/Actavis's price increased by 200% and 171% for 10mg and 20mg tablets respectively¹¹⁹⁸ between 2008 and independent entry (in 2015). The lack of adverse impact on Auden/Actavis's volumes and profitability is clearly indicative of the fact that hydrocortisone tablets did not face any form of effective competitive constraint prior to the advent of independent competition from other hydrocortisone tablet suppliers. This is consistent with the qualitative evidence which showed that hydrocortisone tablets were the clearly preferred first-line treatment for adrenal insufficiency with other medicines in the treatment area unlikely to exert a sufficient constraint based on prescribing guidelines.
- 4.65. When assessing the effect of Auden/Actavis's price increases, caution is required. This is because in cases such as this one, where an undertaking appears to have exercised its market power by raising prices above competitive levels, one may observe consumers switching to other products. However, it may be incorrect in those circumstances to conclude that the dominant undertaking lacks market power and to include those other

¹¹⁹⁷ If the price increase would not be profitable (for example, because a sufficiently large number of customers would switch some of their purchases to other substitute products), the test continues by assuming that the hypothetical monopolist controls both the focal product and its closest substitute. If necessary the process is repeated, including other substitute products until the smallest collection of products for which the hypothetical monopolist can profitably impose a price increase is found. This collection of the focal product and its closest substitutes is then the relevant product market. See OFT403, paragraphs 2.5-2.13, and Commission Notice on Market Definition, paragraphs 15-19.

¹¹⁹⁸ For 10mg tablets: an increase from £22.28 in October 2008 (the month the 10mg Unfair Pricing Abuse started) to £66.76 in September 2015 (the month before independent entry commenced for 10mg tablets). For 20mg tablets: an increase from £23.74 in October 2008 (the month the 20mg Unfair Pricing Abuse started) to £64.26 in June 2015 (the month before independent entry commenced for 20mg tablets).

products in the relevant market.¹¹⁹⁹ The CMA has been mindful of this when assessing observed substitution patterns in this case, but considers that the risk of over-inclusion is low given that little discernible switching is observed from hydrocortisone tablets to other medicines in the treatment area). Instead, the fact that there is little evidence of switching to alternative products, even when prices were so significantly above competitive levels, strongly demonstrates that the relevant product market is no wider than hydrocortisone tablets.

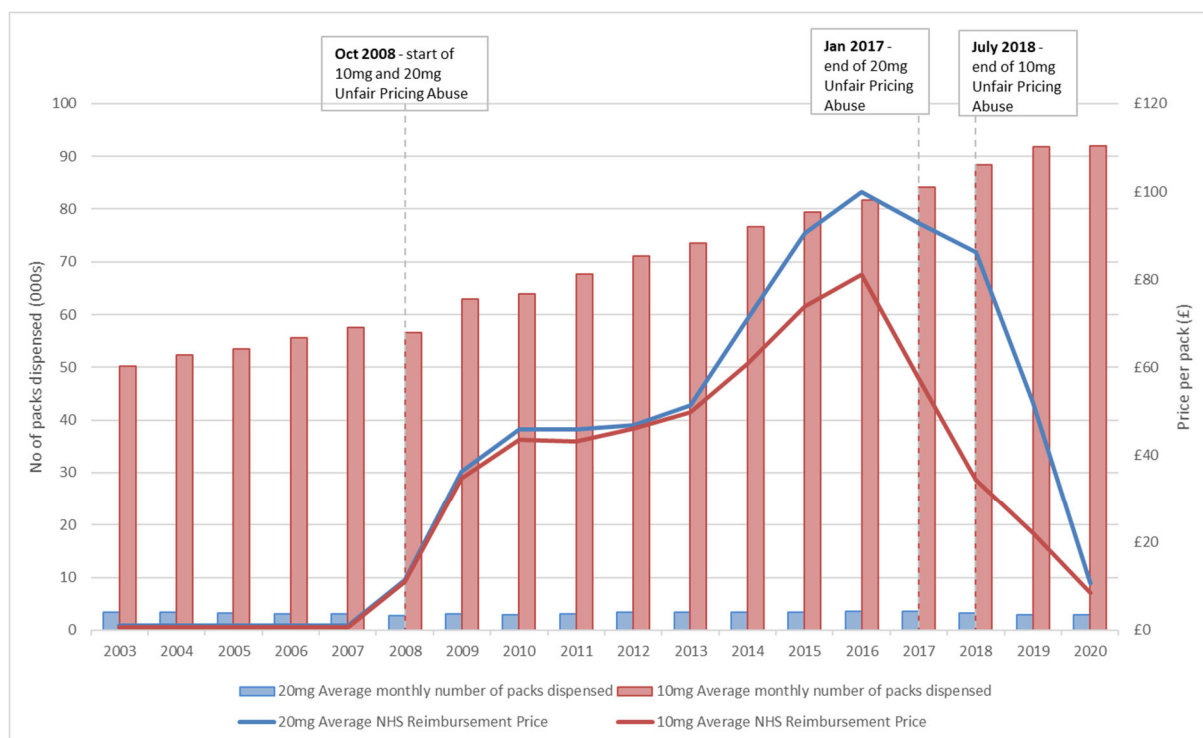
- 4.66. The CMA's conclusion that other potential medicines are not part of the relevant product market is further supported by the fact that it was independent entry by other suppliers of hydrocortisone tablets (all of which supplied skinny label hydrocortisone tablets apart from Waymade's 20mg hydrocortisone tablets) that led to the prices of hydrocortisone tablets starting to decrease (after nearly seven years of unchecked price rises). When set in the context of the scale of the price and volume declines observed following independent entry of other hydrocortisone tablet suppliers, it is clear that no other potential substitutes, prior to independent entry, exerted a sufficient competitive constraint on the focal product (full label hydrocortisone tablets) during the Infringements to be included in the relevant product market.¹²⁰⁰
- 4.67. Figure 4.3 below shows price and volumes trends for hydrocortisone tablets (that is including both full and skinny label tablets from the entry of skinny label tablets onwards) from 2003 to 2020.¹²⁰¹

¹¹⁹⁹ This is commonly known as the 'Cellophane fallacy' following the *US v El Du Pont de Nemours & Co* [1956] 351 US 377 case. See also OFT403, paragraph 5.5.

¹²⁰⁰ The CMA therefore rejects Auden/Accord-UK's submission that it has arbitrarily excluded other medicines from its market definition analysis '*without any proper analysis of actual substitutability from a clinical perspective*' (Document 205217, Auden/Accord-UK's RSSO, paragraphs 3.3 and 3.9). The CMA's analysis demonstrates that in practice, despite the price increases for hydrocortisone tablets, customers did not substitute other medicines for them. Their exclusion from the relevant product market is therefore not arbitrary but based on empirical evidence of demand.

¹²⁰¹ The CMA has included a period both before the price rise and following independent entry after the end of the Infringements to show the stability of the volume trends despite the price rises and falls throughout the period depicted.

Figure 4.3: Yearly average NHS Reimbursement Prices¹²⁰² and average monthly number of packs dispensed¹²⁰³ of hydrocortisone tablets



Source: CMA analysis based on PCA data for England, Wales, Scotland and Northern Ireland.

Notes: (1) Based on items dispensed by pharmacies, appliance contractors and dispensing doctors; (2) Includes sales of Hydrocortone tablets; (3) CMA has used average monthly sales data to enable comparison between years when less than 12 months data is available.

4.68. Figure 4.3 shows that the price trends were that:

- a. From the start of the Infringements to when independent entry of hydrocortisone tablets commenced, that is between 2008 and 2015, the yearly average NHS Reimbursement Price¹²⁰⁴ for both 10mg and 20mg hydrocortisone tablets increased significantly (from a level of £10.95 and £11.35 per pack to £73.82 and £90.42, increases of 574% and 696% for 10mg and 20mg respectively).¹²⁰⁵

¹²⁰² The CMA has used reimbursement price data in this analysis as that is more readily available than Average Selling Prices over the period being considered, but notes that Average Selling Prices follow a similar overall trend to reimbursement prices. The CMA further notes that (to the extent prices are taken into account by prescribers) it is prices to the NHS (that is, the Drug Tariff price or reimbursement prices) which will inform prescriber switching between alternative medicines (either directly, or by influencing listing in CCG formularies for example).

¹²⁰³ The CMA uses PCA data for England, Wales, Scotland and Northern Ireland for market definition as this includes data on all hydrocortisone tablets dispensed, regardless of supplier, and assists the assessment of whether other drugs constrained the price of hydrocortisone tablets in the UK.

¹²⁰⁴ The average NHS Reimbursement Price is the price paid by the NHS to pharmacies for dispensing the medicine. The NHS Reimbursement Price will be equal to the Drug Tariff price unless a concession price has been applied.

¹²⁰⁵ CMA calculations based on NHS BSA data.

- b. Following independent entry by other suppliers of hydrocortisone tablets, yearly average NHS Reimbursement prices fell significantly (from a level of £73.92 and £90.42 per pack in 2015 to £8.41 and £10.74 in 2020, decreases of 89% and 88% for 10mg and 20mg respectively).¹²⁰⁶

4.69. Figure 4.3 also shows the following volume trends during the relevant period:

- a. average monthly number of packs of 10mg hydrocortisone tablets dispensed increased steadily (an increase of approximately 4%¹²⁰⁷ annually).
- b. average monthly number of packs of 20mg hydrocortisone tablets dispensed remained broadly stable.

4.70. Further, these price increases were very profitable for Auden/Actavis, as set out at section 5.C.IV. Auden/Actavis earned gross profits of around £190 million for 10mg hydrocortisone tablets, compared with the supply costs paid to Tiofarma of £7 million, and gross profits of over £10 million for 20mg compared with the supply costs paid to Tiofarma of £0.5 million prior to independent entry taking place.¹²⁰⁸

4.71. Despite the changes in prices, the volume trends remained constant. The CMA has no reason to believe that absent Auden/Actavis's price changes, volumes of hydrocortisone tablets would have been materially different (for example, increased or increased at a materially faster rate) and no party has provided evidence to suggest that would have been the case. Nor is there any evidence to suggest that hydrocortisone tablets were being used in a different treatment area. Therefore, increases in patient numbers reflect the number of new patients requiring treatment for adrenal insufficiency¹²⁰⁹ and not patient switching (since less than 0.1% of prescriptions were for patients switching).¹²¹⁰ As explained in section 3.C.IV above and 6.B.II.b.ii below, there is a finite demand that suppliers of hydrocortisone tablets can compete for, with demand being stable and growing slowly.¹²¹¹

¹²⁰⁶ CMA calculations based on NHS BSA data.

¹²⁰⁷ CMA calculations based on NHS BSA data.

¹²⁰⁸ Auden/Actavis earned profits in excess of cost-plus of around £170 million for 10mg hydrocortisone tablets, and around £10 million for 20mg hydrocortisone tablets prior to independent entry taking place. The direct costs from the CMO remained below [£] per pack for both 10mg and 20mg hydrocortisone tablets throughout the Unfair Pricing Abuses.

¹²⁰⁹ The volume of prescriptions for new patients (at around 2% - see section 3.C.II) is consistent with there being steady growth in patient numbers, particularly in the context that 95% of patients requiring treatment for adrenal insufficiency receive hydrocortisone tablets.

¹²¹⁰ See section 3.C.II.

¹²¹¹ With 10mg tablets increasing steadily, and 20mg volumes broadly stable.

- 4.72. Had other medicines in the relevant treatment area been substitutes for full label hydrocortisone tablets, it would be expected that hydrocortisone tablet volume trends would change after prices changed. Therefore, taken together, these price and volume trends show that there was little or no substitution between hydrocortisone tablets and the other potential medicines in the treatment area:¹²¹²
- a. The fact that the series of significant price increases of hydrocortisone tablets set out in figure 4.3 did not result in a change in volume trends or a reduction in profitability (and to the contrary, profits increased significantly) shows that other medicines in the treatment area, whether individually or taken together, did not act as a sufficient competitive constraint on the focal product to be included in the relevant product market.¹²¹³
 - b. Despite the price falls following independent entry of other hydrocortisone tablet suppliers, there was no change to existing volume trends in dispensing of 10mg and 20mg hydrocortisone tablets (ie there was not a discernible increase in demand for hydrocortisone tablets). If hydrocortisone tablets were competing sufficiently closely with other medicines in the treatment area for them to form part of the same relevant market, it would be expected that such a fall in prices would be accompanied by switching to the product that had become relatively cheaper (hydrocortisone tablets). The fact that no such switching is evident demonstrates that other medicines in the treatment area are not in the same relevant product market.
- 4.73. Further, the CMA considers that Plenadren cannot be regarded as an effective competitive constraint on hydrocortisone tablets, for the same reasons as other medicines explained above, and because:
- a. Plenadren is used by less than 1% of all patients with adrenal insufficiency (see section 3.C.III above) and its usage has remained stable at this low level since its launch in the UK in September 2012.
 - b. The introduction of Plenadren in September 2012 did not prevent further increases in NHS Reimbursement Prices or change the trend in volumes of hydrocortisone tablets dispensed so as to be regarded as

¹²¹² Excluding skinny label hydrocortisone tablets which were not available until October 2015, see section 4.B.II.c.iii below for the CMA's analysis which finds that skinny label tablets form part of the relevant market.

¹²¹³ The European Commission has previously held that low levels of substitution and inelastic own-price elasticity of demand can be evidence that a specific product constitutes a separate relevant product market (see, for example, Case M.1313 *Danish Crown/Vestjyske Slagterier*, Commission decision of 9 March 1999, paragraphs 27–29; and Case M.619 *Gencor/Lonrho*, Commission decision of 24 April 1996, paragraphs 41 to 43).

an effective competitive constraint.¹²¹⁴ In fact, soon after the introduction of Plenadren, the rate of price increases for hydrocortisone tablets intensified significantly (with increases to the yearly average NHS reimbursement price of 62% (from £49.88 to £81.11) for 10mg tablets and 94% (from £51.43 to £99.96) for 20mg tablets between 2013 and 2016) with no evidence that this resulted in switching to Plenadren.¹²¹⁵

Representations on whether other medicines in the treatment area form part of the same relevant market

'The CMA should consider a range of clinically substitutable products'

- 4.74. Auden/Actavis submitted that the CMA placed *'too much weight on price differentials'* and *'should consider a range of clinically substitutable products.'* In particular, Auden/Actavis submitted that *'the CMA has entirely ignored recent jurisprudence from the General Court in Servier'* and should consider the *'entire economic context, in particular factors other than price'*.¹²¹⁶
- 4.75. In its judgment in *Servier* (currently on appeal to the Court of Justice) the General Court found that the Commission had not sufficiently considered whether perindopril was subject to competitive constraints from other products, deriving not only from price but also from non-price factors. The General Court emphasised that price and volume analysis does have a role to play in the assessment of competitive constraints in the pharmaceutical sector. Those constraints must however be assessed in their full context.¹²¹⁷
- 4.76. The CMA has, in its analysis, taken account of the entire economic context, having considered both qualitative and quantitative evidence in the round before forming a judgement as to the relevant market. The CMA does not agree that clinical substitutability is of decisive importance when defining the relevant market. Rather, it is substitutability in practice (ie how prescribers actually chose between and prescribed different medicines and how pharmacies dispensed different medicines, consistent with the CAT's finding in *Phenytoin* that *'What matters, for this competition analysis, is what pharmacists actually did'*),¹²¹⁸ that shows the degree of competitive

¹²¹⁴ See figure 4.3, which shows average NHS Reimbursement Prices and the number of packs of hydrocortisone tablets dispensed continuing to increase, notwithstanding entry of Plenadren in the UK. This is consistent with Auden/Actavis's sales data and IMS Health data.

¹²¹⁵ This is consistent with Auden/Actavis's sales data.

¹²¹⁶ Document 205217, Auden/Actavis RSSO, paragraphs 3.3-3.18, and 3.28-3.29.

¹²¹⁷ T-691/14 *Servier v Commission*, paragraphs 1385 and 1571.

¹²¹⁸ *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 132.

constraint from potential substitutes. While clinical substitutability plays a role, it is not sufficient for including a product within the relevant market.

'The CMA's market definition is too narrow'

- 4.77. Auden/Actavis submitted that the CMA's market definition is too narrow, and that *'there are clearly other effective treatments of adrenal insufficiency including, for example, other hydrocortisone based products such as Plenadren, and prednisolone.'*¹²¹⁹
- 4.78. Regarding widening the market to include Plenadren, Auden/Actavis submitted that:¹²²⁰
- a. Plenadren was excluded from the market *'exclusively on the price differential between Plenadren and Hydrocortisone Tablets and the limited prescriptions for Plenadren'*, but the reason Plenadren is not prescribed more widely is *'its very similarity to Hydrocortisone Tablets'*, which implies it should be in the relevant market.¹²²¹
 - b. It is flawed to suggest that because Plenadren is not widely included in CCGs' formularies, it cannot be in the same product market as hydrocortisone tablets. The clinical evidence *'supports the proposition that Plenadren and Hydrocortisone Tablets are directly comparable and functionally substitutable and should be in the same market.'*
 - c. The granting of the orphan designation in itself recognises that Plenadren is a *'similar medicinal product'* to hydrocortisone tablets, and therefore, since an orphan designation is intended to provide the manufacturer *'market exclusivity'* and the MHRA cannot issue MAs for *'similar competitor medicines'*, hydrocortisone tablets must fall within the same market as Plenadren.¹²²²
- 4.79. Auden/Actavis submitted that prednisolone can be used to treat adrenal insufficiency and *'the lower prescription levels compared to hydrocortisone tablets alone is not a sufficient justification to exclude this product from the relevant product market.'*¹²²³
- 4.80. Auden/Actavis also submitted that hydrocortisone muco-adhesive buccal tablets contain the same active pharmaceutical ingredient as hydrocortisone tablets, and, although not indicated for adrenal insufficiency, *'it is clear that*

¹²¹⁹ Document 205217, Auden/Actavis's RSSO, paragraph 3.1.

¹²²⁰ Document 205217, Auden/Actavis's RSSO, paragraphs 3.12 and 3.20-3.32.

¹²²¹ Document 205217, Auden/Actavis's RSSO, paragraph 3.22.

¹²²² Document 205217, Auden/Actavis's RSSO, paragraph 3.30.

¹²²³ Document 205217, Auden/Actavis's RSSO paragraphs 3.33-3.34.

there has been substantial off-label use of this product for the treatment of adrenal insufficiency.’ It submitted that excluding hydrocortisone muco-adhesive buccal tablets from the relevant product market on the basis of not being indicated during the relevant period *‘runs contrary to CMA’s entire case that skinny label Hydrocortisone Tablets form part of the relevant product market notwithstanding that they were not licenced for the primary indication’*.¹²²⁴

- 4.81. As set out at section 4.B.II.c.ii, the evidence demonstrates that the relevant market is no wider than hydrocortisone tablets. Other medicines are not routinely prescribed to treat the same conditions as hydrocortisone tablets: 95% of adrenal insufficiency patients receive hydrocortisone tablets. Despite substantial and repeated price rises for hydrocortisone tablets, totalling over 200% (therefore substantially in excess of the 10% levels usually associated with a hypothetical monopolist test), there was no loss of hydrocortisone tablet volumes to alternative treatments. This shows there was extremely limited (if any) switching between hydrocortisone tablets and other potential treatments (including Plenadren), and gives a strong indication that other medicines, whether individually or in combination, do not form part of the same relevant market.
- 4.82. As to the further specific points made by Auden/Actavis, neither Plenadren nor prednisolone was excluded from the relevant product market solely on the basis of the price differential, or on the basis of limited prescription volumes, but on the basis of a lack of switching between hydrocortisone tablets and those medicines as described above. The CMA’s analysis of why the relevant product market is no wider than hydrocortisone tablets applies equally to hydrocortisone muco-adhesive buccal tablets as well. It is for these reasons, and not their off-label use, that they are not considered to form part of the relevant product market.
- 4.83. As explained in section 3.D.III above, Plenadren was granted an orphan designation because it was considered to offer a clinical benefit over and above that provided by hydrocortisone tablets. Its supplier was able to satisfy the authorities that its modified-release formulation offered *‘a clinically relevant advantage or a major contribution to patient care’* as compared to immediate-release hydrocortisone tablets.¹²²⁵ There is therefore a genuine

¹²²⁴ Document 205217, Auden/Actavis’s RSSO paragraphs 3.35-3.38.

¹²²⁵ Article 3(2) of Regulation 847/2000. See also EMA recommendation for maintenance of orphan designation at the time of marketing authorisation, EMA/729720/2011; and [COMP assesses whether Plenadren still meets orphan designation criteria Recommendation to maintain the period of market exclusivity at 10 years \(europa.eu\)](#).

clinical difference between Plenadren and hydrocortisone tablets and it was this difference that was recognised by the regime.

- 4.84. While hydrocortisone tablets and Plenadren are '*similar medicinal products*' for the purposes of the orphan designation regime, this does not mean that they belong in the same relevant product market for competition law purposes. While clinical substitutability is an important factor in identifying **potential** substitutes, it is not sufficient in itself to determine that a medicine warrants inclusion in the relevant product market (see paragraph 4.76).
- 4.85. As explained in section 4.B.I, the test requires that products '*sufficiently compete with each other to be sensibly regarded as being in the same market*'.¹²²⁶ As explained in section 4.B.II.c.ii, both qualitative and quantitative evidence demonstrates that this is not the case for Plenadren and hydrocortisone tablets. Notwithstanding the orphan designation, prescribers (informed by CCGs' formularies) have concluded that Plenadren's clinical advantages are for most patients outweighed by its cost and as a result it is prescribed in minimal volumes and does not compete sufficiently with hydrocortisone tablets to be included in the relevant market.

ii. Whether skinny label hydrocortisone tablets form part of the relevant product market

Qualitative evidence

- 4.86. The CMA has reviewed a range of qualitative evidence on non-price and price parameters of competition to inform its assessment of whether skinny label tablets form part of the same relevant product market as the focal product (full label hydrocortisone tablets). This includes examining dispensing considerations, views of wholesalers and pharmacies on the decision to stock and dispense full or skinny label tablets, as well as views and internal documents of suppliers of hydrocortisone tablets to determine how they viewed competitive constraints.
- 4.87. The review of qualitative evidence below is structured as follows:
- a. product characteristics;
 - b. dispensing considerations; and
 - c. views on substitution by market participants:

¹²²⁶ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97.

- i. views of pharmacy purchasers of hydrocortisone tablets;
- ii. Auden/Actavis's internal documents and submissions; and
- iii. views of third-party suppliers of hydrocortisone tablets.

Product characteristics

- 4.88. In terms of characteristics, full and skinny label hydrocortisone tablets are bioequivalent (see section 3.D.I above). This means that they have identical effects in the body and are used to treat the same conditions.¹²²⁷ They are the same product. The only difference is the indications listed on the patient information leaflet as a result of the granting of orphan designation status to Plenadren. MAs granted after orphan designation status was awarded to Plenadren are not indicated for adrenal insufficiency in adults (see section 3.D.III.c above). This means that whereas full label hydrocortisone tablets are indicated for treating adrenal insufficiency in adults and adolescents, skinny label hydrocortisone tablets are only indicated for treating adrenal insufficiency in adolescents. A skinny label MA therefore does not represent a genuine 'clinical' distinction, but rather arises as a result of regulatory circumstance.
- 4.89. Moreover, the evidence demonstrates that prescribers do not generally draw a distinction between full and skinny label hydrocortisone tablets. In fact, as explained below, almost all prescriptions for hydrocortisone tablets were open, without specifying a supplier or indication. For example:
- a. [Professor of Endocrinology] was not aware of the difference between full and skinny label tablets.¹²²⁸
 - b. None of the GP software providers contacted by the CMA had flags or warnings relating to hydrocortisone tablets in their software which would prevent or caution against a GP writing an open prescription.¹²²⁹
- 4.90. On the basis of characteristics from a prescribing perspective, no material distinction can be drawn between full and skinny label hydrocortisone tablets.

¹²²⁷ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] ([redacted]) to Auden Mckenzie dated 20 May 2014 (This view was shared by the MHRA, which advised [Chief Pharmaceutical Officer for NHS England] and assisted him in responding to Auden's correspondence. Document 206640, note of call between the CMA and the MHRA on 31 March 2021, paragraph 2.1 and Document 206557, note of call between the CMA and NHS England and NHS Improvement on 22 March 2021, paragraph 2.1.); and Document 00288, letter from [redacted] (MHRA) to [redacted] (Auden Mckenzie) dated 19 December 2014.

¹²²⁸ Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 3, page 3.

¹²²⁹ See section 3.C.III.a above.

Dispensing considerations

- 4.91. For the purposes of assessing whether skinny label tablets form part of the relevant market, the substitution decision between full and skinny label hydrocortisone tablets is taken at the point of dispensing a medicine by pharmacies.¹²³⁰
- 4.92. As explained in section 3.E.III.a above, nearly all prescriptions for hydrocortisone tablets are open. This means that the prescription tends to specify only the generic drug name but not the specific supplier or brand, or specify whether the hydrocortisone tablets should be full or skinny label. Pharmacies also informed the CMA that the particular condition of the patient is also rarely specified on the prescription. The prescription simply states '*hydrocortisone tablets*'.
- 4.93. Upon receipt of an open prescription specifying hydrocortisone tablets,¹²³¹ pharmacies are unable to substitute a medicine other than hydrocortisone tablets, such as another form of hydrocortisone or another medicine (such as prednisolone or Plenadren). However, pharmacies can choose between different suppliers of hydrocortisone tablets (if more than one supplier sells the same drug).
- 4.94. This means that, upon receipt of an open prescription specifying hydrocortisone tablets, the decision of whether to dispense a full or a skinny label product, and to choose which manufacturer's or supplier's hydrocortisone tablets to dispense, falls to the pharmacy. As set out in 3.E.III.c above, pharmacies can and do dispense off-label (as well as off-label use being expected prior to skinny label tablets becoming available, see section 3.E.IV.a above), and in the case of full and skinny label hydrocortisone tablets, there would not be expected to be any clinical impact in doing so given that they are bioequivalent.

¹²³⁰ Consistent with this, AMCo, Cinven and Waymade all noted in their representations that decisions between full and skinny label hydrocortisone tablets take place at the pharmacy level and therefore the analysis should focus on pharmacy and wholesaler stocking and dispensing behaviour (Document 204922, AMCo's RSSO, paragraphs 4.36-4.40, Document 206670, AMCo's RLOF, paragraph 4.10, Document 204967, Cinven's RSSO paragraphs 5.23-5.29, Document 204903, Waymade's RSSO, paragraphs 8.121-8.127). AMCo and Cinven further submitted that the relevance of the evidence presented by the CMA on the views of prescribers, patients, the DHSC/NHS and the drug tariff was unclear (Document 204922, AMCo's RSSO, paragraphs 4.36-4.40 and 4.61-4.64, Document 204967, Cinven's RSSO, paragraphs 5.24-5.29). As explained in this section, the role of prescribers is important – they leave prescriptions open which is the reason dispensers have a choice between full and skinny label products. Moreover, the views of prescribers, patients and the DHSC/NHS are important in establishing how decisions over which medicine is used take place, to understand the full context of pharmacy substitution.

¹²³¹ Where a prescription is closed (ie specifies the particular brand or supplier to be used), a pharmacy cannot decide to dispense a different drug (unless the pharmacy contacts the prescriber to agree for a new prescription to be provided), see section 3.E.III.a above.

- 4.95. During the Infringements, commercial considerations over the price difference between full and skinny label tablets were a factor in pharmacies' decisions on which to dispense:
- a. As explained in section 3.B.IV above, the Drug Tariff does not distinguish between full and skinny label tablets, meaning that pharmacies were reimbursed at the same price per pack of hydrocortisone tablets¹²³² regardless of whether they dispensed a full or skinny label product. This indicates that both full and skinny label hydrocortisone tablets were treated as the same medicine by the DHSC.
 - b. As set out in 3.B.IV above, pharmacies face incentives to dispense the cheapest available product because the reimbursement system is designed to promote strong (generic) competition. In particular, a pharmacy is reimbursed at the Drug Tariff price for a medicine that is dispensed, so the cheaper the pharmacy can source the medicine, the greater the margin it is able to earn.

Views on substitution by market participants

- 4.96. Evidence as to how the undertakings in question themselves see the market can be of decisive importance for the purposes of market definition.¹²³³ This section sets out evidence, including both views and internal documents, from the following market participants:
- a. pharmacy customers;
 - b. Auden/Actavis; and
 - c. third-party suppliers of hydrocortisone tablets.
- 4.97. In assessing these contemporaneous documents and views, the CMA observes that the evidence of most significance to an analysis of market definition is objective evidence that relates to the parameters of competition. This may include considerations such as how Auden/Actavis responded to competitor behaviour (including the threat of potential entry), potential

¹²³² There are different drug tariff prices for 10mg and 20mg tablets. The tablet strength will be specified on the prescription. During the Infringements, the NHS Reimbursement Price for 10mg hydrocortisone tablets was set pursuant to the mechanism set out by Scheme M and by reference to applicable sales prices and volumes of 10mg tablets sold by Scheme M members. During the Infringements, the NHS Reimbursement Price for 20mg hydrocortisone tablets was based on the list prices of wholesalers and manufacturers, according to Category A of the Drug Tariff.

¹²³³ *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 103.

entrants' expectations and forecasts, and decisions made by pharmacies and wholesalers as customers.

Pharmacy views

- 4.98. Pharmacy dispensing behaviour is important to assessing whether full and skinny label hydrocortisone tablets are sufficiently interchangeable to form part of the same relevant product market. As set out at paragraph 4.92, given that the overwhelming majority of prescriptions for hydrocortisone tablets are open (demonstrating the interchangeability of full and skinny label tablets from the prescribers' perspective), any decision whether to stock and dispense full or skinny label hydrocortisone tablets will fall to the pharmacist.
- 4.99. [Chief Pharmaceutical Officer for NHS England] considered (on the advice of the MHRA)¹²³⁴ that full and skinny label hydrocortisone tablets are bioequivalent and that it was not necessary to issue guidance regarding their use in order to protect patient safety:
- a. When made aware of the distinction between Auden's full label hydrocortisone tablets and AMCo's skinny label 10mg hydrocortisone tablets, [Chief Pharmaceutical Officer for NHS England] responded that *'there are no material differences between the available generic immediate release hydrocortisone tablets and they are all bioequivalent to the brand leader'*.¹²³⁵
 - b. [Chief Pharmaceutical Officer for NHS England] concluded that *'[b]ased on the advice I have received so far, I do not see that there are any risks to patient safety that would warrant any communication to senior pharmacists'*.¹²³⁶
- 4.100. Consistently with this, short-line wholesalers explained that their customers, predominantly independent pharmacies, switched to purchasing skinny label tablets as they became aware of their availability, based on their decision to purchase the cheapest product that is able to fulfil a hydrocortisone tablets prescription (see section 3.E.IV.c.i above).
- 4.101. However, as set out in section 3.E.IV.c.i above, the views and actions of some of the pharmacies contacted by the CMA demonstrate that a number

¹²³⁴ This view was shared by the MHRA, which advised [Chief Pharmaceutical Officer for NHS England] and assisted him in responding to Auden's correspondence. Document 206640, note of call between the CMA and the MHRA on 31 March 2021, paragraph 2.1 and Document 206557, note of call between the CMA and NHS England and NHS Improvement on 22 March 2021, paragraph 2.1.

¹²³⁵ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [X] dated 20 May 2014.

¹²³⁶ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [X] dated 20 May 2014. See also Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to question 3, page 3.

of large pharmacies had no choice but to purchase Auden/Actavis's tablets, with eight of the ten largest pharmacy chains (Asda, Boots, Lloyds, Morrisons, Rowlands, Sainsbury's, Superdrug and Well) indicating a requirement for full label hydrocortisone tablets.

- 4.102. Pharmacies have explained that their reasons for dispensing only or mostly full label hydrocortisone tablets, regardless of full and skinny label tablets being bioequivalent, are related to non-price factors such as the following:
- a. believing they could not dispense off-label for regulatory reasons; and
 - b. not wishing to dual stock full and skinny label tablets, in particular, for administrative ease and to reduce the risk of errors in dispensing (eg dispensing a skinny label tablet in place of a full label tablet). This meant that those pharmacies who had no choice but to purchase Auden/Actavis's tablets would not dual-stock with skinny label tablets.
- 4.103. These views show that full and skinny label hydrocortisone tablets were perceived by some pharmacies to be interchangeable and by some other pharmacies to be differentiated products where they had no choice but to purchase full label hydrocortisone tablets.

Auden/Actavis's views

- 4.104. Evidence in relation to Auden/Actavis's contemporaneous views of the threat from skinny label tablets and impact on its market position shows that it expected full and skinny label hydrocortisone tablets to be substitutes.
- 4.105. First, as set out in section 3.E.IV.a above, Auden/Actavis's internal documents demonstrate that it expected that there would be demand for skinny label tablets. In particular, Auden/Actavis was concerned about the risk that skinny label tablets posed to its position as the sole supplier of hydrocortisone tablets and took steps to try to protect its market position against the threat that skinny label tablets posed. This is shown by:
- a. Auden both devising a plan (called 'Project Guardian') to limit the competitive threat posed by skinny label tablets and launching Project Guardian (with its aim being to *'develop and deliver a strategy designed to ensure that its current market share for the supply of hydrocortisone tablets (10mg and 20mg respectively) is maintained or strengthened at a time when a competitors [sic] product (namely Amdipharm Mercury Company Limited [AMCo] hydrocortisone tablets 10mg and 20mg)*

threatens to weaken Auden McKenzie's market share',¹²³⁷ see section 3.F.III.h above); and

- b. Auden/Actavis entering into the 10mg Agreement (whereby Auden/Actavis's potential competitors (Waymade, then AMCo) agreed not to enter independently in return for payments from Auden/Actavis, see section 6.D.II.c.ii).

4.106. Second, as set out in section 3.E.IV.a above, the expectation that skinny label tablets would be successful in competing with and winning sales from Auden's full label tablets had a significant impact on the valuation of various transactions. In particular, Allergan anticipated market share erosion of 60% and price erosion of 90% over a three year period once skinny label tablet suppliers entered. That view was fully cognisant of the distinction between full and skinny label tablets but recognised that off-label dispensing would occur, with Allergan expecting that competitors would enter '*without indication for adrenal insufficiency and being launched and dispensed off label*'.¹²³⁸ That assessment resulted in a significant change in the deal structure to achieve '*a total and complete de-risking of Hydrocortisone for Actavis and only an earnout depending on their success to market Hydrocortisone tablets*',¹²³⁹ with Allergan reducing its offer for AM Pharma by £220 million and agreeing an earn-out to address the risk of skinny label entry.

Views of third-party suppliers of hydrocortisone tablets

4.107. As set out in section 3.E.IV.a above, Waymade and AMCo, contemporaneously and prior to market entry, expected that there would be demand for skinny label tablets. This view was shared by other suppliers of skinny label hydrocortisone tablets who considered that skinny label tablets would compete with full label tablets (ie that skinny label tablets would win sales from full label tablets), and in particular, they viewed Auden as their competitor and did not consider that the market was restricted to indications other than adrenal insufficiency in adults (that is, that skinny label products would only fulfil a narrow subset of prescriptions):

¹²³⁷ Document 00062F, Professional Advice (Hydrocortisone) Proposal Prepared for Auden Mckenzie (Pharma Division) Ltd by [Auden's External Consultant] dated 6 February 2014, 2 Client Requirements.

¹²³⁸ Document 00706, Project Apple Presentation January 2015, Hydrocortisone Background. Similarly, Waymade, which has the full range of indications with respect to its 20mg MA, downplayed the significance of having a full label product and considered that short-line wholesalers are more driven by price than range of indications, see Document 01563, Waymade's response to the CMA's section 26 notice dated 4 May 2017.

¹²³⁹ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015

- a. Waymade and AMCo both consistently forecast that they would be successful in winning sales if they entered with skinny label tablets.
- b. Other suppliers continued developing their own skinny label hydrocortisone tablets notwithstanding the limited indications. This demonstrates that they thought they would be able to win sales for such products through competing with full label hydrocortisone tablets, and their internal sales forecasts were consistent with this.
- c. Alissa and Resolution Chemicals (suppliers), DE Pharma, Mawdsleys and Sigma Pharmaceuticals (short-line wholesalers) and multiple retail pharmacy Day Lewis all expected that the market would have reacted in the same way had skinny label tablets been launched earlier.

Conclusion on views of market participants

- 4.108. Overall, the views from pharmacies indicate that while, taken as a whole, full and skinny label hydrocortisone tablets were viewed as interchangeable and there were no risks to patient safety that necessitated issuing guidance on switching between them, some larger pharmacies nonetheless had no choice but to purchase Auden/Actavis's tablets (see section 3.E.IV.c.i above). In addition, the views of both Auden/Actavis and other suppliers of hydrocortisone tablets show that full and skinny label hydrocortisone tablets were expected to be interchangeable. This is evident from their common expectation that entry of skinny label hydrocortisone tablets would lead to skinny label tablets winning sales from full label tablets resulting in price and profit decreases for full label hydrocortisone tablets.

Quantitative evidence

- 4.109. This sub-section presents a quantitative analysis of the extent of the competitive constraint imposed on full label hydrocortisone tablets by skinny label tablets. This is examined by reviewing relevant price and sales trends for hydrocortisone tablets following independent entry by skinny label tablet suppliers, which commenced in October 2015 for 10mg tablets and March 2016 for 20mg tablets.¹²⁴⁰ Although sales and price trends are presented sequentially, these should be read hand-in-hand in this analysis.
- 4.110. Being able to observe directly the impact on full label sales volumes and prices from the independent entry of skinny label tablet suppliers provides powerful information on the degree of competitive constraint from skinny

¹²⁴⁰ Although the first independent 20mg entrant was Waymade in July 2015, Waymade supplied full label tablets. First 20mg skinny label entry commenced in March 2016 with entry by Bristol Laboratories and Resolution Chemicals.

label tablets to inform market definition.¹²⁴¹ This is particularly so given that there were no other changes or events during that time that could have driven these trends (having found that the market was no wider than hydrocortisone tablets only).

- 4.111. In principle, if two products are substitutes, then it is generally expected that a price change in one product will be reflected by sales and/or price variation in the other. For example, it might be expected that if two medicines are competitors then a price decrease in one medicine would be expected to result in a price and/or sales decrease on the part of a competing medicine. Therefore, if full and skinny label hydrocortisone tablets are substitutes, the entry of skinny label tablets at a price below full label tablets ought to lead to switching to skinny label tablets and/or price falls in full label tablets.¹²⁴²
- 4.112. The quantitative evidence shows that skinny label hydrocortisone tablets exerted a sufficient competitive constraint on the focal product (full label hydrocortisone tablets) to be included in the relevant product market after 3 November 2011.¹²⁴³ Following the entry of skinny label hydrocortisone tablets suppliers, full and skinny label hydrocortisone tablet prices have fallen on a similar trajectory, and customers have switched substantial volumes of their purchases to skinny label tablet suppliers. This shows that, notwithstanding the differentiation between full and skinny label hydrocortisone tablets,¹²⁴⁴ skinny label tablet suppliers exerted a sufficient constraint on the focal product to warrant inclusion in the relevant product market.
- 4.113. It was only when independent competition emerged, in the form of skinny label tablet entry (and also one full label tablet entrant (Waymade's 20mg tablets)) that Auden/Actavis's prices and profits stopped increasing, as they

¹²⁴¹ When available, actual examples of substitution between two products will normally be fundamental for market definition: see *Commission Notice on Market Definition*, paragraph 38.

¹²⁴² As explained in paragraph 4.65 above, when assessing the relevant market, caution is required. This is because in cases such as this one, where an undertaking appears to have exercised its market power by raising prices above competitive levels, one may observe consumers switching to other products. However, it may be incorrect in those circumstances to conclude that the dominant undertaking lacks market power and to include those other products in the relevant market. This is commonly known as the 'Cellophane fallacy' following the *US v El Du Pont de Nemours & Co* [1956] 351 US 377 case. See also OFT403, paragraph 5.5. The CMA has been mindful of this when assessing observed substitution patterns in this case and, in particular, observes that the pattern of switching to skinny label tablets is maintained even when price levels are eroded to levels that are less influenced by the market power of Auden/Actavis.

¹²⁴³ That is, the date on which the MA for Plenadren was granted, which triggered the orphan designation status and created the distinction between full and skinny label tablets.

¹²⁴⁴ Product differentiation does not necessarily imply separate markets, although it can affect the competitive conditions which are relevant to the existence of market power. The key question when defining the relevant market is that of a competitive constraint. The price trends set out in this section, when considered together with switching behaviour, demonstrate a sufficient competitive constraint to include skinny label tablets in the relevant product market. However, the CMA considers that the competitive constraint from skinny label tablets has not been sufficiently strong such that it has constrained Auden/Actavis's conduct. These factors are considered in section 4.C.II below.

had done for the previous seven years, and began to fall (see section 4.C.II.c below for the CMA's assessment of Auden/Actavis's dominance following entry).

4.114. This section is structured as follows:

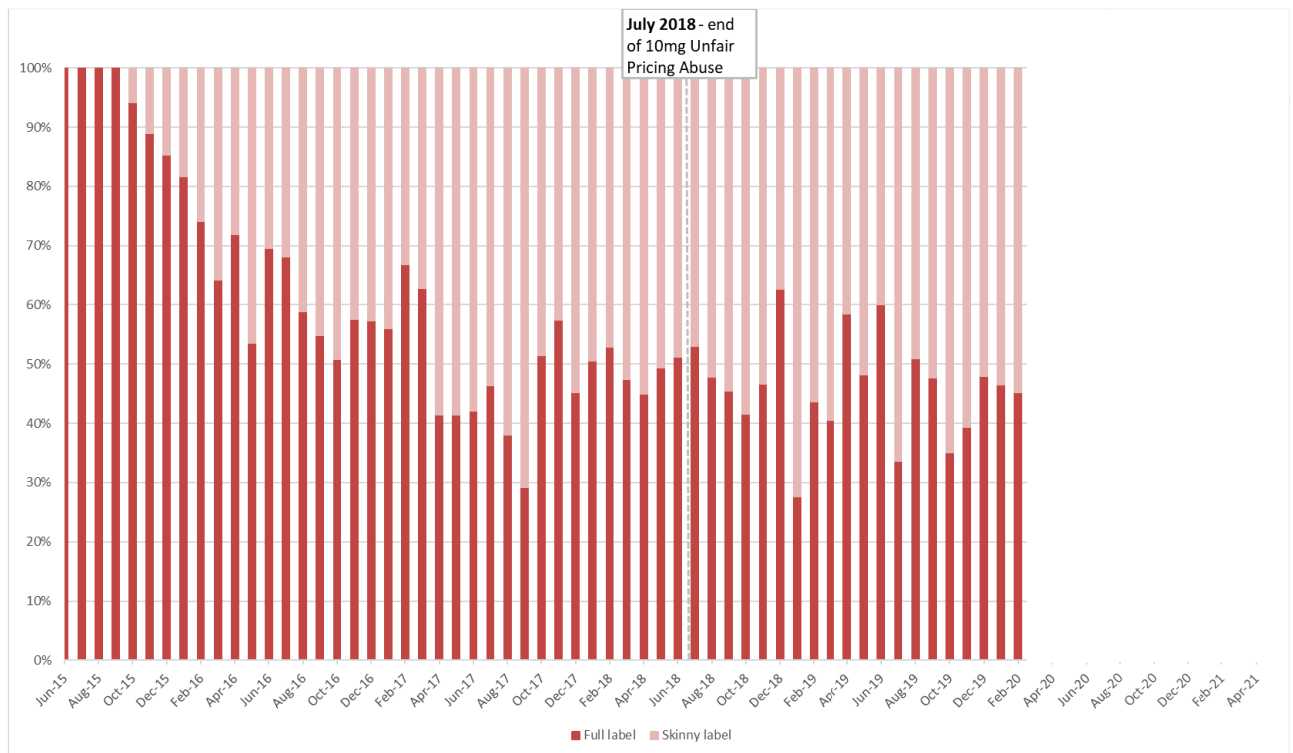
- a. Substitution patterns:
 - i. By pharmacies;
 - ii. By wholesalers; and
 - iii. By hospitals; and
- b. Pricing trends.

Substitution patterns

4.115. Figures 4.4 and 4.5¹²⁴⁵ below show the proportion of full and skinny label hydrocortisone tablet volumes for 10mg and 20mg packs respectively, from October 2015 onwards (that is following entry by independent suppliers of skinny label hydrocortisone tablets, as well as Waymade's 20mg full label tablets).

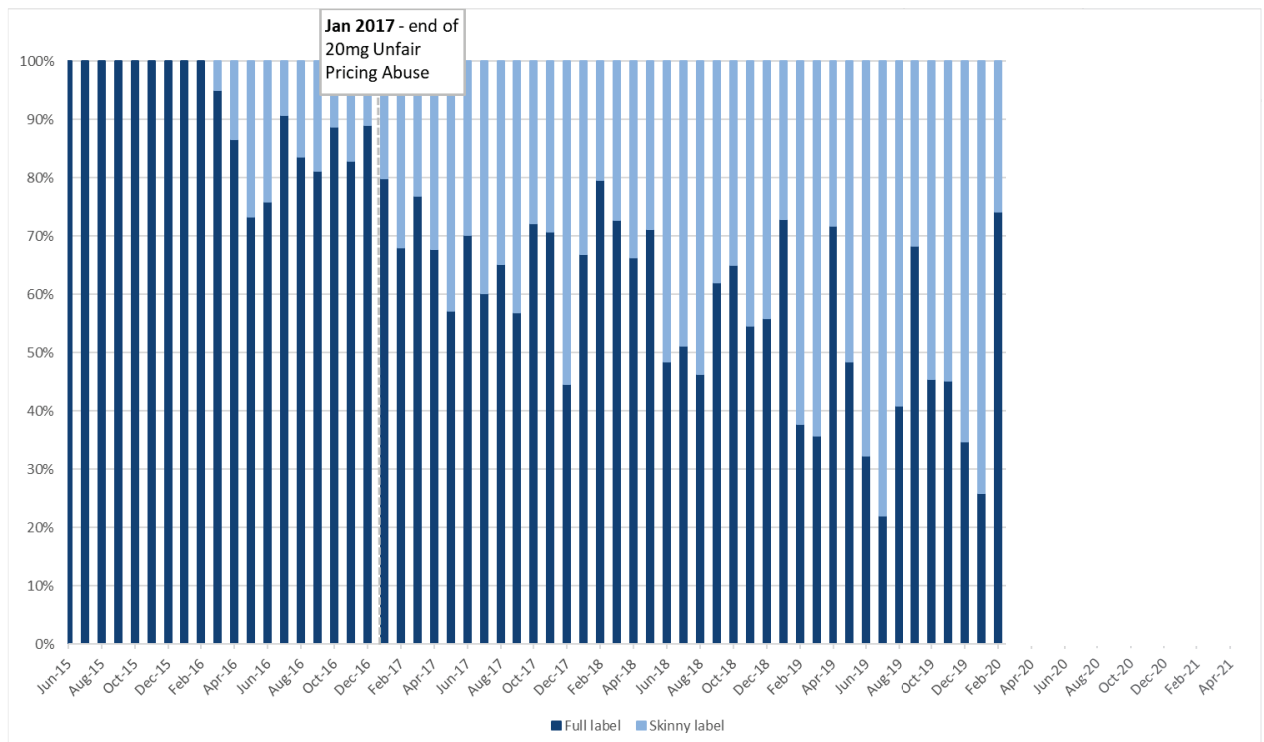
¹²⁴⁵ As set out at 3.E.V.b.v above, volumes are growing steadily for 10mg and are fairly flat for 20mg. Therefore, the volume trends in Figures 4.4 and 4.5 would be very similar had quantities rather than proportions been presented.

Figure 4.4: 10mg hydrocortisone tablets full and skinny label proportions



Source: CMA analysis based on data submitted by relevant parties.

Figure 4.5: 20mg hydrocortisone tablets full and skinny label proportions



Source: CMA analysis based on data submitted by relevant parties.

- 4.116. Figures 4.4 and 4.5 show that following independent entry by skinny label tablet suppliers, there was substantial switching away from full label hydrocortisone tablets to skinny label hydrocortisone tablets:
- Switching occurred fairly rapidly for 10mg hydrocortisone tablets. By October 2016 (that is around 12 months after entry had taken place), approximately half of all 10mg hydrocortisone tablets purchased were skinny label.
 - The rate of switching to skinny label tablets was more gradual for 20mg hydrocortisone tablets. This can be accounted for by the fact that the first independent entrant (Waymade) supplied a full label product, ie that a portion of switching was between the two available full label tablets rather than from full to skinny label tablets. Nonetheless, by June 2018, around 50% by volume had switched to skinny label tablets.
 - Following the initial switching from full to skinny label hydrocortisone tablets, proportions of full and skinny label tablets have broadly stabilised for both tablet strengths (albeit with some monthly fluctuation). In 2017, skinny label hydrocortisone tablets accounted for 52% of all sales volumes of 10mg and 20mg hydrocortisone tablets combined, with skinny label tablets accounting for 52% of all sales volumes of 10mg tablets and 34% of all sales volumes of 20mg tablets.
- 4.117. The fact that skinny label tablet suppliers have been able to win a significant proportion (around 50%) of the total sales volumes of hydrocortisone tablets shows that, despite not being indicated for adults, skinny label hydrocortisone tablets were being dispensed for adult adrenal insufficiency patients during the Infringements, ie being dispensed off-label (consistent with the expectation prior to skinny label tablet entry that pharmacies would use skinny label tablets off-label, see section 3.E.IV.a above). This indicates that for a significant number of pharmacies, full and skinny label hydrocortisone tablets were interchangeable despite differences in their licensed indications.¹²⁴⁶
- 4.118. The next sub-sections consider pharmacy, wholesaler and NHS substitution patterns which corroborate the evidence above that for a significant number

¹²⁴⁶ AMCo submitted that the '[orphan designation] market exclusivity constituted an actual and effective barrier to entry' and that the 'CMA is wrong to dismiss the orphan designation issue as a relevant supply factor', stating that the existence of regulatory barriers is highly relevant for the delineation of the relevant product market (Document 204922, AMCo's RSSO, paragraphs 4.50-4.55). The CMA has not dismissed the role of the orphan designation in its analysis. To the contrary, the CMA has carefully considered evidence on demand for skinny label tablets and suppliers' ability to supply hydrocortisone tablets despite the orphan designation (see section 3.E.IV.a). Given the substitution between full and skinny label tablets (with 50% switching to skinny label tablets), the orphan designation did not act as a barrier to entry for supplying hydrocortisone tablets.

of purchasers, full and skinny label hydrocortisone tablets were interchangeable.

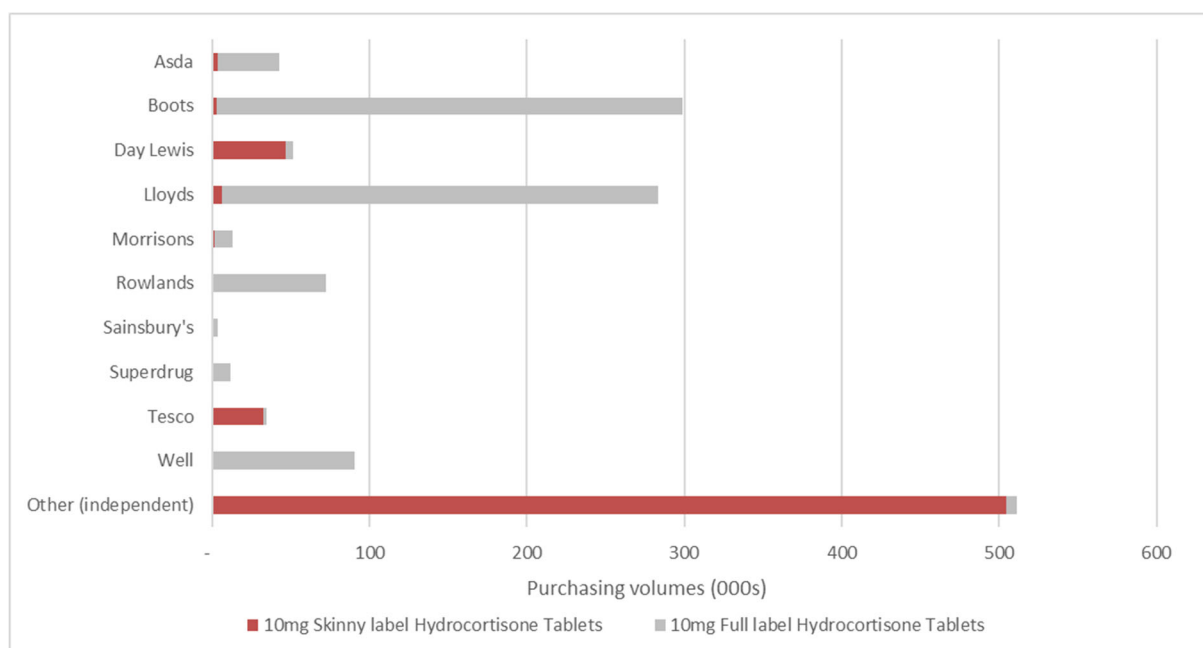
Pharmacy substitution

- 4.119. This sub-section presents evidence on hydrocortisone tablet dispensing¹²⁴⁷ by all pharmacies, including both large chains and smaller and independent pharmacies, to assess whether full and skinny label hydrocortisone tablets were interchangeable in practice. This evidence of actual behaviour by pharmacies is important for assessing market definition, consistent with the CAT's view in *Phenytoin* that '*What matters, for this competition analysis, is what pharmacists actually did*'.¹²⁴⁸
- 4.120. The views of pharmacies set out above showed that while some pharmacies viewed full and skinny label tablets as interchangeable, some pharmacies dispensed only full label hydrocortisone tablets. Consistently with these views and with overall substitution patterns, pharmacy purchasing data shows that, since entry by suppliers of skinny label hydrocortisone tablets, a significant number of pharmacies substituted between full and skinny label hydrocortisone tablets to meet their demand for hydrocortisone tablets.
- 4.121. Figures 4.6 and 4.7 below show the proportion of pharmacies' 10mg and 20mg hydrocortisone tablet purchases which were full and skinny label, from March 2016 to November 2017.

¹²⁴⁷ The data presented is pharmacy purchasing volumes which is a good proxy for pharmacy dispensing behaviour.

¹²⁴⁸ *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 132. See also paragraph 143.

Figure 4.6: Pharmacies' purchases of 10mg full and skinny label hydrocortisone tablets in the UK March 2016 – November 2017

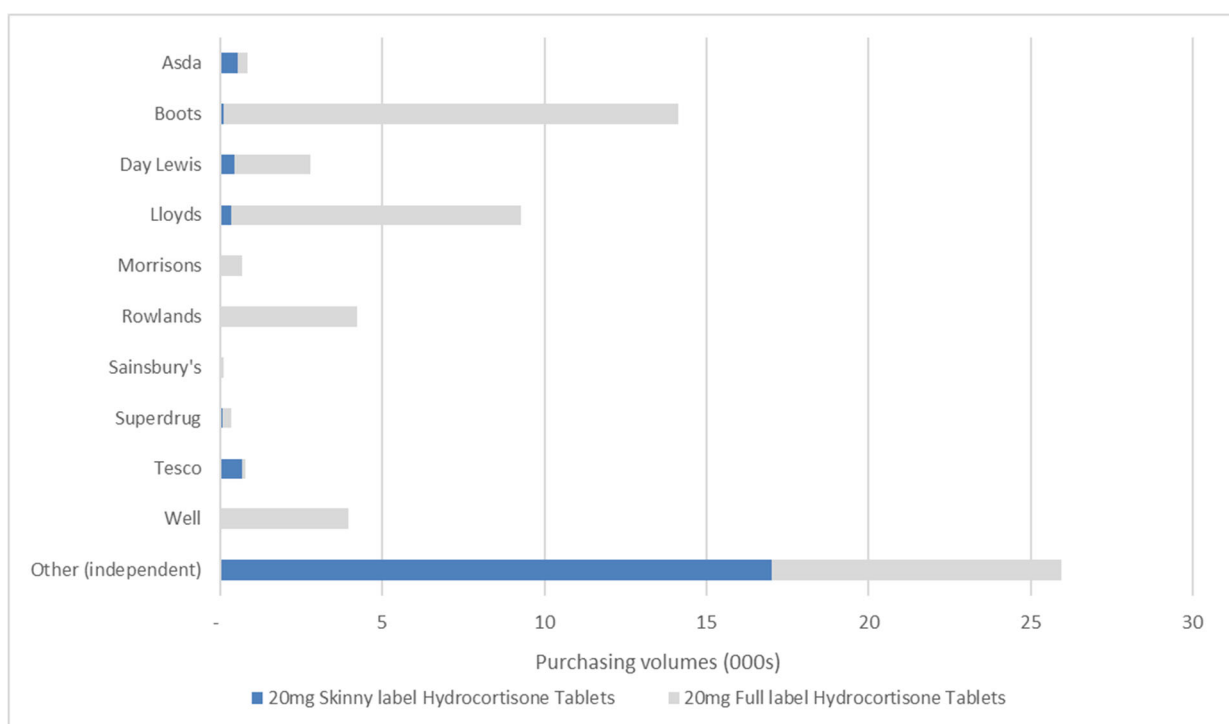


Source: CMA analysis based on data supplied by relevant parties.

Notes: (1) 'Other (independent)' volumes are calculated as: total sales volumes of hydrocortisone tablets in the UK – total volumes sold by AAH, Alliance, DE and Sigma – total volumes purchased by Day Lewis, Rowlands, Tesco and Well. (2) Day Lewis informed the CMA that it has a wholesale function as well as purchasing hydrocortisone tablets for its own pharmacy dispensing.¹²⁴⁹ This means that Day Lewis's purchase volumes shown in this figure are higher than the volumes it dispensed as a pharmacy, and 'Other (independent)' pharmacy volumes are slightly understated. These discrepancies are not material to the CMA's conclusions.

¹²⁴⁹ Document 206416, Note of call between the CMA and Day Lewis on 16 March 2021, paragraph 2.2.

Figure 4.7: Pharmacies' purchases of 20mg full and skinny label hydrocortisone tablets in the UK March 2016 – November 2017



Source: CMA analysis based on data supplied by relevant parties.

Notes: (1) 'Other (independent)' volumes are calculated as: total sales volumes of hydrocortisone tablets in the UK – total volumes sold by AAH, Alliance, DE and Sigma – total volumes purchased by Day Lewis, Rowlands, Tesco and Well. (2) Day Lewis has informed the CMA that it also has a wholesale function as well as purchasing hydrocortisone tablets for its own pharmacy dispensing.¹²⁵⁰ This means that Day Lewis's purchase volumes shown in this figure are higher than the volumes it dispensed as a pharmacy, and 'Other (independent)' pharmacy volumes are slightly understated. These discrepancies are not material to the CMA's conclusions.

4.122. Figures 4.6 and 4.7 show that between March 2016 and November 2017:

- a. certain pharmacies switched significant proportions of their purchases of hydrocortisone tablets to skinny label tablet suppliers. This is consistent with certain pharmacies dispensing skinny label hydrocortisone tablets for adult patients with adrenal insufficiency (ie dispensing off-label).
- b. The proportion of skinny label hydrocortisone tablets purchased varied across customers:
 - i. Two of the ten largest pharmacy chains¹²⁵¹ (Tesco and Day Lewis), and the overwhelming majority of independent

¹²⁵⁰ Document 206416, Note of call between the CMA and Day Lewis on 16 March 2021, paragraph 2.2.

¹²⁵¹ The ten largest pharmacies account for around 57% of the UK pharmacy market (see Table 2 of [the CMA's report on the anticipated acquisition by Celesio AG of Sainsbury's Pharmacy Business](#)).

pharmacies,¹²⁵² switched the majority of their dispensing of hydrocortisone tablets to skinny label tablets.

- ii. Eight of the ten largest pharmacy chains (Asda, Boots, Lloyds, Morrisons, Rowlands, Sainsbury's, Superdrug and Well) dispensed primarily full label hydrocortisone tablets.

- 4.123. The pharmacy data also shows that pharmacies tended to mostly dispense either full or skinny label tablets, rather than dispensing a mix of both full and skinny label tablets (ie pharmacies would not tend to dual-stock). This shows that full and skinny label hydrocortisone tablets are differentiated products from the perspective of certain large customers. As pharmacies tend not to dual-stock full and skinny label tablets (see paragraph 4.95 above), this means that pharmacies were not stocking full and skinny label tablets according to the patients being treated (that is, with skinny label tablets reserved for adolescent adrenal insufficiency patients only). Instead, a pharmacy decision on whether to use skinny label tablets was likely to have been applicable to all tablets dispensed (except in limited circumstances where, for example, the prescription specified a particular supplier or the patient expressed a preference for a particular supplier's tablets).
- 4.124. This, together with the views presented by pharmacies on their dispensing choices (see paragraphs 4.98 to 4.103), also shows that there was and continues to be a significant proportion of total demand that can only be met through full label hydrocortisone tablets, principally due to the two largest customers (Boots and Lloyds) dispensing full label hydrocortisone tablets despite full label tablets being consistently more expensive than skinny label tablets (see paragraph 4.130 below).

Wholesaler purchasing behaviour

- 4.125. Pharmacies' dispensing behaviour also drives wholesalers' purchasing behaviour given that in most instances, wholesaler demand is a function of pharmacy demand,¹²⁵³ and the act of listing a product is not a time-consuming or costly task for the wholesaler.¹²⁵⁴ Evidence on wholesalers'

¹²⁵² CMA calculations show that skinny label tablets accounted for 97% of independent pharmacies' purchases of hydrocortisone tablets. Independent pharmacies accounted for 27% of hydrocortisone tablet sales in the UK.

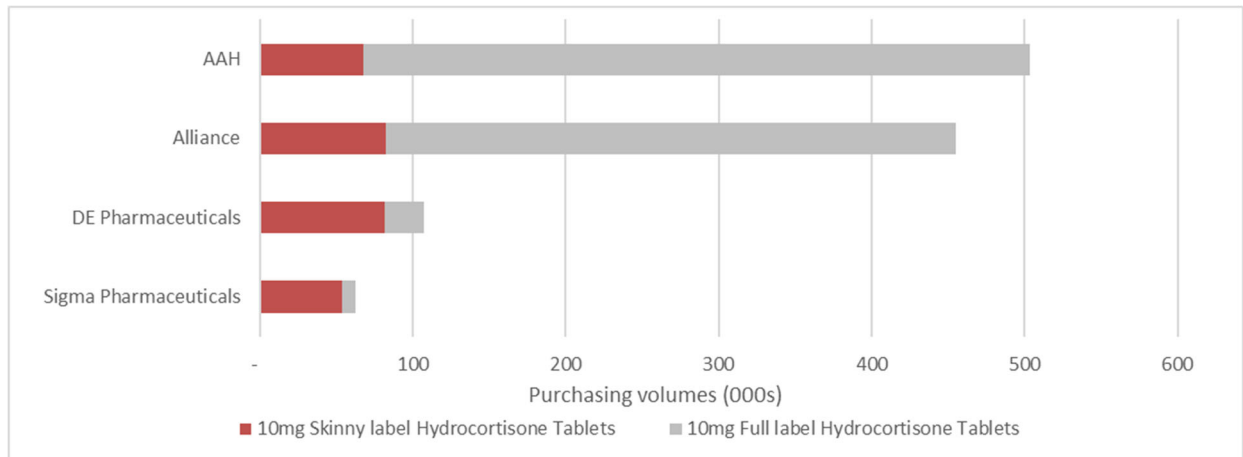
¹²⁵³ Except in some limited scenarios where the pharmacy delegates the purchasing decision to the wholesaler.

¹²⁵⁴ For example, DE Pharma explained to the CMA that to list a product it only requires manufacturers to provide a new product form with the details of the product (PIP code, pack size, strength, trade price, etc.). If DE Pharma decides to sell a product, it will add the product to its system and place an order from the supplier. See Document 206579, note of call between the CMA and DE Pharma of 23 February 2021, paragraphs 3.2 and 3.5. An example of the information a wholesaler would need from a supplier to list the product in its Patient Medical Record (PMR) system can be found in document 206024, spreadsheet titled 'BAPW New Line Form' attached to Document 206023, email from [X] (Mawdsleys) to [Alissa Senior Employee] dated 23 October 2015. A PMR system allows pharmacies to (i) check which wholesalers are listing the product to dispense and (ii) place their orders accordingly. For a list of PMR providers, see [System suppliers list and info: PSNC Main site](#).

purchasing patterns is therefore also relevant when assessing the relevant market in this case.

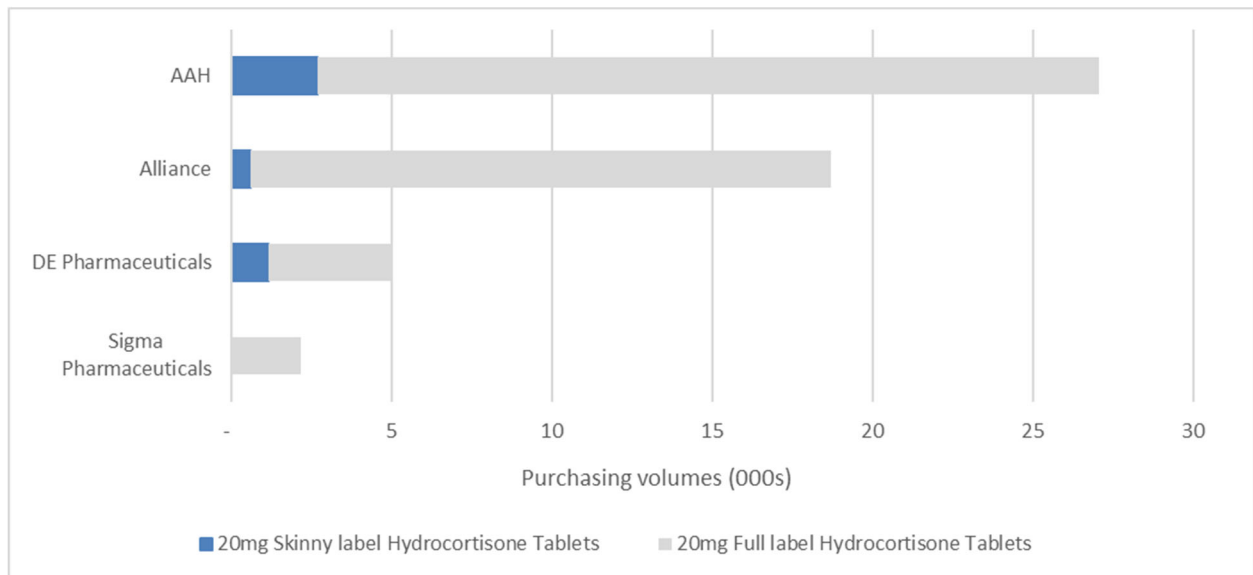
4.126. Figures 4.8 and 4.9 below show the proportion of wholesalers' 10mg and 20mg hydrocortisone tablet purchases which are full and skinny label, from March 2016 to November 2017.

Figure 4.8: Wholesalers' purchases of 10mg full and skinny label hydrocortisone tablets in the UK March 2016 – November 2017



Source: CMA analysis based on data submitted by relevant parties.

Figure 4.9: Wholesalers' purchases of 20mg full and skinny label hydrocortisone tablets in the UK March 2016 – November 2017



Source: CMA analysis based on data submitted by relevant parties.

4.127. Figures 4.8 and 4.9, together with the evidence from wholesalers, show that:

- a. The two largest full-line wholesalers, AAH and Alliance, together accounting for 51% of all sales of hydrocortisone tablets, mainly sold

full label hydrocortisone tablets.¹²⁵⁵ However, their sales volumes of skinny label hydrocortisone tablets, in particular those sold to their customers other than Boots and Lloyds, increased since March 2016.¹²⁵⁶ During the period from March 2016 to November 2017,¹²⁵⁷ sales of skinny label hydrocortisone tablets accounted for 13% and 18% of all AAH and Alliance sales of hydrocortisone tablets, respectively.

- b. Other wholesalers (such as DE Pharma and Sigma)¹²⁵⁸ purchased the majority of their hydrocortisone tablets from skinny label suppliers. DE Pharma and Sigma are both short-line wholesalers who sell primarily to small and independent pharmacies. This purchasing evidence is consistent with the views on pharmacy purchasing behaviour set out at paragraphs 4.98 to 4.103 above, showing that skinny label tablet demand came predominantly from small and independent pharmacies.

Hospital purchasing

- 4.128. That full and skinny label hydrocortisone tablets were treated as the same generic medicine is further confirmed by the fact that the NHS did not distinguish between full and skinny label hydrocortisone tablets in its hospital tenders in England, Scotland and Wales,¹²⁵⁹ which included hydrocortisone tablets amongst a range of other drugs. Indeed, these tenders were awarded to suppliers of skinny label hydrocortisone tablets, which is consistent with full and skinny label tablets being considered as interchangeable.¹²⁶⁰

¹²⁵⁵ See section 3.E.IV.c.ii for AAH and Alliance's views on purchasing full and skinny label tablets.

¹²⁵⁶ In 2017, 38% of AAH's sales to customers other than Lloyds and 60% of Alliance's sales to customer other than Boots were skinny label tablets, see table 3.9 above. See also Document 02267 and Document 02201, responses by AAH and Alliance to question 11 the CMA's section 26 notices dated 19 December 2017. See also Document 02202, response by Alliance to question 6 of the same section 26 notice.

¹²⁵⁷ The period over which the CMA gathered data from pharmacies on their skinny label purchases.

¹²⁵⁸ During the period from March 2017 to November 2017, skinny label hydrocortisone tablets accounted for 74% and 83% of all DE Pharma's and Sigma's sales of hydrocortisone tablets, respectively. In 2017, 84% of DE Pharma's and 94% of Sigma's sales of hydrocortisone tablets were skinny label. CMA analysis based on DE Pharma's and Sigma's purchases of hydrocortisone tablets between March 2016 and June 2017 (Document 01780 and Document 01856, DE Pharma and Sigma responses to the CMA's section 26 notices dated 21 June 2017).

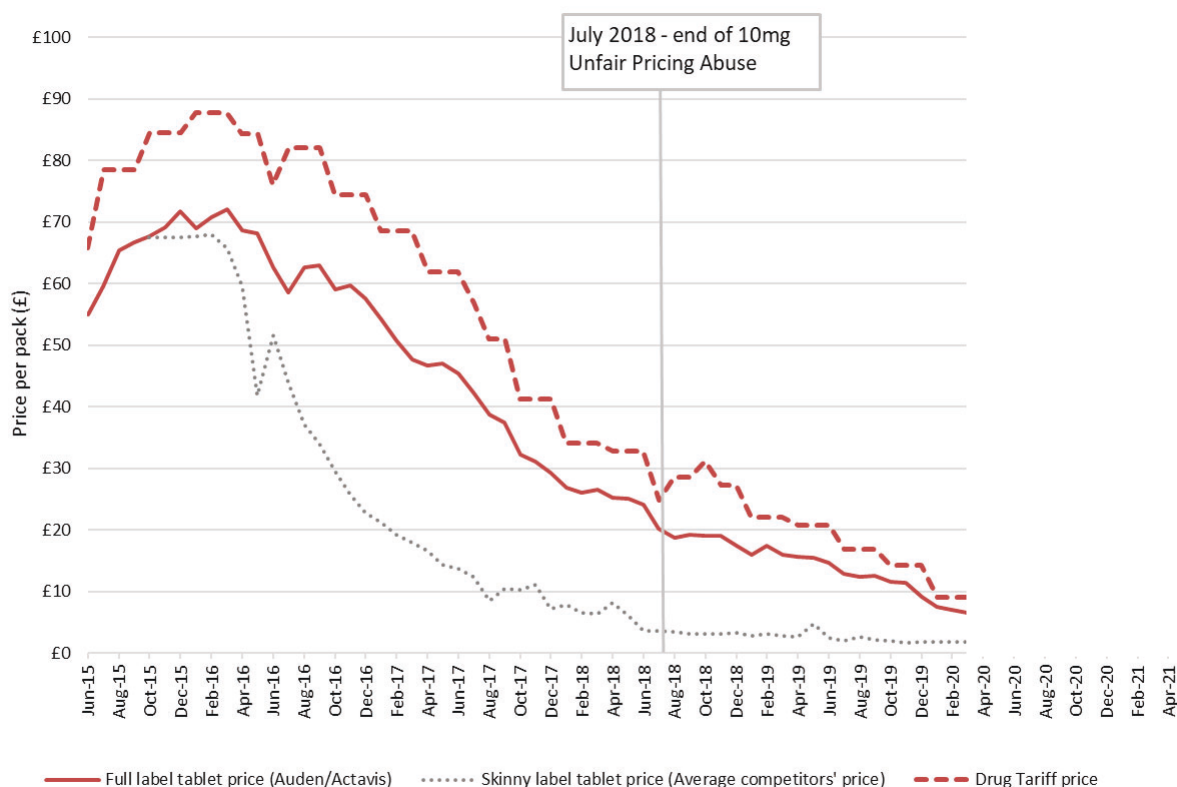
¹²⁵⁹ Document 02238, Intas, Accord and Accord-UK Limited's response to CMA's section 26 notice of 20 December 2017. These tenders covered a number of drugs, including hydrocortisone tablets. Each product line is considered and awarded separately.

¹²⁶⁰ With regard to the NHS tender in England, Actavis lost on price to AMCo for 10mg hydrocortisone tablets and to Bristol Laboratories for 20mg hydrocortisone tablets. With respect to the NHS tender in Scotland, Actavis lost on price to Teva for 10mg hydrocortisone tablets, but was awarded the supply of 20mg hydrocortisone tablets. With respect to the NHS tender in Wales, Actavis lost the supply of both 10mg and 20mg hydrocortisone tablets to Teva (see Document 02238, Intas, Accord and Accord-UK's response to question 3 of the CMA's section 26 notice dated 20 December 2017).

Price trends

4.129. Price trends¹²⁶¹ following independent entry by skinny label tablet suppliers further demonstrate the competitive relationship between full and skinny label tablets. Figures 4.10 and 4.11 below show the evolution of full and skinny label tablet prices and the Drug Tariff price for 10mg and 20mg tablet strengths respectively.

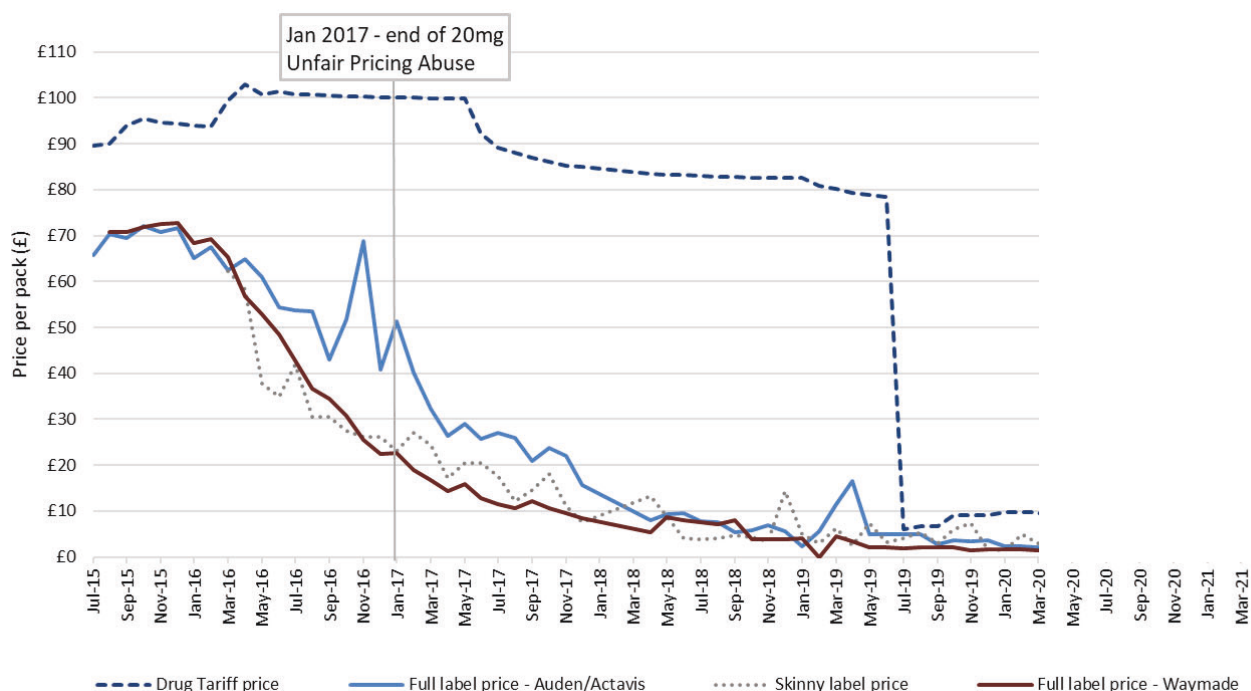
Figure 4.10: Average price of full and skinny label 10mg hydrocortisone tablets



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

¹²⁶¹ Consistently with the General Court's judgments in *AstraZeneca* and *Servier*, price-related factors are relevant to the CMA's assessment of the relevant market when assessed in their own context (see *Servier v Commission*, EU:T:2018:922, paragraph 1411, and T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 183). In a case such as this where the substitution decision is being made by pharmacies which are price sensitive, price trends are clearly relevant.

Figure 4.11: Average price of Auden/Actavis's full label 20mg tablets, Waymade's full label 20mg tablets and skinny label 20mg hydrocortisone tablets



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

4.130. Figures 4.10 and 4.11 show that:

- Both full and skinny label hydrocortisone tablet prices declined following independent entry by other suppliers of hydrocortisone tablets (during the time when switching from full to skinny label tablets was taking place, see paragraph 4.116 above).
- The price declines followed similar trajectories for both full and skinny label tablets (though skinny label tablet prices declined at a faster rate, particularly for 10mg tablets).
- There was a price premium for Auden/Actavis's¹²⁶² full label tablets over skinny label tablets during the Infringements: skinny label tablet prices were below full label tablet prices throughout the period following independent entry. However, the absolute gap between full and skinny label tablet prices has become narrower over time, with the price difference being fully eroded for 20mg during early 2018.

4.131. Consistently with this, since entry by skinny label tablets suppliers, Auden/Actavis's prices have fallen (see section 3.E.V.b.ii above). In the period from March 2016 to December 2017, Auden/Actavis's average

¹²⁶² As shown in figure 4.11, Waymade, as the other 20mg full label supplier, was unable to maintain a premium as compared to competing skinny label tablet suppliers. See further section 4.C.II.c.ii.

monthly prices for 10mg and 20mg hydrocortisone tablets fell by 59% and 75%, respectively.¹²⁶³

- 4.132. Figure 4.10 also shows that the falls in prices have also led to a reduction in the monthly 10mg Drug Tariff price of 53% during this period.¹²⁶⁴ This is because, as explained in section 3.E.I.b above, the 10mg Drug Tariff price (being in Category M) is calculated based on average selling prices from certain suppliers together with an adjustment factor for pharmacy profits. The 20mg Drug Tariff Price, being in Category A and based on certain suppliers' list prices, fell to a lesser extent (15% during this period, as shown in figure 4.11).
- 4.133. The facts that it was skinny label tablet entry that led to full label tablet prices falling (reversing the upwards trend up until that point) and that following skinny label tablet entry both full and skinny label tablet prices have followed a similar trend support the CMA's conclusion that skinny label tablets have acted as a competitive constraint on full label tablets. These falls in price can be attributed to two factors, though the size of each effect is not clear (nor is it necessary to determine the size of each effect):
- a. direct price competition between full and skinny label tablets; and
 - b. for 10mg tablets¹²⁶⁵ the indirect price constraint arising from the Drug Tariff mechanism whereby (lower) skinny label tablet prices progressively reduced the level of the Drug Tariff price.
- 4.134. As explained in section 3.E.I.b, the Drug Tariff price is calculated based on average selling prices, and suppliers then set their own selling prices taking account of the Drug Tariff price and the need for a discount to allow for wholesaler margins. This means that lower average selling prices will, by reducing the Drug Tariff price, indirectly constrain future selling prices. Such an indirect price constraint is directly attributable to the entry of skinny label tablet suppliers because the DHSC did not differentiate between full and skinny label tablets and therefore took into account both full and skinny label hydrocortisone tablet prices in setting the Drug Tariff price.

¹²⁶³ The absolute price decreases over the period for 10mg and 20mg tablets were £42.81 and £46.76, respectively.

¹²⁶⁴ The absolute price decreases over the period for 10mg and 20mg Drug Tariff prices were £46.63 and £14.58, for 10mg and 20mg tablets respectively (from March 2016 to December 2017).

¹²⁶⁵ As explained in section 3.E.I.b, since 20mg hydrocortisone tablets were in category A of the Drug Tariff, the Drug Tariff price was set based on list prices so the indirect constraint on 20mg prices did not arise. This is shown in figure 4.11 where 20mg Drug Tariff prices remained high and did not follow the downwards trajectory of 20mg average selling prices (until 20mg tablets moved to category M of the Drug Tariff in June 2019).

- 4.135. Figures 4.10 and 4.11 also show that following independent entry of hydrocortisone tablet suppliers, the segments for 10mg and 20mg strengths have evolved differently. In particular, there has been a quicker convergence in prices between Auden/Actavis and competing suppliers for 20mg tablets, whereas the convergence has been slower for 10mg tablets with a price differential between full and skinny label tablets persisting throughout the Infringements and beyond. This can be attributed to there being an alternative full label tablet supplier present for 20mg but not for 10mg tablets.
- 4.136. For 10mg hydrocortisone tablets independent entry first occurred in October 2015. Although Actavis lost around half of its volumes and reduced its price over time, that was in response to skinny label tablets only, given that no supplier has been able to obtain a full label MA (see section 3.D.III.c above).¹²⁶⁶ This meant there was no alternative supplier for those customers who had no choice but to purchase full label tablets. Since there was only one supplier of full label 10mg hydrocortisone tablets (Actavis), that supplier was therefore able to charge a premium over skinny label tablets. In fact, 10mg full and skinny label tablet prices [X], see section 3.E.V.b.iv above).¹²⁶⁷
- 4.137. For 20mg hydrocortisone tablets independent entry first occurred in July 2015, by Waymade. That entry meant that Actavis faced competition from another full label tablet supplier.¹²⁶⁸ During the period following independent entry, Actavis's price converged with the prices of other suppliers' 20mg hydrocortisone tablets, although that was not until early 2018, with Actavis maintaining a premium over its competitors' prices until at least the end of the 20mg Unfair Pricing Abuse. Where a second full label tablet supplier was present, it was able to act as a more effective competitive constraint on Actavis – customers who required full label 20mg hydrocortisone tablets faced a choice of suppliers and were able to switch their supply to Waymade or use the threat to switch as leverage to obtain lower supply prices from Actavis (see section 4.C.II.d.ii).
- 4.138. This comparison shows that, while it is clear that skinny label tablets were a constraint on full label tablets, that constraint was asymmetric with skinny label tablets imposing a weaker constraint than full label tablets as a result of the products being differentiated and pharmacies' dispensing decisions. That

¹²⁶⁶ That will remain the case until Plenadren's orphan designation status expires in November 2021.

¹²⁶⁷ The fact that Auden/Actavis's price for 10mg tablets remained significantly above those charged by skinny label tablet suppliers does not contradict the CMA's conclusion that both full and skinny label hydrocortisone tablets are part of the same relevant product market as these are differentiated products; see OFT403 Market definition, paragraph 3.5 and section 4.C.II for the CMA's assessment of dominance.

¹²⁶⁸ See section 4.C.II.c for the CMA's assessment of Actavis's dominance in the post-entry period in the 20mg tablets market.

asymmetric constraint is evident from the fact that there has been a faster convergence in full and skinny label tablet prices for 20mg tablets where there is a second full label tablet supplier for customers to choose from.

- 4.139. Overall, price trends support the evidence on substitution patterns (with 50% by volume switching to skinny label tablets) in showing that full and skinny label hydrocortisone tablets were sufficiently interchangeable to form part of the same relevant product market. Following independent entry by skinny label tablet suppliers (from October 2015 for 10mg tablets and from March 2016 for 20mg tablets), the prices of hydrocortisone tablets (including Auden/Actavis's prices) fell over time and full and skinny label tablets fell on a similar trajectory to one another (albeit with Auden/Actavis retaining a price premium above competitors'), showing that skinny label hydrocortisone tablets imposed a sufficient competitive constraint on full label hydrocortisone tablets, such that they should be included in the same relevant product market.

Representations on whether full and skinny label tablets form part of the relevant product market

'Full and skinny label tablets are not substitutes'

- 4.140. AMCo, Cinven and Waymade submitted that the orphan designation meant that, despite bioequivalence, full and skinny label hydrocortisone tablets were not substitutes from the demand-side perspective of pharmacies. The evidence relied on by the parties which they claimed supports this submission included:¹²⁶⁹
- a. Documents in which pharmacies selected which product to stock based on the indication;¹²⁷⁰
 - b. Evidence on the file showing pharmacists were aware of the differences between full and skinny label products and were not prepared to purchase skinny label product due to the associated compliance risks;¹²⁷¹

¹²⁶⁹ Document 204922, AMCo's RSSO, paragraphs 4.7.2, 4.41-4.49, Document 204967, Cinven's RSSO, paragraphs 5.23, 5.30-5.35, Document 204903, Waymade's RSSO, paragraphs 8.121-8.127. Waymade also submitted in this context that AAH and Alliance, major wholesale customers, would not substitute full for skinny label product (Document 204903, Waymade's RSSO, paragraph 8.126). However, as figure 4.9 shows, both AAH and Alliance did purchase skinny label tablets. Cinven further submitted that the fact of bioequivalence does not alter the unambiguous evidence that a full range of indications is considered essential to a large number of large pharmacies (Document 206665, Cinven's RLOF, paragraph 3.19).

¹²⁷⁰ Document 204903, Waymade's RSSO, paragraph 8.123.

¹²⁷¹ Document 204922, AMCo's RSSO, paragraph 4.44.

- c. Evidence on the file showing an absence of demand from major wholesalers and large pharmacies for skinny label tablets and that customers viewed full and skinny label differently, which informed their decisions over whether to stock and dispense skinny label tablets.¹²⁷²
 - d. Evidence that eight out of 10 large pharmacies purchase either no or only small quantities of skinny label tablets.¹²⁷³
 - e. Evidence that a '*significant proportion of the market*' purchase the full indication product is materially inconsistent with the assertion that a significant number of pharmacies substitute between full and skinny label product.¹²⁷⁴
- 4.141. AMCo, Cinven and Waymade further submitted that there was no possibility for supply-side substitution between full and skinny label products (despite full and skinny label tablets being bioequivalent) due to the orphan designation which created a barrier for skinny label suppliers to expand their sales, citing:¹²⁷⁵
- a. Evidence from suppliers of skinny label tablet suppliers:
 - i. that the orphan designation created a significant barrier to entry and that they are unable to supply mainline wholesalers and major pharmacy groups who are unwilling to stock skinny label products;¹²⁷⁶
 - ii. that '*manufacturers were concerned about the willingness of customers to stock reduced indication products*';¹²⁷⁷ and
 - iii. skinny label suppliers' experience of entering the market.¹²⁷⁸

¹²⁷² In this context Cinven submitted that It is not correct to say that pharmacies do not distinguish between full and skinny label tablets. Document 204967, Cinven's RSSO, paragraphs 5.23, 5.30-5.35. See also Document 206665, Cinven's RLOF, paragraph 3.17, in which Cinven submitted that the large part of the market remaining with full label product highlights '*the error in the CMA's theoretical assessment as to whether pharmacists could dispense a reduced indication product, as opposed to the practical reality of whether pharmacists would stock and dispense a reduced indication product.*'

¹²⁷³ Document 204967, Cinven's RSSO, paragraph 5.31, Document 204922, AMCo's RSSO, paragraph 4.44. Waymade submitted that five of the ten largest pharmacy chains purchased very low volumes of skinny label tablets or none at all. Document 204903, Waymade's RSSO, paragraph 8.124.

¹²⁷⁴ Document 204922, AMCo's RSSO, paragraphs 4.46. See also Document 206670, AMCo's RLOF, paragraph 4.11.

¹²⁷⁵ Document 204922, AMCo's RSSO, paragraphs 4.65-4.73, Document 204967, Cinven's RSSO, paragraphs 5.51-5.59.

¹²⁷⁶ Document 204922, AMCo's RSSO, paragraph 4.67. See also Document 206670, AMCo's RLOF, paragraphs 4.8-4.9.

¹²⁷⁷ Document 204967, Cinven's RSSO, paragraph 5.58.

¹²⁷⁸ Document 204903, Waymade's RSSO, paragraph 8.125.

- b. [AMCo Senior Employee 2]’s email to [Amdipharm Senior Employee] dated 2 January 2014¹²⁷⁹ identifying a low number of prescriptions identified as ‘*Adrenal insufficiency in adults*’ which AMCo claimed was reflective of an internal discussion concerning commercial negotiations between Auden and AMCo, and furthermore, the interpretation of that IMS dataset was later corrected.¹²⁸⁰
 - c. Project Guardian material which AMCo submitted shows ‘*Auden only feared a competitive constraint arising if pharmacies dispensed medical products “off-label” against regulatory guidance*’ and that Auden/Actavis successfully sought to emphasise the lack of substitutability between full and skinny label products.¹²⁸¹
- 4.142. The CMA rejects these submissions for the following reasons. First, the parties have focused only on demand from the largest pharmacies and wholesalers. This is a highly partial view of hydrocortisone tablet demand and ignores demand from other customers, particularly from independent pharmacies. It was also primarily this section of the market which switched to skinny label tablets and made up a significant proportion of the roughly 50% of the market that switched to skinny label tablets (as set out in figures 4.6 and 4.7 above).
- 4.143. Much of the analysis submitted by AMCo, Cinven and Waymade in support of their representations relied on responses from pharmacies seeking to explain full and skinny label hydrocortisone tablets purchasing behaviour. However, it is how full and skinny label tablets were substituted for one another in practice (ie what pharmacies and wholesalers actually did)¹²⁸² that demonstrates whether the degree of the constraint was sufficient for them to be placed in the same relevant product market.
- 4.144. Purchasing patterns when skinny label tablets entered the market demonstrate that around half of customers, by volume, switched their purchases from full to skinny label. Further, the introduction of skinny label tablets resulted in declines in the price of both full and skinny label tablets (reversing the trend of increases in hydrocortisone tablets that had prevailed in the seven years prior to skinny label tablet entry). As set out above, this evidence demonstrates that skinny label tablets exerted a sufficient

¹²⁷⁹ Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.

¹²⁸⁰ Document 204922, AMCo’s RSSO, paragraphs 4.70-71.

¹²⁸¹ Document 204922, AMCo’s RSSO, paragraph 4.72.

¹²⁸² As the CAT said in *Phenytoin*, ‘*What matters, for this competition analysis, is what pharmacists actually did*’, *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 132. See also paragraph 143.

constraint on full label tablets to be included in the same relevant product market.

- 4.145. Accordingly, the CMA does not accept that the sources of evidence relied upon by the parties demonstrate a lack of substitution between full and skinny label tablets overall, rather they demonstrate a lack of substitution between full and skinny label tablets by **some** customers. As set out at section 3.E.IV.c.i above, certain pharmacies had no choice but to purchase full label tablets (ie those supplied by Auden/Actavis).¹²⁸³ However, the presence of some customers that are unable to switch products does not necessarily imply separate markets for those products. Instead, it is the switching and price trends overall that are important in determining whether the level of competitive constraints are sufficient to place both products in the same market. In this case, evidence shows that around 50% of customers (by volume) switched to skinny label tablets, and it was the entry of skinny label tablet suppliers that resulted in falls in both full and skinny label tablet prices (whether through direct price competition or an indirect pricing constraint arising from the Drug Tariff mechanism), based on which the CMA has concluded that full and skinny label tablets are in the same relevant product market. See also section 3.E.IV.a above and Annex D for a detailed discussion of the demand for skinny label tablets.

'Market definition should be based on contemporaneous evidence'

- 4.146. AMCo, Auden/Actavis, Cinven and Waymade submitted that market definition should be based on views of how products were likely to interact at the time the parties entered into the relevant Agreements, and should not be made retrospectively by relying on later evidence to draw conclusions about the relevant period, particularly in the context that market definition can change over time.¹²⁸⁴
- 4.147. The implication of the parties' submissions is that the quantitative evidence presented above is not relevant to the question of market definition and should not be relied on. The CMA disagrees. It was not until entry occurred that the level of demand for skinny label tablets and the extent of competitive interaction between full and skinny label tablets could be observed. For this reason, data and evidence on how substitution occurred is highly relevant for market definition.¹²⁸⁵ In this case, the evidence demonstrates substantial

¹²⁸³ See section 4.C.II.c.iii for an analysis of how those customers formed an assured based which enabled Auden to charge a price premium.

¹²⁸⁴ Document 204922, AMCo's RSSO, paragraph 4.77, Document 205217, Auden/Accord's RSSO paragraph 3.19, Document 204967, Cinven's RSSO paragraphs 5.3, 5.23 and 5.33, Document 204903, Waymade's RSSO, paragraph 8.119 and 8.121. See also Document 206665, Cinven's RLOF, paragraph 3.2.

¹²⁸⁵ When available, actual examples of substitution between two products will normally be fundamental for market definition: see *Commission Notice on Market Definition*, paragraph 38.

switching to skinny label tablets (with approximately 50% by volume purchasing skinny label tablets).¹²⁸⁶

- 4.148. In any event, the CMA considers that evidence on how full and skinny label tablets were likely to interact prior to entry by skinny label tablets is consistent with the evidence on how the market subsequently evolved. As explained in section 3.E.IV.a above, the evidence prior to entry does not show an absence of demand (as the parties submitted), but instead reveals uncertainty over the **level** of expected demand. At the point at which skinny label tablet suppliers had not yet entered the market, the degree of substitutability between full and skinny label hydrocortisone tablets was untested, and there was uncertainty over the extent to which pharmacies would be willing to stock skinny label products.
- 4.149. As regards Cinven's submission that the relevant market changed over time, there is no evidence to suggest that the market changed in this case. The only change in '*market conditions*' was independent entry taking place, which could have taken place earlier absent the Agreements, and indeed market participants have confirmed they would have purchased skinny label tablets earlier had they been available (see Annex D.IV). There is no suggestion that had that entry taken place earlier, or by a different company, the same substitution would not have taken place (see market demand section).

'The price difference between full and skinny label tablets is larger than a SSNIP'

- 4.150. Cinven and Waymade submitted that the price differential between full and skinny label tablets is larger than a SSNIP in the price of full label hydrocortisone tablets which implies that full and skinny label tablets are in separate markets.¹²⁸⁷ AMCo made the related submission that full label tablets traded at a significant premium with an ongoing price differential, which suggests Auden's pricing was not constrained by the availability of the cheaper skinny label tablets.¹²⁸⁸ In support of its position, Cinven made the following submissions:

¹²⁸⁶ In any event, it is well-established that evidence outside the period in which impugned conduct occurred may be used to inform the assessment of whether an infringement occurred during that period. For example, see (by analogy) *Streetmap v Google* [2016] EWHC 253 (Ch), paragraph 90: '*it is for [a claimant or, here, the competition authority] to establish that the conduct was reasonably likely to harm competition. In determining that question, the court will take into account, as a very relevant consideration, evidence as to what the actual effect of the conduct has been.*'

¹²⁸⁷ Document 204903, Waymade's RSSO, paragraph 8.129, Document 204967, Cinven's RSSO, paragraphs 5.3, 5.17, and 5.41-5.45. See also Document 206665, Cinven's RLOF, paragraph 3.32.

¹²⁸⁸ Document 204922, AMCo's RSSO, paragraphs 4.83-4.85.

- a. The continued difference in prices between full and reduced indication products is a significant factor pointing to the existence of a separate market for full indication product.¹²⁸⁹
- b. [X] *‘even though reduced indication products had taken some volumes from full indication products, the fact that Auden Mckenzie’s prices following entry had not fallen below pre-entry levels indicated that sales of reduced indication products would not be able to constrain a SSNIP on full indication products, i.e. that even after market entry, demand substitutability remained limited’*
- c. Auden’s current prices for 10mg tablets [X] are more than a 10% SSNIP above two proxies for the competitive price level: prevailing 20mg full label prices [X] and the CMA’s cost-plus estimate for 10mg full label hydrocortisone tablets (of £4.20 per pack).¹²⁹⁰
- d. Further, Cinven submitted a critical loss analysis, which sought to demonstrate that the relevant market is no wider than 10mg full label tablets. Cinven submitted that its *‘analysis shows that the volumes which would need to switch to reduced indication products in response to a 5-10% price differential in order to make a SSNIP on the full indication product unprofitable (i.e. the critical loss) is greater than the actual losses that would be expected to occur’*.¹²⁹¹

4.151. The purpose of market definition is to understand competitive constraints acting on full label tablets, and in turn to assess dominance of the supplier of those tablets, Auden/Actavis. In this case, it is clear that a competitive relationship between full and skinny label tablets exists: skinny label tablet entry led to substantial switching from full to skinny label tablets (of around 50% by volume), and substantial price falls (reversing the previous seven years of unchecked price rises for full label tablets). Being able to clearly observe the impact of entry taking place, with direct evidence of the changes this brought about and knowing that there are no other changes in the meantime to explain those trends (nor competitive constraints from other medicines given that the CMA has concluded that the market was no wider

¹²⁸⁹ Cinven submitted that pharmacies considered skinny label hydrocortisone tablets to be differentiated from full label tablets and that a large portion of customers do not purchase skinny label tablets despite the significant price difference. (Document 206665, Cinven’s RLOF, paragraphs 3.24-3.32). However, the CMA disagrees that these facts points to separate markets for full and skinny label tablets, as Cinven suggested, and instead considers that these facts, together with the trends in prices and volumes following skinny label entry, support the CMA’s findings that full and skinny label tablets formed part of the same relevant product market, and that Auden/Actavis was dominant in that market in the post-entry period with full label customers providing an assured base (see section 4.C.II.c below).

¹²⁹⁰ Document 204969, Cinven’s CRA analysis, paragraphs 4, 12 and 46-53.

¹²⁹¹ Document 204967, Cinven RSSO, paragraphs 5.49-5.50, Document 204969, Cinven’s CRA analysis, paragraphs 4 and 19-45.

than hydrocortisone tablets), provides strong evidence of full and skinny label tablets being in the same relevant product market. In the face of such clear evidence that skinny label tablets imposed a competitive constraint on full label tablets, exercises such as a SSNIP test or critical loss analysis, both hypothetical exercises reliant on the data and assumptions being used, are unnecessary.

- 4.152. Further, the existence of an ongoing price differential between full and skinny label tablet prices is not inconsistent with this market definition finding. As set out above, full label tablet prices were clearly constrained (whether directly or indirectly through the Drug Tariff mechanism) by skinny label tablets following their entry by virtue of the obvious and observable fact that it was skinny label tablet entry that led to full label tablets losing sales (to skinny label tablets) and the beginning of a series of price falls (in total contrast to the price trend prior to skinny label tablet entry). Rather than implying a lack of competitive constraint, the ongoing price differential arises due to the degree of the constraint given that full and skinny label tablets are differentiated products. The degree of the competitive constraint is assessed in section 4.C.II.c.
- 4.153. In any event, the critical loss analysis provided by Cinven (which it said was based on conservative assumptions biased towards finding a wider product market) is not informative for market definition due to the way it has been carried out. Cinven's analysis focuses on observations when the ratio of full to skinny prices was close to 1.¹²⁹² The period in which that price ratio occurred was immediately following entry, a time of transition when skinny label tablet prices were close to full label tablet prices and uptake of skinny label tablets was only just commencing. In other words, rather than seeking to assess substitutability during a competitive period, the analysis focusses on a period when competition was only just becoming established. Moreover, there are very few data points to show the impact when prices were around that level (since prices of full and skinny label tablets were not close to each other for more than a matter of months). In addition to being unnecessary, Cinven's critical loss analysis is therefore also uninformative as it is conducted with limited data for a period that is not representative of competition between full and skinny label tablets.

¹²⁹² Cinven's analysis focussed on the time when relative prices of full and skinny label tablets were similar in order to be able to estimate the volume impact on a 5% increase in full label tablet prices, based on the trendline between prices and volumes which it had calculated. Document 204969, Cinven's CRA analysis, paragraph 35 and Figure 3.

'The CMA's quantitative analysis does not demonstrate a competitive relationship between full and skinny label tablets'

- 4.154. Cinven submitted that it was entirely unclear *'why the CMA considers the proportion of customers that switched to be significant enough to define a single market or what it assess to be the relevant threshold for substitution to be significant enough'*.¹²⁹³ Cinven submitted that the CMA had not undertaken any quantitative analysis of the hypothetical monopolist test, and had not taken into account the cellophane fallacy, which was, it stated, contrary to the approach in *Phenytoin*.¹²⁹⁴
- 4.155. Although the substitution to skinny label tablets has formed an important part of the market definition assessment, it has not been this assessment in isolation or based on any specific threshold that has been determinative for the market definition reached. It is also not necessary for the CMA to determine and apply a *'threshold'* for whether substitution is *'significant enough'*. Taking such an approach (which is not required in law) would reduce the determination of the relevant market to the application of a mathematical calculation, which would ignore the relevant context, including the qualitative evidence relating to substitution and interchangeability. Instead, the CMA has considered both qualitative and quantitative evidence in context and in the round, bearing in mind also that market definition is a step in the process of determining whether an undertaking is dominant, not an end in itself. In particular, the CMA has considered the impact of skinny label tablet entry through both price and volume trends, and has concluded that those impacts of falling prices and switching volumes can only have come about because of the competitive constraint from skinny label tablets. With this evidence being available and being able to observe the impacts of entry directly, it has not been necessary to conduct a hypothetical monopolist test. However, in conducting this analysis, the CMA has been mindful of the cellophane fallacy, as explained at footnote 1242 above.
- 4.156. AMCo submitted that the CMA's quantitative analysis of prices and volumes did not demonstrate a competitive relationship between full and skinny label suppliers, in particular, stating that:¹²⁹⁵
- a. The erosion of Auden's volumes by April 2017 does not constitute evidence of a competitive relationship between full and skinny label

¹²⁹³ Document 204967, Cinven's RSSO, paragraph 5.13.

¹²⁹⁴ Document 204967, Cinven's RSSO, paragraph 5.13 and 5.36-5.40.

¹²⁹⁵ Document 204922, AMCo's RSSO, paragraphs 4.76-4.92. *'Contrary to the CMA's claims, an analysis of the interaction between full and reduced indication product in terms of volumes and prices shows that reduced indication product did not exercise a sufficient competitive constraint on the full indication product to be included in the same market as it.'* Document 204922, AMCo's RSSO, paragraph 4.7.3

tablets during the relevant period, and some volume interaction between two products is not conclusive evidence of there being a single product market encompassing those two products.

- b. The CMA has not shown there is any price/volume interaction in respect of the supply of product to different sets of customers, and the dominance analysis was clear in saying full label product was the only option for many customers (citing evidence that Alliance and Sigma were unsuccessful in price negotiations with Auden), suggesting a complete lack of interchangeability between full and skinny product from a demand perspective.¹²⁹⁶

4.157. The CMA rejects AMCo's submission. First, AMCo's characterisation of there being '*some*' volume interaction considerably understates the position where around 50% of volumes were switched to skinny label tablets. Secondly, the CMA's analysis is not premised solely on the volume impact, but has considered both the price and volume trends following entry by skinny label tablet suppliers, and concluded that these trends demonstrate that skinny label tablets imposed a sufficient constraint on full label tablets to warrant inclusion in the same product market. Third, the CMA recognises that certain customers had no choice but to purchase full label tablets (which is assessed in section 4.C.II.c.iii), but the presence of some customers purchasing only full label tablets does not, as AMCo suggests, amount to a '*complete lack of interchangeability*'. Across all customers, there were a substantial portion of customers that switched to skinny label tablets, including some customers, such as AAH and Alliance, that purchased both full and skinny label tablets.

iii. Different tablet strengths

4.158. In determining the relevant market for the purposes of this Decision, the CMA has also considered whether 10mg and 20mg hydrocortisone tablets are differentiated products within the same product market or whether they are in different product markets.

4.159. The evidence shows there was a lack of interchangeability between 10mg and 20mg strengths on the demand side:

- a. First, both 10mg and 20mg hydrocortisone tablets contain the same active ingredient (albeit in different quantities) and are used to treat the same conditions. However, 10mg hydrocortisone tablets are used

¹²⁹⁶ See also Document 206670, AMCO's RLOF, paragraph 4.12 and Document 206694, AMCo's letter to the CMA dated 15 June 2021.

considerably more frequently (accounting for 96% of sales by volume)¹²⁹⁷ because 20mg hydrocortisone tablets are used normally only on a short-term basis for patients who temporarily need higher doses,¹²⁹⁸ accounting for around 4% of all hydrocortisone tablets dispensed (see paragraph 3.125).

- b. Secondly, the evidence shows that while both tablet strengths can be used to treat the same conditions, substitution on the demand side between 10mg and 20mg tablets is likely to be limited. Patients often need to spread doses of hydrocortisone tablets throughout the day in 10mg or 5mg doses (see paragraph 3.124 above). Although a 10mg tablet can be replaced with (half) a 20mg tablet, 10mg tablets are often further subdivided by being split into two or even four to make 5mg or 2.5mg doses. However, it is difficult to divide a 20mg hydrocortisone tablet into 5mg or 2.5mg.¹²⁹⁹
- c. The lower demand and reduced substitutability on the demand side for 20mg tablets might be a factor that is reflected in their prices, which, per pack of 30 tablets, were not significantly above those of 10mg tablets throughout the majority of the Infringements, despite containing twice as much of the active ingredient. Alternatively, this may simply reflect that on the supply side all other costs associated with making and selling the tablets are similar for both 10mg and 20mg tablets.¹³⁰⁰
- d. Prescriptions tend to specify the tablet strength,¹³⁰¹ so pharmacies are not able to make switching decisions between the different strengths. Pharmacies are reimbursed at a different price depending on which tablet strength they dispense, because there are separate reimbursement prices for each tablet strength, and the different strengths have moved to different categories of the Drug Tariff at different times.¹³⁰²

¹²⁹⁷ See section 3.C.II above.

¹²⁹⁸ Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, page 2.

¹²⁹⁹ Although breaking a 20mg tablet into two 10mg doses is also a possibility (see Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to questions 1 and 2, page 2).

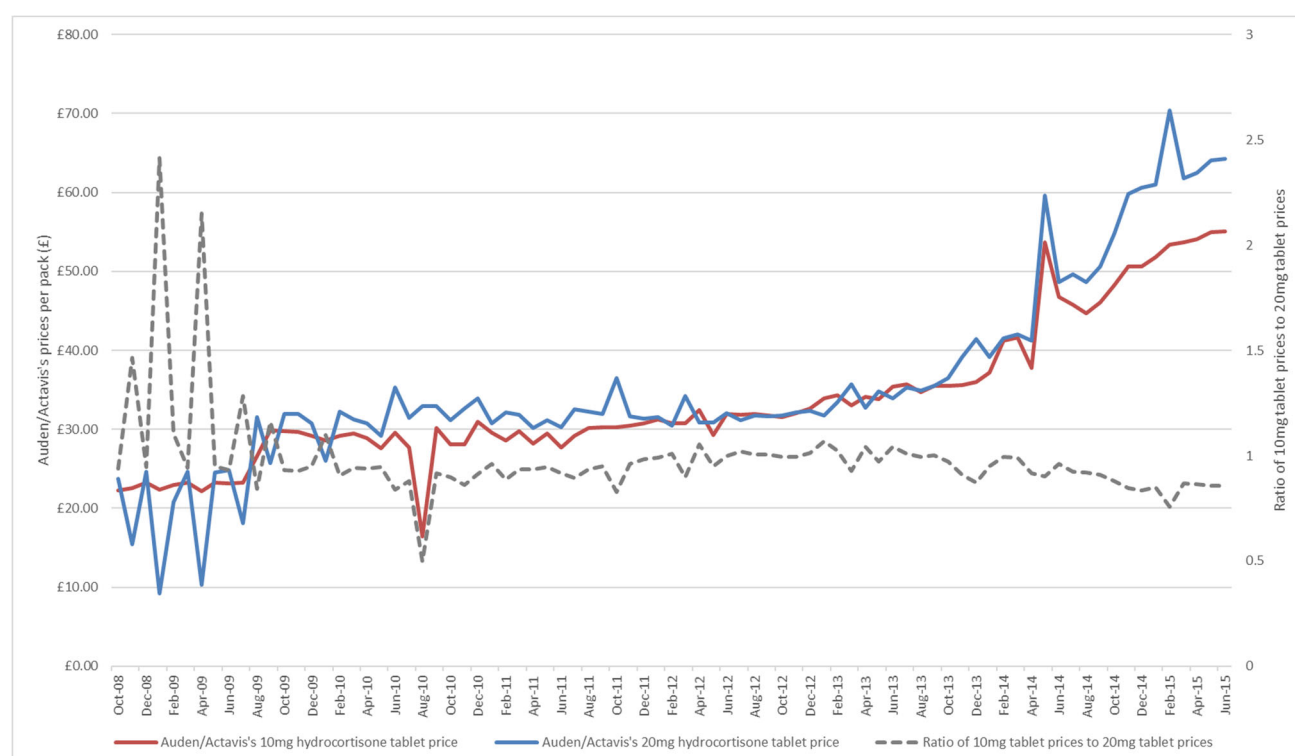
¹³⁰⁰ This similarity in costs means that, while in principle one 20mg tablet could be substituted by two 10mg tablets, this is likely to be uneconomic in practice given the additional costs of manufacturing and distributing two tablets instead of one.

¹³⁰¹ Document 00603, response to question 10, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹³⁰² 10mg tablets moved from Category A to Category M in June 2014. 20mg tablets moved from Category A to Category M in June 2019. See section 3.E.I.b above.

- 4.160. The evidence on competitive conditions on the supply-side changed during the Infringements, following the entry of independent competing suppliers of 10mg and 20mg hydrocortisone tablets.
- 4.161. Prior to entry by competing suppliers of hydrocortisone tablets, Auden/Actavis adopted similar prices per pack for both 10mg and 20mg tablets. This is shown in figure 4.12 below, which illustrates that, aside from some fluctuations in Auden/Actavis's 20mg hydrocortisone tablet prices during 2008 and early 2009, the price ratio of 10mg and 20mg tablets was reasonably constant, at just under 1, throughout the period prior to the entry of competing suppliers.

Figure 4.12: Auden/Actavis's 10mg and 20mg hydrocortisone tablet prices, and ratio of those prices



Source: CMA analysis of data submitted by Auden/Actavis

- 4.162. The broadly consistent ratio of 10mg to 20mg prices means that 20mg tablets were relatively cheaper for a given dose. Despite this, their usage remained around only 4% of total hydrocortisone tablet volumes. These price and volume trends therefore do not suggest that there were different competitive constraints as between 10mg and 20mg tablets during that time. This is to be expected given the lack of competitive constraints Auden/Actavis was facing and is consistent with a monopolist supplier

setting optimal prices based on market conditions for each tablet strength.¹³⁰³

- 4.163. However, given during that period there were no other suppliers of either strength of hydrocortisone tablets, it makes no difference whether 10mg and 20mg hydrocortisone tablets are considered separately or as a combined product market for the dominance assessment.¹³⁰⁴ This is because Auden/Actavis's market share was 100% even when the market is given its widest possible definition.
- 4.164. Therefore, the CMA has adopted the widest possible market definition prior to independent entry and treated 10mg and 20mg hydrocortisone tablets as being part of the same relevant product market. This is despite some of the evidence (particularly from the demand side) suggesting that there may have always been separate markets for 10mg and 20mg tablets. However, that distinction was only properly observable as a result of independent entry, following which it has been possible to see that 10mg and 20mg tablet prices have evolved differently in response to the introduction of competition. Given that the primary role of market definition in this case is to determine whether Auden/Actavis held a dominant position, adopting the widest possible market definition errs in Auden/Actavis's favour – if it was dominant in a wider market then it will also have been dominant if the market is defined more narrowly.
- 4.165. Following independent entry by competing hydrocortisone tablet suppliers (from July 2015), the 10mg and 20mg market segments evolved differently (as set out at paragraphs 4.135 to 4.137 above):
- a. The degree of competition in those segments differed primarily due to the granting of the orphan designation status to Plenadren, because Auden/Actavis's 10mg and 20mg hydrocortisone tablets along with Waymade's 20mg hydrocortisone tablets benefitted from the orphan designation. As explained in section 3.D.III.C above, the orphan designation prevented any other supplier from being able to obtain a full label MA and resulted in there being an alternative full label supplier

¹³⁰³ During the period prior to independent entry Auden/Actavis did face a competitive constraint in the form of potential entry from full and skinny label tablet suppliers, but this potential entry did not constrain its behaviour to an appreciable extent in the market at that time, not least because Auden/Actavis's response to the threat of competitive entry (from Waymade and AMCo) was to buy that threat off, see section 6.D.II below.

¹³⁰⁴ The CMA also notes that, contrary to Cinven's suggestions (Document 204967, Cinven's RSSO, paragraph 5.19) it makes no difference for the agreements assessment whether 10mg and 20mg strengths are considered separately or as a combined product market because AMCo, as a potential supplier of 10mg hydrocortisone tablets, would be competing in the same market as Auden/Actavis under either scenario (see section 6.C.II.b.iv).

for 20mg tablets whereas Auden/Actavis was the only full label supplier for 10mg tablets.

- b. These differences show that 10mg and 20mg hydrocortisone tablets were in separate product markets following independent entry because Actavis faced different competitive constraints as between 10mg and 20mg hydrocortisone tablets in the period following independent entry.

4.166. The CMA has therefore concluded, based on a lack of demand-side substitutability and different competitive conditions between 10mg and 20mg tablets, that 10mg and 20mg hydrocortisone tablets were in separate relevant markets following independent entry. While 10mg and 20mg tablets may have been in separate markets prior to independent entry as well, the CMA has erred in Auden/Actavis's favour and given the relevant market its widest possible definition, concluding that 10mg and 20mg hydrocortisone tablets were part of the same relevant market prior to independent entry.¹³⁰⁵

Representations on the CMA's assessment of different tablet strengths

4.167. AMCo and Cinven submitted that there is an inconsistency or internal incoherence in finding that the orphan designation led the market to segment into separate markets for 10mg and 20mg tablet strengths, but the orphan designation did not have a sufficient impact on interchangeability between full and skinny label tablets to define separate full and skinny label markets.¹³⁰⁶ Cinven further submitted that skinny label tablets pose a weaker constraint than full label tablets and this had led to different price trends and competitive dynamics in the 10mg and 20mg markets due to the presence of a second full label supplier in 20mg market: this same reasoning means full and skinny label 10mg tablets are not part of same relevant market.¹³⁰⁷

4.168. The CMA does not consider that its analysis is inconsistent. To the contrary, it is consistent that where a market contains two differentiated products, with asymmetric constraints where one is a stronger constraint on the other than vice versa (as with full and skinny label tablets), that competition will be more intense and prices will erode faster when there are a greater number of competitors supplying the full label product. That does not, however, mean that the two differentiated products are not in the same market.

¹³⁰⁵ As set out at paragraph 4.5 above, whether 10mg and 20mg hydrocortisone tablets were in separate markets, or the point at which they became separate, does not affect the outcome of the CMA's dominance analysis.

¹³⁰⁶ Document 204922, AMCo's RSSO, paragraphs 4.56-4.60, Document 204967, Cinven's RSSO paragraphs 5.4 and 5.7-5.13.

¹³⁰⁷ Document 204969, Cinven's CRA analysis, paragraphs 4 and 13-18.

4.169. The expectation in theory is borne out by the facts in this case. The 10mg and 20mg markets evolved differently following entry (because the presence of a second full label supplier in the 20mg market increased the constraint on Auden/Actavis when compared to 10mg market where all entrants were skinny label suppliers). This led to different competitive dynamics for each of the tablet strengths and the divergence of 10mg and 20mg prices, highlighting that 10mg and 20mg tablet strengths were in separate markets. This reflects the asymmetric constraint between full and skinny label tablets (ie that a full label competitor imposed a greater constraint than facing only skinny label competitors) rather than the absence of constraint from skinny label tablets as the parties suggested. The orphan designation conferred market power to Auden/Actavis as supplier of full label tablets (see section 4.C.II.c.iii below), which is not inconsistent with the constraint from skinny label tablets being sufficient to place them in the same market (see paragraphs 4.13 to 4.17 above).

d. The relevant geographic market

4.170. Consistently with previous cases in the pharmaceutical sector,¹³⁰⁸ the CMA has concluded that the relevant geographic market is national in scope.¹³⁰⁹ In previous cases, differences were noted in the regulatory schemes for authorising and reimbursing medicines across countries, marketing strategies used by pharmaceutical companies, doctors' prescribing practices and prices.

4.171. The CMA considers that it is appropriate to define the relevant geographic market in this case as UK-wide, in particular because:

- a. In order for suppliers to sell hydrocortisone tablets in the UK, it is necessary to obtain a MA from the MHRA, where the MA covers the whole of the UK.¹³¹⁰
- b. The pricing framework which determines how pharmacies are reimbursed for the dispensing of hydrocortisone tablets (see section 3.C.V above) is specific to the UK, and not shared by other countries.

¹³⁰⁸ See, for example, Case 37507 *AstraZeneca*, Commission decision of 15 June 2005, paragraph 503 and Case CA98/02/2011 *Reckitt Benckiser*, OFT decision of 12 April 2011, paragraphs 4.170 to 4.171.

¹³⁰⁹ The CMA notes that none of the parties have submitted that the CMA was wrong to conclude that the relevant geographic market was UK-wide and that Cinven supported the CMA's geographic market definition (see Document 204967, Cinven's RSSO, footnote 434).

¹³¹⁰ The existence of Parallel Imports is not inconsistent with the market being national in scope since parallel importers need to obtain a parallel import product licence from the MHRA to sell in the UK.

C. Dominance

I. Legal framework for dominance

4.172. The Chapter II prohibition requires that an undertaking holds a dominant position within the United Kingdom.

4.173. Dominance is ‘*a position of economic strength enjoyed by an undertaking, which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers*’.¹³¹¹ While a dominant position is characterised as the ability to act independently, the existence of some degree of competition does not preclude a finding that an undertaking holds a dominant position.¹³¹²

4.174. The existence of a dominant position derives from a combination of several factors. Taken separately, these may not necessarily be determinative.¹³¹³

a. Market shares

4.175. Market shares are a ‘*highly important*’ factor.¹³¹⁴ Market shares are to be interpreted in the light of the relevant market conditions, and in particular of the dynamics of the market and of the extent to which products are differentiated.¹³¹⁵

i. The undertaking's market share

4.176. Save in exceptional circumstances, the retention of very large market shares over a long period proves dominance. The importance of a ‘*generally very large market share*’ held throughout the entire relevant period cannot be disregarded.¹³¹⁶ For these purposes, ‘*very large*’ means 50% or above:

*‘the possession, over a long period, of a very large market share constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position [...] market shares of more than 50% constitute very large market shares’.*¹³¹⁷

¹³¹¹ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 65.

¹³¹² C-85/76 *Hoffman-La Roche v Commission*, EU:C:1979:36, paragraph 39.

¹³¹³ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 66; Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 39.

¹³¹⁴ Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 39.

¹³¹⁵ Commission *Guidelines on its enforcement priorities in applying Article 102 to abusive exclusionary conduct*, paragraph 13.

¹³¹⁶ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 245.

¹³¹⁷ C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 176. Compare T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraph 103: ‘*During the period at issue, WIN ... had a very high*

4.177. The European Courts have explained:

*‘An undertaking which has a very large market share and holds it for some time, by means of the volume of production and the scale of the supply which it stands for – without holders of much smaller market shares being able to meet rapidly the demand from those who would like to break away from the undertaking which has the largest market share – is by virtue of that share in a position of strength which makes it an unavoidable trading partner and which, because of this alone, secures for it, at the very least during relatively long periods, that freedom of action which is the special feature of a dominant position’.*¹³¹⁸

4.178. This means that *‘A dominant position may be [rebuttably] presumed from market shares above 50%’.*¹³¹⁹

4.179. The higher the market share, the stronger the presumption: a market share of 70-80% or above by value or volume is, absent exceptional circumstances, *‘in itself, a clear indication of the existence of a dominant position’.*¹³²⁰ For example:

- a. In *Aberdeen Journals*, the CAT found that Aberdeen Journals had a market share of 78% by value and 67% by volume from January to March 2000 (or 73% by value and 63% by volume excluding a title partially distributed outside the geographic market). The CAT held that

market share [between 50% and 72%] which, save in exceptional circumstances, proves that it had a dominant position’ (emphasis added). Compare the Commission’s decision in COMP/38.233 *Wanadoo Interactive*, paragraph 212 (upheld in T-340/03): ‘Very large market shares, in excess of 50%, must be regarded as serious, and indeed sufficient, evidence of the existence of a dominant position, save in exceptional circumstances’ (emphasis added). See also C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60; *Aberdeen Journals v OFT* [2003] CAT 11: ‘market shares of this order [78% by value / 67% by volume; or 73% by value / 63% by volume] suffice to establish that Aberdeen Journals was dominant unless exceptional circumstances are shown’ (paragraph 310); and T-66/01 *Imperial Chemical Industries v Commission*, EU:T:2010:255, paragraph 256. Compare also Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 41: very large market shares are in themselves evidence of the existence of a dominant position; and C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60: ‘With regard to market shares the Court has held that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position ... That is the situation where there is a market share of 50%’.

¹³¹⁸ T-65/98 *Van den Bergh Foods v Commission*, EU:T:2003:281, paragraph 154; C-395/96 P and C-396/96 P *Compagnie Maritime Belge Transports v Commission*, EU:C:2000:132, paragraph 132 (‘an undertaking which has a very large market share and has held it for some time is in a position of strength which makes it an unavoidable trading partner’); C-23/14 *Post Danmark A/S v Konkurrenceradet*, EU:C:2015:651, paragraph 40. See also Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 41.

¹³¹⁹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 288; C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60. The European Courts have frequently affirmed the use of this presumption. See eg T-30/89 *Hilti v Commission* [1991] ECR II-1439, paragraph 92; T-340/03 *France Télécom v Commission* [2007] ECR II-107, paragraphs 99–101; T-57/01 *Solvay v Commission* [2009] ECR II-4621, paragraphs 275–305.

¹³²⁰ T-30/89 *Hilti v Commission*, EU:T:1991:70, paragraph 92; T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraph 103; *Aberdeen Journals v OFT* [2003] CAT 11, paragraph 310. See also T-191/98 *Atlantic Container Line v Commission*, EU:T:2003:245, paragraphs 906-907.

'market shares of this order suffice to establish that Aberdeen Journals was dominant unless exceptional circumstances are shown'.¹³²¹

- b. In *Albion Water Limited v Ofwat*, the CAT – noting that *'market share is, generally speaking, an important indicator of market power'* and *'plays a central role in the assessment of dominance'* – found that Dŵr Cymru's possession of a market share of 100% over many years gave rise to *'a very strong presumption that Dŵr Cymru is in a dominant position'*.¹³²²

Competition and declining markets

- 4.180. The concept of dominance does not equate to that of monopoly or of an *'unassailable position'*.¹³²³ the test assumes the existence of some competition, and even allows for periods of *'very lively competition'*.¹³²⁴ Thus, *'price reductions and the loss of a certain amount of market share'* do not in themselves indicate the absence of dominance.¹³²⁵ A dominant undertaking is able to act to an **appreciable** extent – not necessarily absolutely – independently of such competition.¹³²⁶ it is able *'if not to determine, at least to have an appreciable influence on the conditions under which that competition will develop, and in any case to act largely in disregard of it so long as such conduct does not operate to its detriment'*.¹³²⁷
- 4.181. Where market shares change over time, this should be taken into account. However, a decline in market shares which are still very large (ie over 50% by value or volume) cannot in itself constitute proof of the absence of a dominant position.¹³²⁸ As explained above, the importance of a *'generally very large market share'* held throughout the entire relevant period cannot be disregarded.¹³²⁹
- 4.182. A declining trend in market shares has been considered in a number of cases and Commission decisions. The focus of these cases has been on the

¹³²¹ *Aberdeen Journals v OFT* [2003] CAT 11, paragraphs 309-310.

¹³²² *Albion Water Limited v Ofwat* [2006] CAT 36, paragraphs 118 to 123.

¹³²³ T-24/94 *Compagnie Maritime Belge Transports v Commission*, paragraph 72. The phrase was the Commission's but was consistent with the General Court's judgment.

¹³²⁴ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 113 to 121 and 196.

¹³²⁵ T-24/94 *Compagnie Maritime Belge Transports v Commission*, paragraph 72 – as above, the phrase was the Commission's but was supported in the General Court's judgment. Compare the OFT's decision in Case CE/5281/04 *Cardiff Bus*: *'It is not necessary for a finding of dominance that an undertaking has eliminated all opportunity for competition in the market'* (paragraph 5.7).

¹³²⁶ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 108 to 129; Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraphs 39 and 70 to 71.

¹³²⁷ Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 39.

¹³²⁸ T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraphs 103 and 104. See also T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 223 to 224; T-24/93 *Compagnie Maritime Belge Transports v Commission*, paragraph 77.

¹³²⁹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 245.

size of the retained market share and the speed of the decline, rather than the scale of loss:

- a. In *Compagnie Maritime Belge*, the Commission found that Cewal was (collectively) dominant during 1988-1989, with a market share of over 90% by volume.¹³³⁰ According to Cewal, its market share had declined substantially in the subsequent years: to 64% in 1992.¹³³¹ The General Court nonetheless found that Cewal remained dominant, since its *'market shares remained high, despite their steady erosion ... whilst retention of market share may show that a dominant position has been retained, a decline in market shares which are still very large cannot in itself constitute proof of the absence of a dominant position'*.¹³³²
- b. In *AstraZeneca*, AstraZeneca's market share by value declined to varying degrees in all the relevant markets.¹³³³ Despite the decline in AstraZeneca's value market shares, the General Court upheld the Commission's finding that AstraZeneca was dominant in each of these markets throughout the relevant periods.¹³³⁴ Though AstraZeneca's sales volumes had declined during the relevant periods, the Court noted that *'the fact that AZ was able to maintain a much higher market share than those of its competitors while charging prices higher than those charged for other PPIs is a relevant factor showing that AZ's behaviour was not, to an appreciable extent, subject to competitive constraints'*; *'the ability of AZ to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it was able to exercise market power in respect of price'*.¹³³⁵ In Germany, where AstraZeneca's competitive position was comparatively weakest, the Court observed that although the data showed *'an uninterrupted downward trend in AZ's market share, it was still very significant in 1997 (53.99%)*. *A dominant position may be presumed from market shares above 50%*. Therefore, in circumstances where market shares remain above 50%, the presumption of dominance continues to apply in spite of a downward trend affecting the undertaking's market share. The Court emphasised that only in 1999 – *'two years after the last year selected for the purpose of assessing the dominant position'* – did AstraZeneca's market share in Germany fall below 50%, and in light of

¹³³⁰ The Commission used market shares by tonnage transported: Commission Decision IV/32.448 *Cewal*, paragraph 57.

¹³³¹ Cewal's market share after 1989 was relevant, because the Commission found ongoing dominance and imposed directions to bring the abusive conduct to an end. See recitals 61 and 97, and Article 3, of the decision.

¹³³² T-24/93 *Compagnie Maritime Belge Transports v Commission*, paragraph 77.

¹³³³ COMP/A.37.507/F3 *AstraZeneca*, Annex, tables 24 to 30; T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 246-252.

¹³³⁴ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 294.

¹³³⁵ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 261 and 266.

this fact upheld the Commission's finding of dominance until the end of 1997.¹³³⁶

- c. In *British Airways*, British Airways' market share by volume declined from 46.2% in 1992 to 39.7% in 1998.¹³³⁷ The Court nonetheless found that British Airways remained dominant, since it maintained its 'very largely preponderant' position on the market.¹³³⁸ Where market shares have declined to a level below the threshold at which the presumption of dominance applies, therefore, dominance can still be established based on market share and additional relevant factors. For example, the Court took into account British Airways' '*particularly powerful position in relation to its nearest rivals and the largest travel agents*', its hub network and its range of transport services.¹³³⁹ The Court also rejected BA's argument that the increase in its competitors' market shares demonstrated that its conduct could not have been abusive, finding that '*the growth in the market shares of some of BA's airline competitors, which was modest in absolute value having regard to the small size of their original market shares, does not mean that BA's practices had no effect*'.¹³⁴⁰

ii. Relative market shares

- 4.183. In addition to the market share of the putative dominant undertaking, the relationship between its share and those of its competitors (especially the next largest) is also an important factor.¹³⁴¹
- 4.184. An undertaking's possession of '*a particularly high market share and, in any event, a share which [is] much higher than those of its competitors*' is '*an entirely relevant indicator of its market power*', which may be '*out of all comparison to those of other market players*'.¹³⁴² The existence of '*a substantial gap*' between the undertaking's market share on the one hand, and the share of its closest rival and/or cumulative shares of its main competitors on the other, is evidence of dominance.¹³⁴³

¹³³⁶ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 288.

¹³³⁷ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraph 211. The Court used the number of tickets capable of being sold through travel agents in the UK as '*the appropriate criterion for measuring the economic strength which BA is capable of exercising in relation to those agents and the other companies which purchase the distribution services in question*' (paragraph 192).

¹³³⁸ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 223 to 224.

¹³³⁹ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 212 and 217.

¹³⁴⁰ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraph 298.

¹³⁴¹ Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 48; T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraph 210.

¹³⁴² T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 253.

¹³⁴³ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 224-225.

iii. The appropriate metric

4.185. Market shares may be measured by volume and/or by value. The European Commission states that *'both volume sales and value sales provide useful information. In cases of differentiated products, sales in value and their associated market share will usually be considered to better reflect the relative position and strength of each supplier'*.¹³⁴⁴

4.186. The meaning of *'differentiated'* products in pharmaceutical markets has been considered by the Commission in *AstraZeneca*:

'When products such as pharmaceutical products can be broadly used for the same purpose, but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated'.¹³⁴⁵

4.187. The Commission went on to state:

'AZ asserts that volume (in particular measured in terms of the number of prescriptions) is a better reflection of competition in the pharmaceutical market than sales measured by value. AZ's contention cannot be accepted. The products at stake in this case are differentiated in nature (eg in terms of dosage forms, pack sizes and strength). For such products sales in value and their associated market share will – according to the Notice on market definition – usually better reflect the relative position and strength of each supplier. This guidance is also relevant to the pharmaceutical sector'.¹³⁴⁶

4.188. The General Court and Court of Justice used the market share figures determined by the Commission in their judgments.

4.189. This approach has been followed in both antitrust and merger cases. For example:

- a. In *Warner-Lambert/Gillette* (a decision finding infringements of Articles 101(1) and 102), the Commission noted that *'The market shares based on value are a more reliable indicator of the strength of the various suppliers on this market in view of the heterogeneous nature of the product and the range of product prices'*.¹³⁴⁷

¹³⁴⁴ European Commission *Notice on market definition*, paragraph 55.

¹³⁴⁵ Commission decision COMP/A.37.507/F3 *AstraZeneca*, recital 370.

¹³⁴⁶ Commission decision COMP/A.37.507/F3 *AstraZeneca*, recital 394. Compare OFT decision in Case CE/8931/08 *Reckitt Benckiser*, paragraph 5.8.

¹³⁴⁷ Commission Decision IV/33.440 *Warner-Lambert / Gillette*, paragraph 22.

- b. In *IBM/Telelogic*, a merger decision, the Commission held that *'value-based market shares ... better reflect market power than volume-based shares. In cases of differentiated products it is generally accepted that market shares in value reflect better the relative position and strength of each competitor'*.¹³⁴⁸

4.190. The Commission has also considered the implications of a discrepancy between volume and value market shares in the pharmaceutical sector in the context of a merger decision. In *Glaxo Wellcome / Smithkline Beecham*, the Commission noted in relation to Glaxo's 'Zovirax' product:

'In volume terms, the decline of "Zovirax" market share has been more marked than when assessed in value terms. However, the fact that "Zovirax" has been able to maintain its market position in value terms at a relatively high level despite generic competition is more relevant for the assessment of this case than the fact that the sales volumes have declined. Indeed, this demonstrates that, despite generic acyclovir taking sales volumes, "Zovirax" has been able to generate revenue for GW at far higher levels than competing generic products'.¹³⁴⁹

b. Pricing behaviour and financial performance

i. Pricing behaviour

4.191. The European Commission has found dominance on the basis of an undertaking's conduct in a number of decisions.¹³⁵⁰ The European Courts have confirmed that an undertaking's conduct can establish its dominance: in assessing dominance, *'it may be advisable to take account if need be of the facts put forward as acts amounting to abuses without necessarily having to acknowledge that they are abuses'*.¹³⁵¹ Conduct can reinforce market power, and certain conduct may only be possible where an undertaking possesses substantial market power. For example, the CAT has held that an undertaking that is in a position to price without reference to the costs of supplying its customers is *'plainly under no competitive constraint as to the prices it charges'*.¹³⁵²

¹³⁴⁸ Commission Decision COMP/M.4747 *IBM/Telelogic*, paragraph 135.

¹³⁴⁹ Decision in COMP/M.1846 *Glaxo Wellcome / Smithkline Beecham*, paragraph 106.

¹³⁵⁰ See, for example, Case No. IV/30.698 *ECS/AKZO*, paragraph 56 and Case E-2/36.041 *PO-Michelin*, paragraphs 197 to 199.

¹³⁵¹ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 67-68. See also T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 261 to 269; upheld in C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 181.

¹³⁵² *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 36, paragraph 180. Compare the CAT's judgment in *Genzyme v OFT* [2004] CAT 4, paragraph 257: *'the very state of affairs which forms the subject matter of the present case itself indicates the ability of Genzyme to disregard the wishes of its customers and consumers'*.

- 4.192. An undertaking's pricing behaviour can therefore form an important part of dominance analysis.¹³⁵³
- 4.193. The CMA's guidance on the assessment of market power states that: *'Market power can be thought of as the ability profitably to sustain prices above competitive levels'*.¹³⁵⁴
- 4.194. The Commission's guidance on Article 102 enforcement priorities similarly states, *'an undertaking which is capable of profitably increasing prices **above the competitive level for a significant period of time** does not face sufficiently effective competitive constraints and can thus generally be regarded as dominant.'* For these purposes, *'the expression 'increase prices' includes **the power to maintain prices above the competitive level**, while the meaning of a 'significant period of time' depends on the product and market characteristics, though 'normally a period of two years will be sufficient'*.¹³⁵⁵
- 4.195. An undertaking's ability profitably to sustain prices above competitive levels can therefore be a strong indication of dominance.
- 4.196. The CMA's guidance goes on to state that:
- 'An undertaking's conduct in a market or its financial performance may provide evidence that it possesses market power. Depending on other available evidence, it might, for example, be reasonable to infer that an undertaking possesses market power from evidence that it has:*
- *set prices **consistently above an appropriate measure of its costs**, or*
 - *persistently earned **an excessive rate of profit'***.¹³⁵⁶
- 4.197. The ability of an undertaking to maintain a price premium over its competitors can also be indicative of dominance. In the context of pharmaceutical markets, the General Court has held that an undertaking's ability *'to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it [is] able to exercise market power in respect of price, since neither competing producers, nor social security*

¹³⁵³ See, for example, T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 284 to 286 ; Case IV.30.787 *Eurofix-Bauco v Hilti*, paragraph 71, upheld in-30/89 *Hilti AG v Commission*, EU:T:1991:70, paragraph 93; Commission Decision in Case IV/30.178 *Napier Brown – British Sugar*, paragraph 55.

¹³⁵⁴ *Assessment of market power guidelines* (OFT415), paragraph 3.1.

¹³⁵⁵ European Commission *Guidance on enforcement priorities in applying Article 102 TFEU*, paragraph 11 (emphasis added).

¹³⁵⁶ *Assessment of market power guidelines* (OFT415), paragraph 6.5 (emphasis added). See also *Abuse of a dominant position* (OFT405), paragraph 4.13.

systems, which [bear] the cost of the medicines, nor indeed patients, [are] able to force [it] to bring its prices into line with those of competing products'. This shows that its behaviour is 'not, to an appreciable extent, subject to competitive constraints from its competitors, its customers and, ultimately, consumers'.¹³⁵⁷

- 4.198. By contrast, *'the fact that an undertaking is compelled by the pressure of its competitors' price reductions to lower its own prices is in general incompatible with that independent conduct which is the hallmark of a dominant position'*.¹³⁵⁸ However, as in relation to market shares, declining prices are not in themselves incompatible with dominance – the question is whether the undertaking can still be said to be *'to an appreciable extent'* free of constraint, since dominance does not imply the absence of **any** competitive constraint: *'an undertaking does not have to have eliminated all opportunity for competition in order to be in a dominant position'*.¹³⁵⁹ The CAT has emphasised that *'Dominance does not require a power to behave in all respects independently of customers or competitors'*; an ability to set prices *'to an appreciable extent independently'* of customers *'would ordinarily be sufficient to find that there were not such competitive constraints ... as to preclude a finding of dominance'*.¹³⁶⁰

ii. Financial performance

- 4.199. An undertaking's financial performance can also be a relevant factor in assessing its market power.¹³⁶¹
- 4.200. Persistent significantly high returns, relative to those which would prevail in a competitive market of similar risk and rate of innovation, are particularly strongly indicative of substantial market power (and therefore dominance).¹³⁶²
- 4.201. The ability to sustain an overall profit margin is consistent with dominance; but *'a reduced profit margin or even losses for a time are not incompatible with a dominant position'*. In particular, where *'customers continue to buy*

¹³⁵⁷ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 261 and 266.

¹³⁵⁸ Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 71.

¹³⁵⁹ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 113. See also Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 39; and C-322/81 *Michelin NV v Commission*, paragraph 52: the question is whether the undertaking retains *'preponderant strength in relation to its competitors, even when allowance is made for some competition'*.

¹³⁶⁰ *Socrates Training Limited v Law Society of England and Wales* [2017] CAT 10, paragraph 134 (emphasis in original).

¹³⁶¹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 284 to 286.

¹³⁶² *Assessment of market power guidelines* (OFT415), paragraph 6.6. See, for example, Commission Decision in Case AT.39612 *Perindopril (Servier)*, recitals 2579-2580, 2595 and 2598. The General Court annulled this aspect of the decision on the basis of the Commission's market definition rather than its dominance analysis: T-691/14 *Servier v Commission*, EU:T:2018:922, paragraphs 1595-1608.

more goods from [the undertaking] which is the dearest vendor, this is ‘a particular feature of the dominant position’ which is more significant than its overall profit margin and may, in context, be ‘*determinative*’ of the question of market power.¹³⁶³

c. Market context

4.202. In assessing the existence and degree of market power, relevant evidence from all indicators should be considered in the round.¹³⁶⁴ In addition to market shares, pricing behaviour and financial performance, factors that contribute to and provide further indicators of an undertaking’s substantial market power such as barriers to entry and expansion, other market features and (the absence of) countervailing buyer power should also be considered.

i. Barriers to entry and expansion

4.203. It is important to consider whether actual and/or potential competition (from existing competitors and from new entrants who are not currently active in the relevant market) is inhibited by market features such as barriers to entry and expansion.¹³⁶⁵

4.204. Such barriers may allow an undertaking profitably to sustain prices above the competitive level; an undertaking with a large market share in a market protected by significant entry barriers is likely to have market power.¹³⁶⁶ Such barriers include not only factors that prevent new entry entirely, but also those that impede new entry and expansion.¹³⁶⁷

4.205. Such barriers arise when an undertaking has an advantage (not solely deriving from superior efficiency) over potential or actual entrants as a result of, for example:

- a. **Special rights:** An undertaking’s possession of special rights may contribute to barriers to entry and expansion. For example, intellectual property rights may impede competition (without necessarily being ‘*such as to exclude all competition on the market*’).¹³⁶⁸
- b. **An assured customer base:** Where an undertaking ‘*enjoys a particularly powerful position in relation to ... the largest [distributors of its product]*’, neither the ‘*possibly modest size*’ of its sales to other large

¹³⁶³ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 126 to 128.

¹³⁶⁴ *Assessment of market power guidelines*, OFT415, paragraph 3.6.

¹³⁶⁵ *Assessment of market power guidelines*, OFT415, paragraph 3.3 and section 5.

¹³⁶⁶ *Assessment of market power guidelines*, OFT415, paragraphs 5.3 to 5.7.

¹³⁶⁷ *Assessment of market power guidelines*, OFT415, paragraphs 5.5-5.6.

¹³⁶⁸ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 274.

customers, nor *'fluctuations of [its] share of the total [market]'*, call into question a finding of dominance.¹³⁶⁹

- c. **Exclusionary behaviour:** The undertaking's behaviour may also contribute to barriers to entry and expansion. Exclusionary behaviour includes conduct that raises entry barriers, and practices that make it harder for existing competitors to become more forceful competitors.¹³⁷⁰ In particular, in pharmaceutical markets, the *'holder of the first marketing authorisations'* is *'alone in being able to apply an exclusionary strategy against competing generic products ... and to do so even though it [is] in the interest of national health systems for prices of pharmaceutical products to come down'*.¹³⁷¹

ii. Other market features

- 4.206. Other market features may reinforce the market power of undertakings. In particular, in pharmaceutical markets, the fact that pharmacies are reimbursed by public bodies for the drugs they dispense reinforces the market power of suppliers:

'[T]he health systems which characterise markets for pharmaceutical products tend to reinforce the market power of pharmaceutical companies, since costs of medicines are fully or largely covered by social security systems, which to a significant extent makes demand inelastic'.¹³⁷²

iii. The absence of countervailing buyer power

- 4.207. The retention of very large market shares and the consistent profitable setting of prices above the competitive level each in themselves provide strong indications that an undertaking is able to act to an appreciable extent independently of its competitors and customers and is therefore dominant. Barriers to entry and expansion, and exclusionary conduct, may also provide strong evidence.

¹³⁶⁹ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 217 to 219.

¹³⁷⁰ *Assessment of market power guidelines*, OFT415, paragraph 5.6.

¹³⁷¹ T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 268.

¹³⁷² T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 262.

- 4.208. It is also important to consider, however, whether that body of evidence is rebutted by evidence that the undertaking's market power was in fact effectively constrained, in practice, by countervailing buyer power.¹³⁷³
- 4.209. In this context, it is not enough that a buyer has some market power – the question is *'not just the presence or absence of [buyer power] ... but the degree of such [buyer power] and the extent to which it operated as a constraint on [the undertaking]'s ability to exert market power'*.¹³⁷⁴
- 4.210. The assessment of countervailing buyer power is *'an assessment of how the market actually operates (or is likely to operate) on the true facts, not on artificial "facts" or partial facts'*. Any potential constraint *'must be viewed realistically and for what it is'*; it turns on *'the actual relationship'* between buyer and supplier in practice.¹³⁷⁵
- 4.211. In the context of pharmaceutical markets, generally the NHS ultimately bears the cost of drugs dispensed. The DHSC, which is responsible for the NHS, holds certain powers to intervene in drug pricing. The CAT has held that *'[t]his aspect of countervailing buyer power is better described as a form of regulatory power'*.¹³⁷⁶ However, the potential for economic regulation is not a competitive constraint in itself.¹³⁷⁷ The CAT, Court of Appeal, European Commission and European Courts have consistently held, in the pharmaceutical sector and in other sectors, that the prospect of *'regulatory'* intervention does not negate the possibility of dominance.¹³⁷⁸

¹³⁷³ *Assessment of market power guidelines*, OFT415, paragraphs 6.1 to 6.4. See also *Genzyme Limited v Office of Fair Trading* [2005] CAT 32, paragraph 243. Compare C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, in which the intervener's arguments that the State's monopsonist power and framework of price regulation constrained AstraZeneca's market power were dismissed in light of the strong presumption of dominance that its market shares and pricing established: paragraphs 177 and 181.

¹³⁷⁴ *National Grid v GEMA* [2009] CAT 14, paragraph 60 (emphasis in original).

¹³⁷⁵ *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, paragraphs 105(i), 110(c) and 126.

¹³⁷⁶ *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 205.

¹³⁷⁷ *Assessment of market power guidelines*, OFT415, paragraph 3.4.

¹³⁷⁸ In *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, the CAT agreed with Ofcom that *'a potentially regulated person cannot claim that it does not have [significant market power] because regulation has procured a situation in which it no longer has it'* and went on to hold that *'the possibility of regulation being brought to bear on H3G is a factor that cannot be prayed in aid by H3G as militating against its having [significant market power]'*. As *'a form of regulation'*, potential intervention by Ofcom was *'to be disregarded as a matter of principle'* in the assessment of Hutchison's market power (paragraphs 98-99 and 138(b)). See also *Hutchison 3G UK Limited v Office of Communications* [2008] CAT 11, paragraph 122: *'The fact that a company with a large market share is constrained in its pricing decisions by the threat of ex post regulation of one sort or other does not mean that the company is not dominant.'* Upheld in *Hutchison 3G (UK) Limited v Ofcom* [2009] EWCA Civ 683, paragraphs 60-61 and 66: *'The possibility or probability of ex post regulation (such as fixing a reasonable price by dispute resolution) may in fact operate as a constraint on the freedom of an undertaking which has a large market share, but it is not relevant to a decision as to whether that undertaking has SMP [significant market power] ... A regulatory provision which, if used, would have an effect on the freedom of an operator to act independently of its customers cannot be allowed to provide an a priori answer to the question whether that operator does or does not have SMP'*. See also *National Grid v Ofgem* [2009] CAT 14, paragraph 80; *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* (Case No. 1001/1/1/01), paragraphs 153-155 and 165-168. Similarly, in C-280/08 P *Deutsche Telekom AG v Commission*, EU:C:2010:603, Deutsche Telekom

4.212. Further, in the specific context of the DHSC's powers to intervene in drug pricing, the CAT has confirmed that when assessing buyer power it is not necessary to decide the precise extent of those powers as a question of statutory interpretation or otherwise. Consistently with the case law, the question is whether the DHSC was, as a matter of fact (in the particular case), able to exercise buyer power in the form of regulatory power materially to influence pricing.¹³⁷⁹ The CAT has noted that:

*'to be an effective constraint on behaviour the buyer in question must not only have the theoretical capability of exercising countervailing pressure on suppliers but there has to be a real possibility that this pressure will be exercised in practice and to a sufficient extent.'*¹³⁸⁰

4.213. In its judgment on the appeal on the issue of abuse, the Court of Appeal noted that *'It is important to start by noting two fundamentals of the [CAT] judgment'* (market definition and dominance), and went on to note that (notwithstanding the DHSC's powers): *'the CAT accepted that Flynn and Pfizer were essentially able to set and sustain high prices for phenytoin capsules and that they did not face sufficient competitive pressure, whether from within or from outside the relevant market, to constrain their behaviour, because they each held dominant positions'*.¹³⁸¹

4.214. In its order refusing permission for Pfizer to appeal the CAT's findings on dominance, the Court of Appeal confirmed that:

*'the CAT was clearly entitled to conclude that it did not need to decide the precise extent of the Department of Health's powers and to find that the Department had no effective means to limiting the appellants' prices. Both the case law and common sense show that the focus should be on whether there is an **effective** constraint rather than the theoretical position, and Case C-280/08 Deutsche Telekom v Commission confirms that the failure of the Department to exercise any powers it may have had could not have absolved the appellants from their "special responsibility not to allow their conduct to impair genuine undistorted competition".'*¹³⁸² [emphasis in original]

argued that because of the framework of price regulation in which it operated, it could not have abused its dominant position (it did not dispute dominance). The General Court and Court of Justice rejected its argument, the Court of Justice finding that *'regulation did not in any way deny [Deutsche Telekom] the possibility of adjusting its retail prices ... or, therefore, of engaging in autonomous conduct that is subject to Article [102]'* (paragraph 92).

¹³⁷⁹ *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 207.

¹³⁸⁰ *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 203.

¹³⁸¹ *CMA v Flynn Pharma and Pfizer Inc.* [2020] EWCA Civ 339, paragraphs 192 and 217.

¹³⁸² *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey, dated 17 December 2018.

4.215. In *Deutsche Telekom v Commission* the Court of Justice had stated:

*'the mere fact that the appellant was encouraged by the intervention of a national regulatory authority such as RegTP [the regulator] to maintain the pricing practices which led to the margin squeeze of competitors who are at least as efficient as the appellant cannot, as such, in any way absolve the appellant from responsibility under Article 82 EC.'*¹³⁸³

d. Representations on the legal test for dominance

- 4.216. Intas/Accord-UK submitted that there was a separate legal test for dominance in excessive and unfair pricing cases: an undertaking could only be found to have a dominant position in such cases where there was no market entry, nor likelihood of entry within a reasonable time, such that the undertaking was an '*unavoidable trading partner*' subject to no material competitive constraints and not lowering prices.¹³⁸⁴ Intas/Accord-UK effectively submitted that only a monopolist could engage in excessive and unfair pricing.
- 4.217. Intas/Accord-UK submitted that the CMA should apply this alternative legal test only to the period in which it owned Accord-UK without taking into account any continuity in facts with the preceding nine years.¹³⁸⁵ By focusing on this period alone it submitted that the CMA had found '*an unconventional kind of short-lived, temporary dominance, which is alien to the Chapter II prohibition.*'¹³⁸⁶
- 4.218. Intas/Accord-UK also submitted that the CMA was not entitled to rely on factors relating to abuse at the stage of establishing dominance because this gave rise to circularity.¹³⁸⁷
- 4.219. The CMA rejects these submissions for the following reasons.
- 4.220. First, there is no separate legal test for dominance in excessive and unfair pricing cases. The legal test for dominance is set out in section 4.C.I above. It is that the undertaking has the power to behave, to an **appreciable** extent, independently of its competitors, customers and ultimately of consumers.

¹³⁸³ C-280/08 *Deutsche Telekom AG v Commission*, EU:C:2010:603, paragraph 84.

¹³⁸⁴ Document 205212, Intas/Accord-UK's RSSO, paragraphs 9, 37-52, 56-76; 87-92 and 98-100; Document 205566, Intas/Accord-UK hearing slides, slides 13-19.

¹³⁸⁵ Document 205212, Intas/Accord-UK's RSSO, paragraphs 4, 34-36.

¹³⁸⁶ Document 205212, Intas/Accord-UK's RSSO, paragraph 99.

¹³⁸⁷ Document 205212, Intas/Accord-UK's RSSO, paragraphs 77-86; Document 205566, Intas/Accord-UK hearing slides, slide 22.

This was the test applied in the seminal excessive and unfair pricing case, *United Brands*.¹³⁸⁸

- 4.221. As *United Brands* recognised, this test allows for, and even assumes the existence of, some competition. Dominance is not the same as monopoly: the Court of Justice recognised that ‘*an undertaking does not have to have eliminated all opportunity for competition in order to be in a dominant position*’, and found *United Brands* to be dominant with a market share of between 40% and 45%.¹³⁸⁹
- 4.222. As explained in section 4.C.I.a above, dominance therefore does not require that the undertaking is free from any competitive constraint and is not incompatible with falling prices.
- 4.223. Nor does dominance require that the undertaking is an ‘*unavoidable trading partner*’ in the sense of customers having no choice of supplier whatsoever. An ‘*unavoidable trading partner*’ need not be a monopolist: ‘*an undertaking which has a very large market share [as explained above, this means a share above 50%] and has held it for some time is in a position of strength which makes it an unavoidable trading partner*’.¹³⁹⁰ That description applies to Auden/Actavis throughout the Unfair Pricing Abuses.
- 4.224. Secondly, it is artificial to apply the legal test for dominance to the Intas/Accord ownership period in isolation, without considering the continuity with the previous nine years. The CMA is not required to conduct a ‘*bottom up*’ dominance analysis every time the directly infringing entity is acquired by a new parent company. The CMA has not found short-lived or temporary dominance in the ‘Intas period’ (ie the period beginning with Intas’ acquisition of Accord-UK on 9 January 2017) in itself, but a dominant position held by Auden/Actavis throughout the periods of the Unfair Pricing Abuses.
- 4.225. Thirdly, as explained in section 4.C.I.b above, having regard to an undertaking’s pricing behaviour and financial performance is a legitimate component of dominance analysis. Market power can itself ‘*be thought of as the ability profitably to sustain prices above competitive levels*’.¹³⁹¹ This approach has been followed in numerous cases at European and UK level. It does not amount to circularity: the European courts have confirmed that in assessing dominance, ‘*it may be advisable to take account if need be of the*

¹³⁸⁸ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 66.

¹³⁸⁹ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 108-119 and 129.

¹³⁹⁰ C-395/96 P and C-396/96 P *Compagnie Maritime Belge Transports v Commission*, EU:C:2000:132, paragraph 132.

¹³⁹¹ *Assessment of market power guidelines* (OFT415), paragraphs 3.1 and 6.5.

*facts put forward as acts amounting to abuses without necessarily having to acknowledge that they are abuses’.*¹³⁹²

II. The CMA's assessment of dominance

a. Summary of dominance findings

4.226. For the reasons set out in this section, the CMA has concluded that Auden/Actavis held a dominant position in the relevant market(s) for at least the period from 1 October 2008 until 31 July 2018 for 10mg hydrocortisone tablets and for at least the period from 1 October 2008 until 8 January 2017 for 20mg hydrocortisone tablets.

4.227. The CMA has assessed whether Auden/Actavis held a dominant position by reference to two periods:

- a. from the beginning of the Unfair Pricing Abuses on 1 October 2008 until the end of June 2015, when Auden was the only supplier of 10mg and 20mg hydrocortisone tablets in the UK (the **‘Pre-Entry Period’**); and
- b. from the first independent competitor’s entry in July 2015 until the end of the Unfair Pricing Abuses (the **‘Post-Entry Period’**):
 - i. in relation to 10mg hydrocortisone tablets, on **31 July 2018**; and
 - ii. in relation to 20mg hydrocortisone tablets, on **8 January 2017**.

4.228. The CMA has made no finding in relation to whether Auden/Actavis held a dominant position for 10mg or 20mg hydrocortisone tablets outside of those periods. This is because the CMA has exercised its discretion to determine its administrative priorities and has not prioritised the periods before 1 October 2008 and after 31 July 2018 as part of the 10mg Unfair Pricing Abuse and before 1 October 2008 and after 8 January 2017 as part of the 20mg Unfair Pricing Abuse.¹³⁹³

4.229. As explained in section 4.B.II.a above, the CMA has defined the relevant market as the supply of hydrocortisone tablets in the UK, that is including both 10mg and 20mg tablets, before entry, but concluded that the market segmented into separate markets for 10mg and 20mg tablets after

¹³⁹² Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 67-68. See also T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 261 to 269; upheld in C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 181.

¹³⁹³ In relation to the start date of both Unfair Pricing Abuses and the end date of the 10mg Unfair Pricing Abuse, the CMA has not prioritised investigating whether Auden/Actavis’s prices were excessive and unfair below £20 per pack. In relation to the end date of the 20mg Unfair Pricing Abuse, the CMA has not prioritised investigating whether Actavis held a dominant position for 20mg hydrocortisone tablets after that date.

independent entry. In accordance with this finding, the CMA analyses 10mg and 20mg tablets together for the Pre-Entry Period, but analyses 10mg and 20mg tablets separately for the Post-Entry Period, where there are relevant differences.

4.230. The CMA has concluded that throughout the Infringements, Auden/Actavis held a dominant position in the relevant market(s). The CMA bases its conclusions on:

- a. Auden/Actavis's market shares. Prior to independent entry, for over seven years of the Infringements, Auden/Actavis was the sole supplier¹³⁹⁴ of 10mg and 20mg hydrocortisone tablets in the UK (with a market share of 100%). Following independent entry, Auden/Actavis retained very large market shares (exceeding 60% by value). Such very large market shares are strong evidence of dominance and constitute in themselves, save in exceptional circumstances, proof of the existence of a dominant position;¹³⁹⁵
- b. Auden/Actavis's pricing behaviour and financial performance, as reflected in its price-setting decisions to raise prices repeatedly and significantly (by 147% and 171% for 10mg and 20mg tablets respectively)¹³⁹⁶ in the Pre-Entry Period and price above competitors (charging prices of on average 145% and 23% above competitors for 10mg and 20mg tablets respectively) in the Post-Entry Period, and the profitability of its pricing conduct, which show that it was able to exercise significant market power; and
- c. The market context within which Auden/Actavis operated throughout the Infringements, which indicates that no exceptional circumstances existed that would rebut the presumption of dominance that Auden/Actavis's very large market shares create.¹³⁹⁷ The CMA has concluded that the market context provides a further indication of

¹³⁹⁴ Although Waymade and AMCo supplied limited volumes of Auden/Actavis's hydrocortisone tablets pursuant to supply arrangements, the CMA has found that this was payment in return for their non-entry and did not represent genuine competitive entry.

¹³⁹⁵ C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 176. See also T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraph 103. Compare the Commission's decision in COMP/38.233 *Wanadoo Interactive*, paragraph 212 (upheld in T-340/03); C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60; *Aberdeen Journals v OFT* [2003] CAT 11, paragraph 310. Compare also T-66/01 *Imperial Chemical Industries v Commission*, EU:T:2010:255, paragraph 256; Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 41; and Commission Decision in Case AT.39612 *Perindopril (Servier)*, recital 2561.

¹³⁹⁶ For 10mg tablets: an increase of £32.78 from £22.28 in October 2008 (the month the 10mg Unfair Pricing Abuse started) to £55.06 in June 2015 (the end of the Pre-Entry Period). For 20mg tablets: an increase of £40.52 from £23.74 in October 2008 (the month the 20mg Unfair Pricing Abuse started) to £64.26 in June 2015 (the end of the Pre-Entry Period).

¹³⁹⁷ Compare Commission *Guidelines on its enforcement priorities in applying Article 102 to abusive exclusionary conduct*, paragraph 13: market shares should be interpreted in light of the relevant market conditions, and in particular of the dynamics of the market and of the extent to which products are differentiated.

Auden/Actavis's dominance, corroborating the evidential significance of its very large market shares, pricing behaviour and financial performance. The market context considered includes:

- i. Auden/Actavis's agreements with AMCo and Waymade;
- ii. the orphan designation granted to Plenadren, which from November 2011 created a barrier to expansion and provided Auden/Actavis with an assured customer base for 10mg hydrocortisone tablets and thereby preserved its ability to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers; and
- iii. the absence of countervailing buyer power.

4.231. The CMA has considered the representations it received from the parties on the SSO. In this respect, it has taken account of the submissions made by Auden/Actavis and Intas/Accord-UK that Auden/Actavis did not hold a dominant position.¹³⁹⁸ Following a thorough assessment of all the relevant evidence and representations, the CMA has concluded that Auden/Actavis held a dominant position in the relevant market(s) for at least the period from 1 October 2008 until 31 July 2018 for 10mg hydrocortisone tablets and for at least the period from 1 October 2008 until 8 January 2017 for 20mg hydrocortisone tablets. The CMA further addresses the representations at sections 4.C.I.d, 4.C.II.c.iv and 4.C.II.d.ii.

b. The Pre-Entry Period

4.232. For around seven years (from 2008 until 2015), Auden/Actavis was the sole supplier of hydrocortisone tablets,¹³⁹⁹ imposing significant price increases in the relevant market (increasing prices by 147% for 10mg tablets and 171% for 20mg tablets¹⁴⁰⁰ during the period). Such price increases were very profitable, and without loss of volumes (in fact, hydrocortisone tablet volumes were growing steadily). As set out in this section, this demonstrates that Auden/Actavis was able to act independently of its competitors,

¹³⁹⁸ Document 205212, Intas/Accord-UK's RSSO chapter 3, Document 205217, Auden/Actavis RSSO, chapter 3. See also Document 206676, Intas/Accord-UK's RLOF, paragraph 6 and pages 5-8.

¹³⁹⁹ See section 4.C.II.b.i below on the relevance of Auden/Actavis's supply arrangements with Waymade and AMCo to its market shares.

¹⁴⁰⁰ These are increases from £22.28 per pack of 10mg tablets and £23.74 per pack of 20mg tablets in October 2008 (that is, the start of the Infringements), to £55.06 per pack for 10mg tablets and £64.26 per pack for 20mg tablets in June 2015. As explained in section 3.E.V.b.ii above, Actavis's prices continued to increase after the Pre-Entry Period: at their peak its prices for both 10mg and 20mg hydrocortisone tablets reached around £72 per pack.

customers and end-consumers to an appreciable extent during the Pre-Entry Period.

i. Retention of very large market shares

- 4.233. From 1 October 2008 until July 2015 – nearly seven years – Auden was the sole supplier of 10mg and 20mg hydrocortisone tablets in the UK¹⁴⁰¹ with a market share by volume and value of 100%.¹⁴⁰² As explained in section 4.B.I.a above, this provides a clear indication that Auden held a dominant position.¹⁴⁰³ Indeed, a market share of 100% over many years creates ‘a *very strong presumption*’ of dominance.¹⁴⁰⁴ No exceptional circumstances existed which rebut this presumption (see section 4.B.II.c below).
- 4.234. During the Pre-Entry Period Auden entered into supply arrangements with Waymade and AMCo under which it supplied each with limited volumes of its hydrocortisone tablets at a substantial discount to its other customers (87% and 97% respectively). Waymade and AMCo then sold those volumes in the market for a profit. This did not affect Auden’s position as monopolist: Waymade and AMCo continued to sell Auden’s hydrocortisone tablets. The CMA has found that these supply arrangements were payments in return for AMCo’s and Waymade’s agreement not to enter the market (see section 6 below). The supply arrangements therefore bought off, rather than increased, the competitive constraints Auden faced.¹⁴⁰⁵
- 4.235. The possession, over a long period, of a very large market share ‘*constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position*’.¹⁴⁰⁶ Moreover, as explained in the sections that follow,

¹⁴⁰¹ Although there are some parallel imports of hydrocortisone tablets supplied into the United Kingdom, volumes are very low. The CMA’s analysis based on IMS Health data shows that, on average, parallel imports accounted for 1% or significantly less of all wholesalers’, pharmacies’ and hospitals’ volumes of hydrocortisone tablets throughout the Infringements. As a result, the CMA has not considered them further in its assessment of dominance (including in its calculation of market shares), as they do not materially impact the CMA’s findings.

¹⁴⁰² The relevant market is taken to include 10mg and 20mg tablet strengths as set out in paragraph 4.229 above. However, the same conclusion that Auden was the sole supplier with a 100% market share would be reached were the tablet strengths considered as separate markets because Auden was the sole supplier of both of those tablet strengths.

¹⁴⁰³ See, eg, T-30/89 *Hilti v Commission*, EU:T:1991:70, paragraph 92.

¹⁴⁰⁴ *Albion Water Limited v Ofwat* [2006] CAT 38, paragraph 123. See also C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60; T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 288; T-30/89 *Hilti v Commission* [1991] ECR II-1439, paragraph 92; T-340/03 *France Télécom v Commission* [2007] ECR II-107, paragraphs 99 to 101; T-57/01 *Solvay v Commission* [2009] ECR II-4621, paragraphs 275 to 305.

¹⁴⁰⁵ Compare C-591/16 P *Lundbeck v Commission*, paragraphs 133 and 137; C-586/16 P *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*, paragraphs 82-84. See also GSK v CMA [2018] CAT 4 (*Paroxetine*), paragraphs 297-298 and 308, C-307/18 *GSK v Commission*, paragraphs 103-110, and GSK v CMA [2021] CAT 9, paragraphs 54, 57 and 103-106. See also Opinion of Advocate General Kokott in C-591/16 P *Lundbeck v Commission*, paragraph 142.

¹⁴⁰⁶ C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 176. See also T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraph 103. Compare the Commission’s decision in COMP/38.233 *Wanadoo Interactive*, paragraph 212 (upheld in T-340/03); C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60; *Aberdeen Journals v OFT* [2003] CAT 11, paragraph 310. Compare also T-66/01 *Imperial Chemical Industries v*

other evidence corroborates the conclusion that Auden held a dominant position throughout the Pre-Entry Period.

ii. Pricing behaviour and financial performance

4.236. Auden's pricing behaviour and financial performance throughout the Pre-Entry Period in themselves demonstrate its ability to exert substantial market power, and therefore its dominance, corroborating the strong evidential weight of its very large market shares.¹⁴⁰⁷

4.237. During the Pre-Entry Period, Auden was able profitably to increase and sustain supra-competitive prices for hydrocortisone tablets, as demonstrated by:

- a. Very significant price increases without loss of volumes. As shown in section 3.E.V.a.ii above, Auden implemented frequent and very significant price increases for hydrocortisone tablets during the Pre-Entry Period. By the end of the Pre-Entry Period in June 2015, Auden's prices had increased by 147% for 10mg tablets and 171% for 20mg tablets.¹⁴⁰⁸ As explained in section 4.B.II.c.i above, Auden did not lose any volumes as a result of these price increases, which is strong evidence of its substantial market power.
- b. Pricing significantly above costs. Throughout the Pre-Entry Period, Auden was able consistently to set prices at a level which significantly exceeded its costs. The direct costs from the CMO remained below [**£1-£4**] for both 10mg and 20mg hydrocortisone tablets throughout the Pre-Entry Period and Cost-Plus was less than £5 per pack for 10mg hydrocortisone tablets, and £6 per pack for 20mg hydrocortisone tablets (see section 5.C.III below). An undertaking that is in a position to price without reference to its costs is plainly under no competitive constraint as to the prices it charges.¹⁴⁰⁹

Commission, EU:T:2010:255, paragraph 256; Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 41; and Commission Decision in Case AT.39612 *Perindopril (Servier)*, recital 2561.

¹⁴⁰⁷ *Assessment of market power guidelines* (OFT415), paragraph 6.5. Compare Case IV.30.787 *Eurofix-Bauco v Hilti*, paragraph 71; T-30/89 *Hilti AG v Commission*, EU:T:1991:70, paragraph 93. See also Commission Decision in Case IV/30.178 *Napier Brown – British Sugar*, paragraph 55.

¹⁴⁰⁸ These are increases from £22.28 per pack of 10mg tablets and £23.74 per pack of 20mg tablets in October 2008 (that is, the start of the Infringements), to £55.06 per pack for 10mg tablets and £64.26 per pack for 20mg tablets in June 2015. As explained in section 3.E.V.b.ii above, Actavis's prices continued to increase after the Pre-Entry Period: at their peak its prices for both 10mg and 20mg hydrocortisone tablets reached around £72 per pack.

¹⁴⁰⁹ See paragraph 4.191.

- c. Excessive profits. Throughout the Pre-Entry Period, Auden's exercise of pricing power enabled it persistently to earn supernormal profits,¹⁴¹⁰ returns that were significantly above those which would be expected to prevail in a competitive market characterised by similar levels of risk (as demonstrated by a comparison between Auden/Actavis's prices and the current average price of Actavis's competitors (see section 5.D.III.a below)), and that did not represent a return on previous innovation (since Auden acquired the hydrocortisone tablets MAs rather than invented the drug and did not make any investments in hydrocortisone tablets, see section 5.D.II.b.ii below).¹⁴¹¹
 - i. As a result of the price increases it imposed, Auden earned profits over the Pre-Entry Period significantly above an appropriate measure of its costs, plus a reasonable rate of return (that is, Cost Plus) in percentage terms of at least 450%, for 10mg and 20mg hydrocortisone tablets, with prices reaching over 1,100% above this level by July 2015 (Differentials reached over £45 per pack for both 10mg and 20mg hydrocortisone tablets).^{1412, 1413}
 - ii. This resulted in profits in excess of Cost Plus during the Pre-Entry Period in real terms of around £170 million for 10mg hydrocortisone tablets, and around £10 million for 20mg hydrocortisone tablets.
 - iii. Auden's gross margins were around [X]% (and as high as [X]% during the latter part of the Pre-Entry Period).¹⁴¹⁴

4.238. The fact that Auden was able to repeatedly increase its prices to such an extent and to profitably sustain such increases demonstrates that any competitive constraints exerted on Auden were insufficient to prevent it from holding a dominant position in the market for hydrocortisone tablets in the UK during the Pre-Entry Period.

¹⁴¹⁰ *Assessment of market power guidelines* (OFT415), paragraph 6.6; Case IV.30.787 *Eurofix-Bauco v Hilti*, paragraph 71. Compare Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 249; and Case AT.39612 *Perindopril (Servier)*, recitals 2579 to 2580, 2595 and 2598.

¹⁴¹¹ *Assessment of market power guidelines* (OFT415), paragraph 6.5.

¹⁴¹² See section 5.C.

¹⁴¹³ Compare Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 126 to 128.

¹⁴¹⁴ Source: CMA calculations based on data submitted by Auden in relation to the Pre-Entry Period.

iii. Market context – Auden’s Agreements with AMCo and Waymade

- 4.239. The CMA has concluded that entry into the Agreements with Waymade and AMCo was a key factor in enabling Auden to prolong its dominant position during the Pre-Entry Period.¹⁴¹⁵
- 4.240. During the Pre-Entry Period, both Waymade and AMCo developed their own hydrocortisone tablets and posed a competitive threat to Auden (see section 6.C.II below).
- 4.241. When faced with this threat, Auden entered into the Agreements with Waymade and AMCo under which it agreed to supply them with specified quantities of hydrocortisone tablets at a heavily discounted supply price. As a result, Auden made significant payments to its potential competitors which the CMA has concluded were made in return for their agreement not to enter the market independently with their own products (see section 6.D.II below). These Agreements prevented, or at least considerably delayed, the entry of new competitors.
- 4.242. In this way, Auden’s arrangements with its potential competitors Waymade and AMCo acted to prolong its dominance (see section 6.C.II below). Auden continued (and even accelerated) its price increases during the Agreements: see figures 4.1 and 4.2 above. Auden/Actavis’s prices increased by 99% and 92% for 10mg and 20mg tablets respectively during the Agreements.¹⁴¹⁶

c. The Post-Entry Period

- 4.243. From July 2015 onwards, competitors began to enter the market (see section 3.E above). Following this independent entry, Actavis’s¹⁴¹⁷ market shares and prices declined (see figures 4.13 to 4.19 below). However, notwithstanding these declines, the CMA has concluded on the basis of the analysis in this section that Actavis retained its dominant position throughout the Post-Entry Period.

¹⁴¹⁵ The 10mg Agreement continued into the Post-Entry Period – until 24 June 2016.

¹⁴¹⁶ For 10mg tablets: an increase in Auden/Actavis’s price from £31.55 per pack in October 2012 (the month the 10mg Agreement commenced) to £62.63 per pack in June 2016 (the month the 10mg Agreement terminated). As the Agreement terminated due to the independent competition present in the market which had already begun to reduce Auden/Actavis’s prices, this figure represents an underestimate of the price increase during the 10mg Agreement. For 20mg tablets: an increase in Auden/Actavis’s price from £32.56 per pack in July 2011 (the month the 20mg Agreement commenced) to £62.45 in April 2015 (the month the 20mg Agreement terminated).

¹⁴¹⁷ For ease, the CMA refers in the remainder of this section covering the Post-Entry Period to ‘Actavis’ only. This must be read as referring to AM Pharma during July and August 2015, ie the last two months in which AM Pharma sold hydrocortisone tablets in the UK before this business was transferred intra-group to Actavis UK Limited, which continued the sale of hydrocortisone tablets in the UK from September 2015 onwards. Actavis UK Limited underwent a name change to Accord-UK Limited in March 2018, some time after Intas and Accord acquired it. However, this did not mean the entity selling hydrocortisone tablets in the UK changed.

- 4.244. As explained in section 4.C.I above, price reductions and the loss of a certain amount of market share do not in themselves indicate the absence or loss of dominance. In this case, the evidence shows that notwithstanding a decline in its market shares and prices (from very high levels), Actavis retained the ability to act to an appreciable extent independently of its competitors, customers and ultimately of consumers. This is demonstrated by Actavis's retention of significant market shares despite the entry of competitors and its ability to charge a premium for its product, at a time when competitors' prices were falling at a faster rate.
- 4.245. Actavis was able to retain this position of economic strength despite the emergence of competition due to the barrier to expansion created by the orphan designation. As the only full label supplier of 10mg hydrocortisone tablets, Actavis had an assured base of customers that had no choice but to purchase Auden/Actavis's tablets (see section 3.E.IV.c.i.a) that allowed Actavis to profitably charge a significant premium above its competitors' prices.
- 4.246. Although Actavis was not the only full label supplier of 20mg hydrocortisone tablets, so that it did not benefit from an assured base arising from being the only full label supplier in the same way as it did for 10mg tablets, it continued to retain a position of dominance during the 20mg Unfair Pricing Abuse. This is shown by the fact that Waymade itself did not achieve a substantial market share and Auden/Actavis was able to profitably retain a significant price premium over all competitors, including Waymade, in the 20mg tablets market.

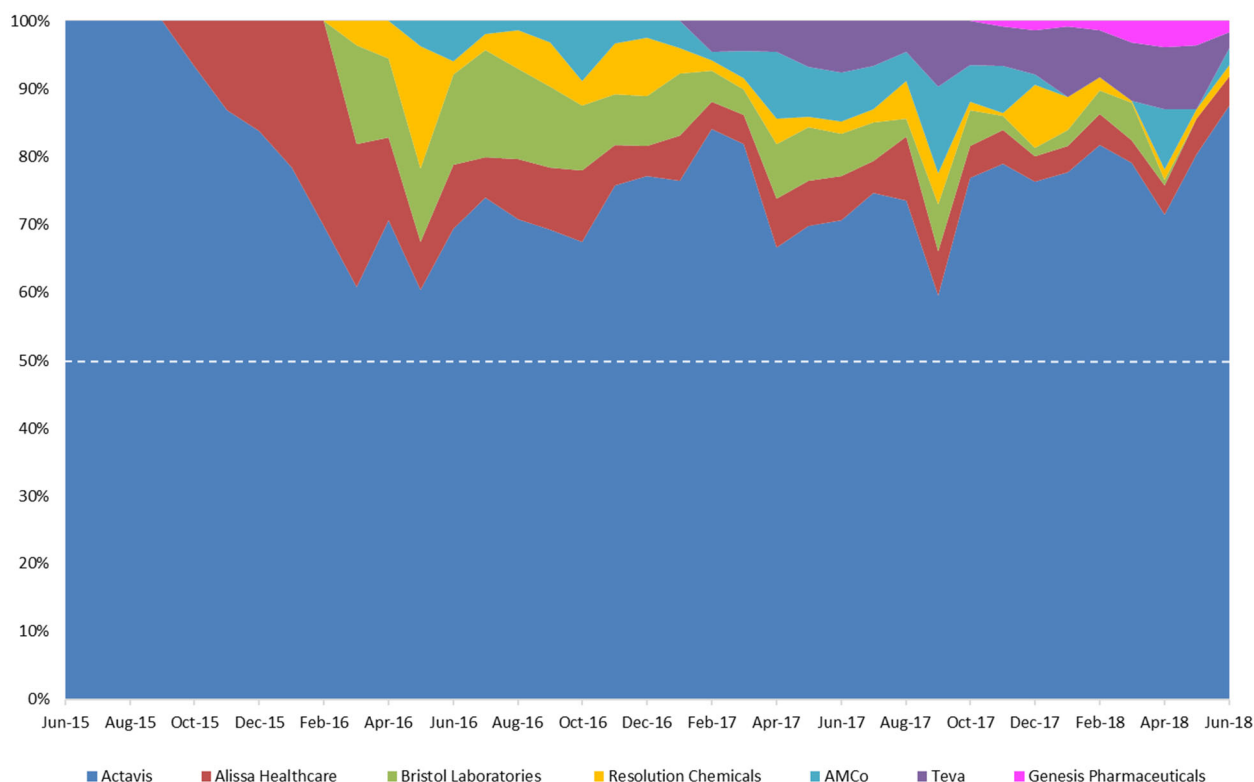
i. Market shares

- 4.247. The CMA has concluded that Actavis continued to hold substantial market power with respect to both tablet strengths during the Post-Entry Period. Whether assessed by value or by volume, Actavis's market shares in the Post-Entry Period indicate continued dominance: although Actavis's market shares declined during the Post-Entry Period,¹⁴¹⁸ they remained very large, whether in value or volume terms, both in themselves, and relative to competitors either individually or cumulatively.
- 4.248. The CMA's conclusions on dominance apply whether 10mg and 20mg hydrocortisone tablets are (i) part of the same relevant product market; or (ii)

¹⁴¹⁸ These market shares should also be considered in the context of steadily growing 10mg hydrocortisone tablet volumes, and relatively flat 20mg tablet volumes (see section 3.E.V.a.ii above).

in separate markets.¹⁴¹⁹ The market shares of the suppliers of 10mg and 20mg hydrocortisone tablets during the Post-Entry Period, by value and volume, are shown in figures 4.13 to 4.16 below.

Figure 4.13: Market shares for the supply of 10mg hydrocortisone tablets during the Post-Entry Period (based on monthly sales value)

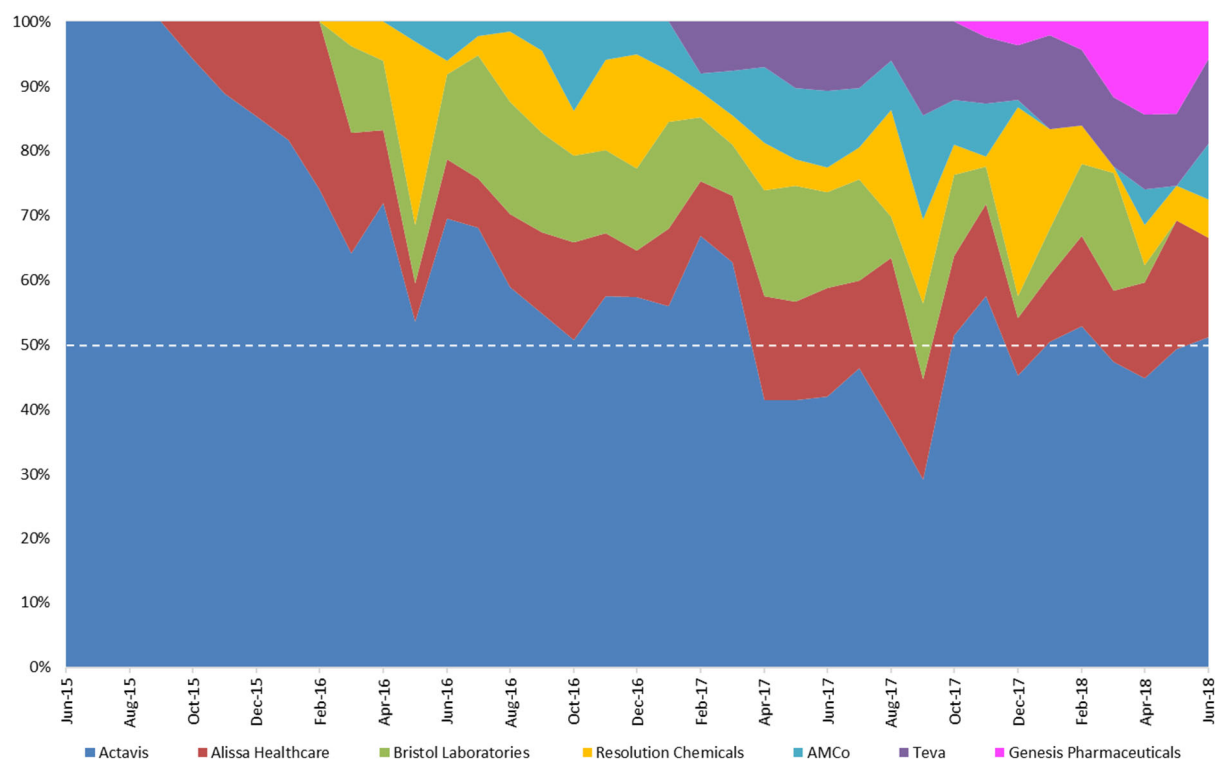


Source: CMA analysis based on data submitted by relevant parties.

Notes: (1) Market shares are based on monthly sales revenues, net of all rebates/discounts; (2) Actavis's average monthly sales revenues exclude intercompany sales but include sales to Waymade and AMCo. As Actavis was supplying Waymade and AMCo at considerably reduced prices, this will understate its market share. Waymade and AMCo's sales that were supplied by Actavis are excluded because supply volumes to Waymade and AMCo were controlled by Actavis (see section 6.D.II below).

¹⁴¹⁹ As explained at paragraph 3.125, since 10mg hydrocortisone tablets account for 96% of all hydrocortisone tablets dispensed, market shares for the supply of hydrocortisone tablets as a whole are in any event in all material respects the same as those presented in this section for the 10mg strength.

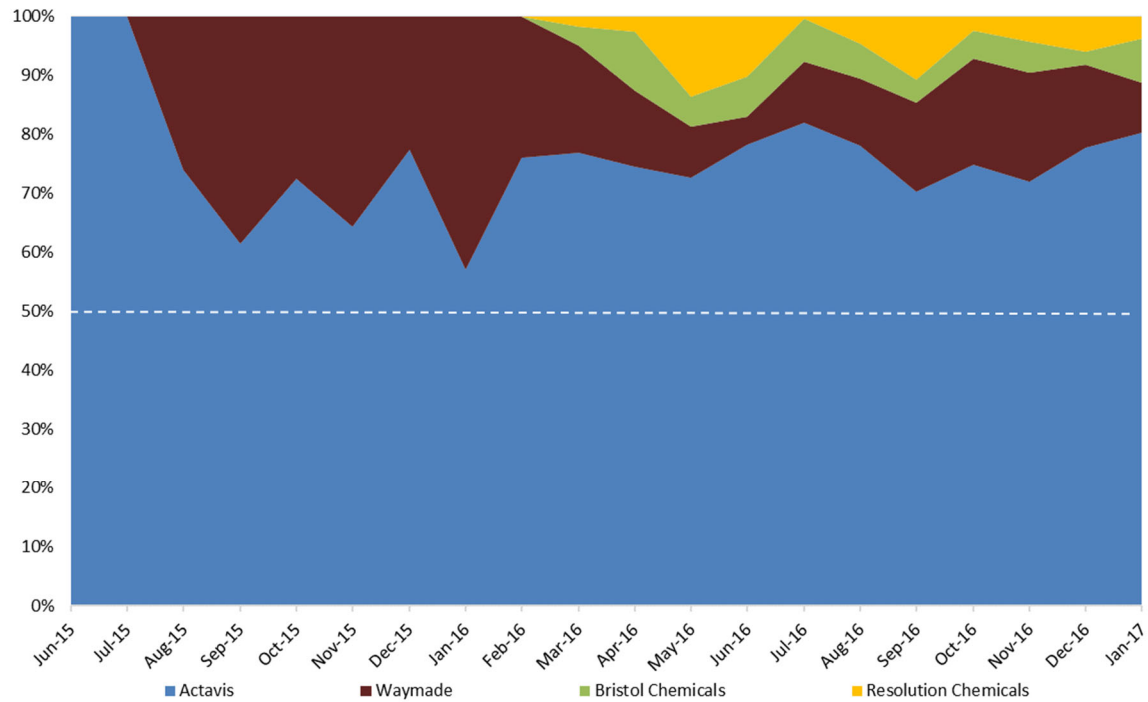
Figure 4.14: Market shares for the supply of 10mg hydrocortisone tablets during the Post-Entry Period (based on monthly sales volumes)



Source: CMA analysis based on data submitted by relevant parties.

Note: AMCo's and Waymade's sales volumes exclude their sales of Actavis's product and Actavis's sales volumes include product sold to AMCo and Waymade pursuant to the Agreements.

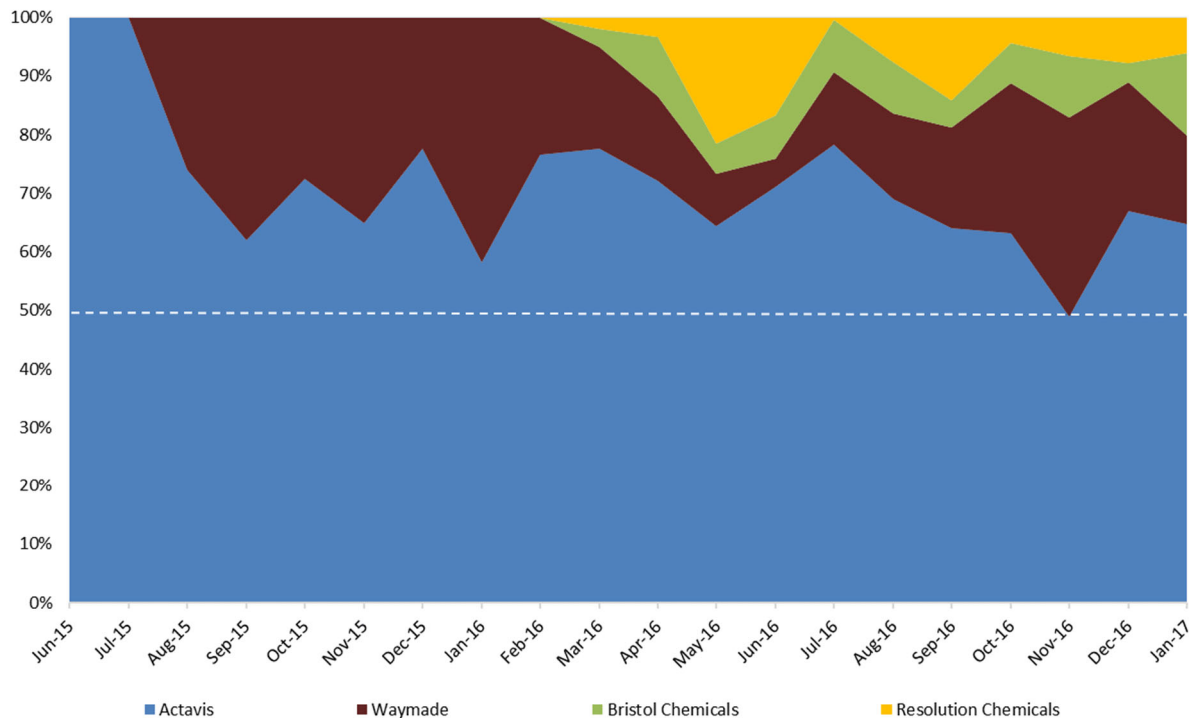
Figure 4.15: Market shares for the supply of 20mg hydrocortisone tablets during the Post-Entry Period (based on monthly sales value)



Source: CMA analysis based on data submitted by relevant parties.

Notes: (1) Market shares are based on monthly sales revenues, net of all rebates/discounts; (2) Actavis's average monthly sales revenues exclude intercompany sales but include sales to Waymade and AMCo. As Actavis was supplying Waymade and AMCo at considerably reduced prices, this will understate its market share. Waymade and AMCo's sales that were supplied by Actavis are excluded because supply volumes to Waymade and AMCo were controlled by Actavis (see section 6.D.II below).

Figure 4.16: Market shares for the supply of 20mg hydrocortisone tablets during the Post-Entry Period (based on monthly sales volumes)



Source: CMA analysis based on data submitted by relevant parties.

Note: AMCo's and Waymade's sales volumes exclude their sales of Actavis's product and Actavis's sales volumes include product sold to AMCo and Waymade pursuant to the Agreements.

Retention of very large market shares

4.249. Figures 4.13 and 4.15 show that at every point during the Post-Entry Period, Actavis's value market share for both tablet strengths remained above the 50% level at which dominance can be presumed:¹⁴²⁰

- a. Actavis's value share of the supply of 10mg and 20mg hydrocortisone tablets remained around 60% or above (for much of the Post-Entry Period, substantially above) despite independent entry.
- b. For 10mg tablets: after declining until March-May 2016, Actavis's value share stabilised above 70%. In July 2018 (the last month of the 10mg Unfair Pricing Abuse), Actavis's value share was 86%.
- c. For 20mg tablets: after declining until August 2015, Actavis's value share remained around 70% or above. At the end of December 2016

¹⁴²⁰ See section 4.C.I.a.i above. Compare in particular the CAT's judgment in *Aberdeen Journals v OFT* [2003] CAT 11: 'In our view the Director is correct to conclude that market shares of this order [78% by value / 67% by volume; and 73% by value / 63% by volume] suffice to establish that *Aberdeen Journals* was dominant unless exceptional circumstances are shown' (paragraph 310).

(the last month before the end of the 20mg Unfair Pricing Abuse), Actavis's value share was 78%.

4.250. Similarly, figures 4.14 and 4.16 show that Actavis's volume share of the supply of 10mg and 20mg hydrocortisone tablets declined but remained above 50% for most of the Post-Entry Period:¹⁴²¹

- a. For 10mg tablets: Actavis's volume share declined until mid-2017, at which time it stabilised at around 50%. For seven months in 2017 (April to September, and December), Actavis's volume share fell below 50% (though for most of that period, it remained between 40 and 50%). During 2018 it recovered to around 50%, fluctuating slightly above and below that level and reaching 53% in July 2018 (the last month of the 10mg Unfair Pricing Abuse).
- b. For 20mg tablets: Actavis's volume share declined during the Post-Entry Period, reaching 67% at the end of the Post-Entry Period. Actavis's volume share only dipped below 50% in one month (November 2016, to 49%, from above 60% in each of the previous six months) and recovered to 67% in the following month (the last month before the end of the 20mg Unfair Pricing Abuse).

4.251. Actavis's retention of a very large value market share demonstrates its continued ability to act to an appreciable extent independently of its competitors, customers and ultimately of consumers throughout the Post-Entry Period. In particular, its market share by value remained above 50%, the threshold at which the presumption of dominance applies. In these circumstances even a downward trend in these shares does not prevent the CMA from relying on this presumption.¹⁴²²

4.252. As figures 4.13 to 4.16 show, Actavis's market shares, both value and volume, declined during the Post-Entry Period, although value market shares increased again after an initial decline. However, as explained in section 4.B.I.a.i above, a decline in market shares cannot, without more evidence,

¹⁴²¹ The monthly market shares of Actavis and other suppliers in the Post-Entry Period were subject to fluctuations, often driven by customers' order patterns and stocking decisions (see for example Document 01613, email from Accord-UK to CMA dated 31 May 2017). This means that individual monthly market shares should not be accorded disproportionate weight when assessing market power. The overall trend during the Post-Entry Period is more significant. This indicates that, despite these monthly fluctuations, Actavis retained the ability to maintain very high market shares by value and volume. Its volumes, though declining overall, remained the highest of any market player. The combination of its continued pricing freedom and enduring volume share resulted in its maintenance of a very large value share throughout the Post-Entry Period.

¹⁴²² Compare T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 288: the Court considered that AstraZeneca remained dominant in Germany, observing that although the data in Germany showed '*an uninterrupted downward trend in AZ's market share, it was still very significant in 1997 (53.99%). A dominant position may be presumed from market shares above 50%*'. In this case the downward trend in Actavis's market share was not uninterrupted.

prove that an undertaking is not dominant – especially where, as here, market shares remain high at the end of the relevant period.¹⁴²³ In fact, the decline in Actavis's market shares was not uninterrupted or inexorable, as demonstrated by figures 4.13 to 4.16.

- 4.253. In particular, the decline of Actavis's market share was more significant in volume than in value terms. Although value and volume market shares are both relevant measurements for assessing market power, the differentiated nature of full and skinny label tablets means that value market shares better reflect the relative position and strength of each supplier in the Post-Entry Period.¹⁴²⁴ As explained in paragraph 4.249, Actavis's value shares were very high throughout the Post-Entry Period, and usually above 60%. Even in volume terms, Actavis's share of supply of 10mg and 20mg hydrocortisone tablets respectively were usually above 50% throughout.
- 4.254. Therefore, although in volume terms the decline of Actavis's market share was more extensive than in value terms, it was able to maintain its market position in volume and especially in value terms at a very high level. Despite competitors taking sales volumes, Actavis's hydrocortisone tablets were able to generate revenue for Actavis at far higher levels than competitors were able to achieve from their sales (as a result of the price premium it was able to charge over competitors' prices) and is more relevant for the assessment of its market power than the fact that its sales volumes declined.¹⁴²⁵
- 4.255. Given that Actavis's shares remained at high levels throughout the Post-Entry Periods, and in the light of the factors explained in the following sections, the decline in Actavis's market shares does not indicate that it lost the **appreciable** independence which is the hallmark of dominance.

Relative market shares

- 4.256. Figures 4.13 to 4.16 show not only that Actavis retained a particularly high market share but also that it retained its preponderant market position as its

¹⁴²³ T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 223 to 224: though British Airways' market share fell below 40%, 'the reduction in BA's market share cannot, in itself, constitute proof that there is no dominant position' given BA's continued preponderance on the market and the gap to its rivals' shares. See also T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraphs 103 and 104; T-24/93 *Compagnie Maritime Belge Transports v Commission*, paragraph 77. See also Case AT.39612 *Perindopril (Servier)*, recitals 2107, 2329-2330, 2566-2568, 2593, where Servier retained its dominant position in France despite its volume share 'diminishing continuously from the first generic entry'.

¹⁴²⁴ European Commission Notice on market definition, paragraph 55: 'In cases of differentiated products, sales in value and their associated market share will usually be considered to better reflect the relative position and strength of each supplier'. See also Commission decision COMP/A.37.507/F3 *AstraZeneca*, recitals 370 and 394. Compare OFT decision in Case CE/8931/08 *Reckitt Benckiser*, paragraph 5.8. See also Commission Decision IV/33.440 *Warner-Lambert / Gillette*, paragraph 22; and Commission Decision COMP/M.4747 *IBM/Telelogic*, paragraph 135.

¹⁴²⁵ Compare the European Commission's Decision in COMP/M.1846 *Glaxo Wellcome / Smithkline Beecham*, paragraph 106.

market shares were much higher than those of its competitors. Actavis maintained a substantial gap by value and by volume to its nearest competitor.¹⁴²⁶ This is an indicator of its continued substantial market power, which was out of all comparison to that of other market players.¹⁴²⁷

- 4.257. The evidence demonstrates that Actavis's competitors had unstable market shares, where new entrants initially obtained a higher market share before dropping following entry of other suppliers. This is indicative of a high degree of rivalry amongst new entrants. However, the fact that these market share fluctuations were primarily among new entrants but had less impact on Actavis's more stable market shares confirms that, as the market developed, skinny label tablet suppliers competed more meaningfully with one another for the contestable portion of the market (sales to customers who were prepared to purchase skinny label product, see section 4.C.II.c.iii below) rather than with Actavis.¹⁴²⁸
- 4.258. The shares attained by Actavis's competitors were unstable throughout the Post-Entry Period, and there was greater volatility in those shares as compared with Actavis's more stable shares.
- 4.259. No individual competitor succeeded in increasing its market share over a sustained period, indicating that no competitor gained sufficient market power to constrain Actavis to an appreciable extent. Competitors' shares (by either value or volume) were usually in the range of 10-20% and rarely above 30% and therefore remained substantially lower than Actavis's shares of above 60% (by value). There was also considerable month-to-month variation in competitors' shares.
- 4.260. For 10mg hydrocortisone tablets, the highest value share attained by an individual competitor during the Post-Entry Period was 30% by Alissa in February 2016. However, after entry by Bristol Laboratories and Resolution Chemicals, Alissa's value share dropped to 7% in May 2016 and remained below or around 10% for the rest of the Post-Entry Period. In volume terms, Resolution Chemicals achieved the highest volume share of a competitor at

¹⁴²⁶ Compare T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 224-225.

¹⁴²⁷ Compare T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 253.

¹⁴²⁸ As figures 3.14 and 3.15 show, skinny label tablet suppliers competed more closely with each other on price than with Actavis. For example, Alissa stated that it considered Teva and Bristol Laboratories to be its main competitors and added that it did not think that it and Actavis was '*operating on a level playing field*'. See Document 01553, Alissa's response to question 8 of the CMA's section 26 notice dated 4 May 2016. Consistently with this, DE Pharma told the CMA that Actavis did not compete on price with skinny label tablet entrants and that price competition between skinny label tablet suppliers increased as more skinny label tablet suppliers entered. See Document 206579, note of call with DE Pharma on 23 February 2021, paragraphs 2.6 and 2.10.

28% in May 2016, but this fell to 2-3% several months later when it changed its pricing strategy.¹⁴²⁹

- 4.261. For 20mg hydrocortisone tablets, Waymade achieved the highest value and volume share of any individual competitor. Its average value share over the period in which it was the only other supplier of 20mg hydrocortisone tablets (August 2015 to February 2016) was 31% but Waymade did not retain this high share: its value share declined to 5% in June 2016, following entry by skinny label suppliers in March 2016.¹⁴³⁰

ii. Pricing behaviour and financial performance

- 4.262. Actavis's pricing behaviour and financial performance throughout the Post-Entry Period in themselves demonstrate that Actavis continued to hold substantial market power, and therefore a dominant position,¹⁴³¹ corroborating the strong evidential weight of its very large market shares.
- 4.263. As explained in section 3.F above, following entry, Actavis's prices followed a steady downward trend.
- 4.264. The decline in Actavis's prices must, however, be seen in the context of the extremely high levels from which they began. As explained above, by the point that independent entry began, Auden/Actavis had been regularly and significantly increasing its prices for nearly seven years. At their peak,¹⁴³² Auden/Actavis's price for both 10mg and 20mg hydrocortisone tablets reached around £72 per pack (compared with £22.08 per pack of 10mg tablets and £23.74 per pack of 20mg tablets in October 2008):¹⁴³³ an increase of 224% for 10mg hydrocortisone tablets and 204% for 20mg. Costs remained low, and in March 2016, when the downward trend began, Actavis's 10mg price exceeded costs, including a reasonable return, by over 3,000% (£70 per pack) (see section 5.C.IV). At the end of the Post-Entry Period, in July 2018, Actavis was still charging £20.23 for 10mg tablets, and, in December 2016, £40.76 for 20mg tablets.
- 4.265. As explained in the sections that follow, Actavis retained the ability to set its prices significantly above those of its competitors. These price patterns

¹⁴²⁹ Resolution Chemicals reduced its price from £52.19 in April 2016 to £31.17, less than half Actavis's May 2016 price (£68.13). In the following months, however, it increased its prices to levels approaching the average competitor price.

¹⁴³⁰ Similarly, Waymade's average volume share over the period in which it was the only other supplier of 20mg hydrocortisone tablets was also 31%. However, like its value share, Waymade's volume share subsequently declined following entry by skinny label suppliers and remained significantly lower than its highest level for the rest of the Post-Entry Period.

¹⁴³¹ Compare Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 68. See also Case No. IV/30.698 *ECS/AKZO*, paragraph 56 and Case E-2/36.041 *PO-Michelin*, paragraphs 197 to 199.

¹⁴³² In March 2016 for 10mg tablets, October 2015 for 20mg tablets.

¹⁴³³ That is, the start of the Unfair Pricing Abuses.

persisted despite the indirect constraint from the Drug Tariff mechanism on Actavis's pricing of 10mg hydrocortisone tablets during the Post-Entry Period. This pricing led to persistent and excessive rates of profit which demonstrates that Actavis continued to hold a dominant position in the relevant market(s) throughout the Post-Entry Period.

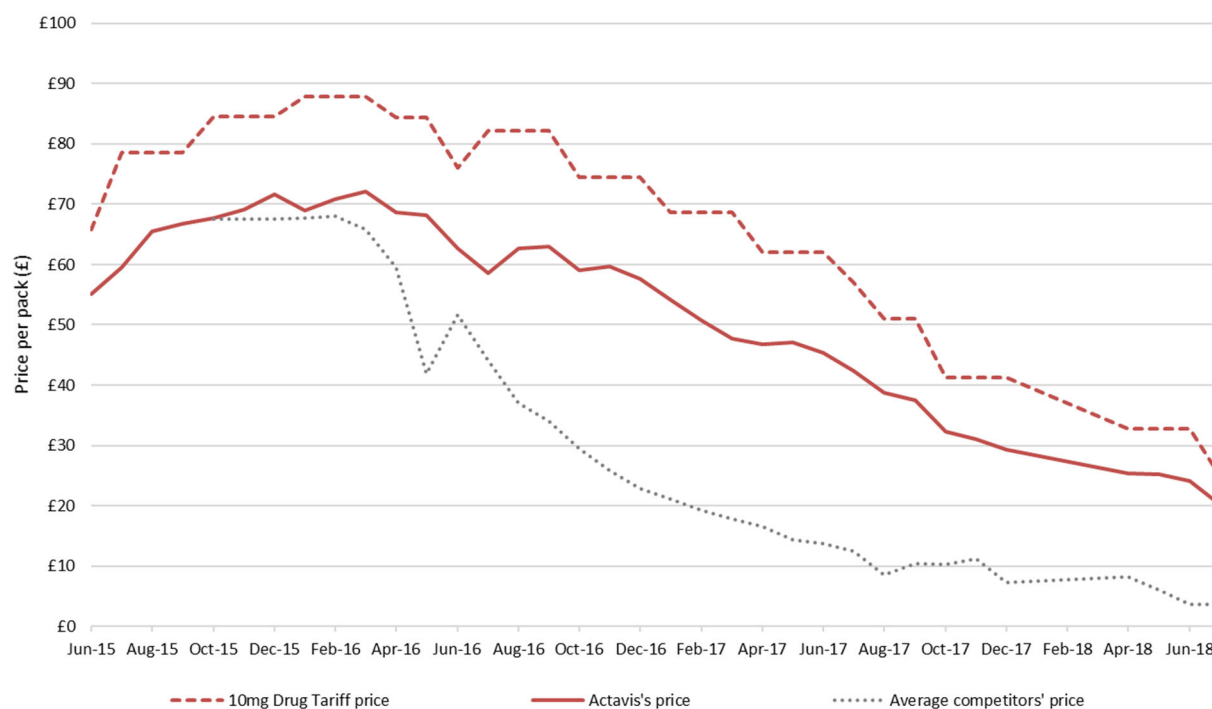
- 4.266. These measures of Actavis's pricing behaviour and financial performance provide mutually reinforcing indicia of its continued dominance throughout the Post-Entry Period.

Pricing behaviour

- 4.267. Throughout the Post-Entry Period, Actavis retained the ability to price significantly above its competitors, as demonstrated by significant absolute and relative price differentials. That Actavis maintained significantly higher prices than its competitors whilst retaining much higher market shares (especially during a period where competition following entry was causing prices to fall as entrants competed to win sales) demonstrates Actavis's ability to exercise substantial market power. This therefore demonstrates that its behaviour remained appreciably independent of competitive constraint.
- 4.268. Figures 4.17 and 4.18¹⁴³⁴ below show the development of Auden/Actavis's prices and competitors' average selling prices of 10mg and 20mg hydrocortisone tablets respectively during the Post-Entry Period.

¹⁴³⁴ Figure 4.17 shows the same prices for Auden/Actavis and average competitors as figure 4.1, but for the Post-Entry Period only.

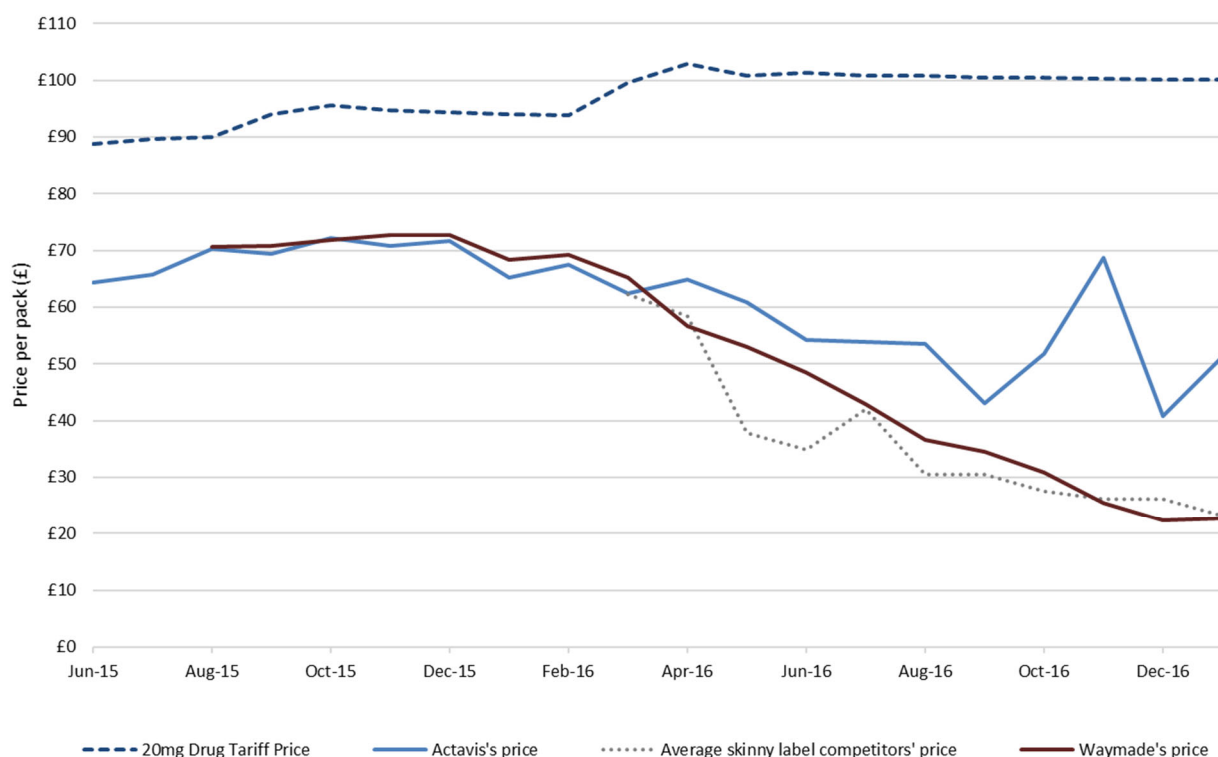
Figure 4.17: Prices and Drug Tariff prices of 10mg hydrocortisone tablets during the Post-Entry Period



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

Note: The average competitors' price is weighted by volumes sold.

Figure 4.18: Prices and Drug Tariff Prices of 20mg hydrocortisone tablets during the Post-Entry Period



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

Note: The average competitors' price is weighted by volumes sold.

4.269. The differences between Actavis's prices and those of its competitors in both absolute and relative terms¹⁴³⁵ during the Post-Entry Period for 10mg and 20mg tablet strengths are shown in figures 4.19 and 4.20 respectively below.

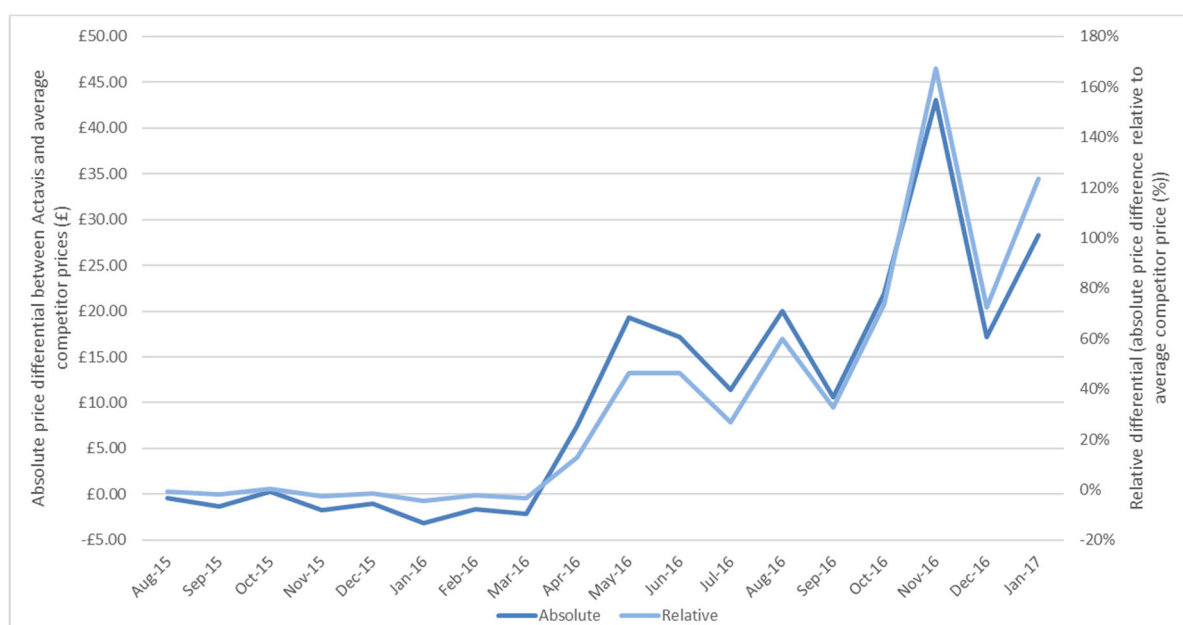
¹⁴³⁵ The CMA has calculated the price differential relative to the weighted average of competitors' selling prices (weighted by volumes sold). However, the result does not change materially were the calculation based on the price differential relative to Actavis's closest competitor on price, because competitors' average prices were all similar without a large spread.

Figure 4.19: Difference between Actavis's and average competitors' prices for 10mg hydrocortisone tablets during the Post-Entry Period



Source: CMA analysis based on data submitted by relevant parties.

Figure 4.20: Difference between Actavis's and average competitors' prices for 20mg hydrocortisone tablets during the Post-Entry Period



Source: CMA analysis based on data submitted by relevant parties.

4.270. The downward trend in prices shown in Figures 4.17 and 4.18 shows that Actavis experienced some degree of constraint on its pricing ability. This constraint is consistent with the finding that full and skinny label

hydrocortisone tablets are in the same relevant market (see section 4.B.II.c.ii above). Actavis's declining prices are not, however, incompatible with it holding a dominant position. As explained in section 4.C.I above, dominance does not imply the absence of any competitive constraint, or that the undertaking has '*eliminated all opportunity for competition*'.¹⁴³⁶ The question is whether the undertaking retains '*preponderant strength in relation to its competitors, even when allowance is made for some competition*'.¹⁴³⁷ Despite independent entry, Actavis's pricing behaviour continued to be consistent with the **appreciable** independence which is the hallmark of dominance.

- 4.271. Figures 4.14 to 4.17 show that, despite declining prices throughout the Post-Entry Period (with declines starting from April 2016), Actavis consistently maintained a substantial premium above the prices of its competitors (because competitors' prices declined at a faster rate). Moreover, this premium increased in relative terms throughout the Post-Entry Period. The ability to maintain a premium is particularly significant in the relevant markets. As explained in section 3.D.I above, hydrocortisone tablets are generic, bioequivalent products, such that this continued premium reflects Actavis's continued significant market power rather than intrinsically greater value in its products (see section 5.D.IV below).
- 4.272. Figures 4.17 and 4.19 show the following price trends for 10mg hydrocortisone tablets:
- a. Although Actavis's price started to decrease following entry by further suppliers in March 2016,¹⁴³⁸ its competitors' prices decreased at a faster rate.
 - b. As a result, the premium Actavis charged over its competitors' prices increased substantially, peaking at **£34.75** in December 2016 and remaining very large (**£16.60**) even at the end of the Post-Entry Period in July 2018.
 - c. These significant absolute differences between Actavis's prices and its competitors' prices, particularly in the context of declining prices overall, meant that the relative price difference was growing throughout the period. Actavis charged a premium of, **on average, 145%** of its competitors' average prices during the Post-Entry Period, and its price

¹⁴³⁶ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 113. See also Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 39.

¹⁴³⁷ C-322/81 *Michelin NV v Commission*, paragraph 52.

¹⁴³⁸ In addition to Alissa's entry in October 2015, see table 3.13 in facts for entry details.

had reached a level of **over five times** its competitors' average price by July 2018.

4.273. Figures 4.18 and 4.20 show the following price trends for 20mg hydrocortisone tablets:

- a. The first competitive entrant (Waymade, a full label tablet supplier) initially set its prices around the same level as Auden. However, from April 2016 onwards Actavis was able to maintain a substantial premium over its competitors – including Waymade (whereas competition among Actavis's competitors led to their prices falling, Actavis's prices did not fall as fast, demonstrating that Actavis was able to act appreciably independently).
- b. Actavis's premium remained significant during the Post-Entry Period, peaking at **£43.03** in November 2016. In fact, the premium to its competitors' average prices increased in the second half of 2016, to **around £21** on average over that period.
- c. These absolute price differences meant that the relative price difference grew throughout the period, such that by December 2016, at the end of the Post-Entry Period for 20mg tablets, Actavis was still charging **£40.76** for 20mg tablets: **nearly twice** its competitors' average prices and **1.5 times** the price of its nearest competitor.¹⁴³⁹ Actavis charged a premium of, **on average, 23%** of its competitors' average prices during the Post-Entry Period.

4.274. It is also important to consider these price trends in the context of the changes in market shares as set out in section 4.C.II.c.i above. Actavis's market share declined initially at a time when the absolute and relative premium between its price and that of its competitors was growing (particularly for 10mg hydrocortisone tablets). However, Actavis's market shares then stabilised, at a time when its competitors' prices continued falling faster than its own prices. This is direct evidence that Actavis was not losing any market share despite its competitors' tablets becoming relatively cheaper in relation to its own, and provides a strong demonstration that Actavis retained an ability to price above competitive levels, thereby demonstrating its market power.

4.275. As the number of entrants increased and competition intensified within both the 10mg and the 20mg hydrocortisone tablets markets, Actavis's price premium increased relative to its competitors. This is not the pattern that

¹⁴³⁹ Resolution Chemicals, with an average selling price of £26.71.

would be expected if competitors were able to appreciably constrain Actavis's conduct: instead, it would be expected that as more competitors entered, competition would become more intense between **all** suppliers and erode Actavis's ability to charge a premium over its competitors' prices. The increasing premium in the face of entry therefore demonstrates Actavis's ability to act appreciably independently of its competitors.

Financial performance

- 4.276. Throughout the Post-Entry Period, Actavis also retained the ability consistently to persistently earn an excessive rate of profit, notwithstanding entry.¹⁴⁴⁰ This, together with Actavis's ability to retain a price premium above competitors, shows the durability of Actavis's substantial market power.
- 4.277. As explained below, throughout the Post-Entry Period, notwithstanding the decline in prices, Actavis's exercise of pricing power enabled it persistently to earn supernormal profits.¹⁴⁴¹ These were returns that did not represent a return on previous innovation, since Auden acquired the hydrocortisone tablet MAs rather than invented the drug, nor did it make any investments in hydrocortisone tablets, (see section 5.D.II.b.ii below):¹⁴⁴²
- a. As a result of the price it charged, Actavis earned profits in excess of costs, including a reasonable rate of return, in percentage terms of between approximately 1,000% and 3,000%¹⁴⁴³ for 10mg hydrocortisone tablets, and between approximately 1,250% and 2,500%¹⁴⁴⁴ for 20mg throughout the Post-Entry Period.¹⁴⁴⁵
 - b. This resulted in profits in excess of costs, including a reasonable rate of return, in real terms of around [£] for 10mg hydrocortisone tablets, and around £3 million for 20mg hydrocortisone tablets. Though profits declined as a result of the price falls since entry, they remained very high.
 - c. Actavis's gross margins remained over [£] % for both 10mg and 20mg tablet strengths, despite entry.¹⁴⁴⁶

¹⁴⁴⁰ *Assessment of market power guidelines* (OFT415), paragraph 6.5.

¹⁴⁴¹ *Assessment of market power guidelines* (OFT415), paragraph 6.6; Case IV.30.787 *Eurofix-Bauco v Hilti*, paragraph 71. Compare Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraph 249; and Case AT.39612 *Perindopril (Servier)*, recitals 2579 to 2580, 2595 and 2598.

¹⁴⁴² *Assessment of market power guidelines* (OFT415), paragraph 6.5.

¹⁴⁴³ Peaking at around 3,150% in December 2015

¹⁴⁴⁴ Peaking at around 2,500% in October 2015

¹⁴⁴⁵ See section 5.C.

¹⁴⁴⁶ For example, in the period from May 2016 to January 2018 during which several competitors entered, its gross margin for 10mg hydrocortisone tablets was stable at [£]-[£] % (leading to average gross profits of £[£] per month in the second half of 2016; approximately £[£] per month thereafter).

The limitations of the Drug Tariff mechanism

- 4.278. In the UK, the Drug Tariff can, in principle, provide a constraint on the pricing of suppliers, since it caps the price that pharmacies can recoup for dispensing.¹⁴⁴⁷ Although the Drug Tariff provided some constraint on Actavis's 10mg hydrocortisone tablet pricing during the Post-Entry Period,¹⁴⁴⁸ that constraint was not sufficient to prevent Actavis's 10mg hydrocortisone tablets prices from profitably remaining at levels much higher than its competitors throughout the Post-Entry Period, as set out above.
- 4.279. Throughout the Post-Entry Period, 10mg hydrocortisone tablets were in Category M of the Drug Tariff.¹⁴⁴⁹ As explained in section 3.E.I.b above, Category M reimbursement prices were set using a weighted average of retrospective sales and volume data, that is, retrospective **net** prices (average selling prices)¹⁴⁵⁰ supplied by members of Scheme M¹⁴⁵¹ (that is, a subset of suppliers in the market).¹⁴⁵² This inclusion of other suppliers' prices in the Drug Tariff calculations created an indirect constraint on Actavis's prices for 10mg hydrocortisone tablets.
- 4.280. This indirect constraint – over time – acted to reduce Actavis's prices even within its assured base. This is because where the Drug Tariff price (which acts as a ceiling on the prices that suppliers can charge¹⁴⁵³ (see section 3.B.IV above)) is set by reference to suppliers' selling prices, direct price competition between suppliers will result in lower prices feeding into the Drug Tariff price calculation. This inclusion of other suppliers' prices in the

¹⁴⁴⁷ Both suppliers and wholesalers set their prices at a discount to the Drug Tariff. Accord-UK explained that its '*net selling prices for Hydrocortisone Tablets will always be below the Drug Tariff*' (Document 02238, Intas, Accord and Accord-UK's response to the CMA's section 26 notice dated 20 December 2017, response to question 1). Wholesalers such as Alliance '*will try to sell the product at a discount to Drug Tariff (because that is the price at which customers are reimbursed and they are therefore looking to achieve a discount to this price)*'. Document 02202, Alliance's response to the CMA's section 26 notice dated 19 December 2017, responses to questions 1, 4, 7 and 10.

¹⁴⁴⁸ During the Pre-Entry Period, the Drug Tariff did not impose any constraint on Auden. That is because the Drug Tariff price was based only on the prices of Auden's hydrocortisone tablets (via those set by its customers), since it was the only supplier in the market. That remained the case for 20mg tablets during the Post-Entry Period because 20mg tablets remained within Category A, which meant that the Drug Tariff price was set based on wholesalers' and manufacturers' list prices (that is, the price before customer-specific discounts or rebates). This is illustrated in figure 4.18 where the Drug Tariff price of 20mg hydrocortisone tablets remained high and unaffected by other suppliers' selling prices, despite the downward price trend in the market.

¹⁴⁴⁹ 10mg hydrocortisone tablets moved into Category M in July 2014 – a year before the entry of competing independent products into the market – and remained in Category M until the end of the Infringements.

¹⁴⁵⁰ Retrospective sales and volume data will be net of any discounts or rebates from list prices given by suppliers.

¹⁴⁵¹ Actavis, which took over sales of hydrocortisone tablets from Auden in September 2015, was a Scheme M member. Of its competitors only AMCo, Teva and Genesis Pharmaceuticals were also Scheme M members during the Post-Entry Period.

¹⁴⁵² See, for example, Document 01987.B, DHSC presentation '*Category M method*' dated September 2016, slide 4; Document 02664.E, spreadsheet with data, calculation and explanation of Category M Drug Tariff price for 10mg hydrocortisone tablets.

¹⁴⁵³ As explained at footnote 1448 above, when there were no other suppliers the Drug Tariff price did not act as a ceiling on Auden's prices as it increased in line with those prices (without there being other suppliers to influence the Drug Tariff Price).

Drug Tariff price calculation meant that the Drug Tariff price entered a downward trajectory reflecting the more rapidly falling prices of the other suppliers (see paragraph 4.271 above), together with Actavis's own falling prices.

- 4.281. Therefore, during the Post-Entry Period, suppliers of skinny label 10mg hydrocortisone tablets posed both a direct and an indirect competitive constraint on Actavis:
- a. a direct constraint, from suppliers of skinny label tablets competing directly with Actavis for sales;¹⁴⁵⁴ and
 - b. an indirect constraint, from suppliers' selling prices contributing to the calculation of the Drug Tariff price of 10mg hydrocortisone tablets, which in turn acted as a ceiling on the prices of suppliers in the market. This is illustrated in figure 4.17 which shows that Actavis's prices declined on a similar trajectory to the Drug Tariff price of 10mg hydrocortisone tablets during the Post-Entry Period.
- 4.282. However, the way the Drug Tariff price was calculated limited the extent of this constraint, which reinforced Actavis's ability to sustain prices above its competitors during the Post-Entry Period. In particular, the extent of this indirect constraint was limited by the fact that most skinny label tablet suppliers were not members of the voluntary Scheme M. That meant that their price and sales data did not contribute to the calculation of the Drug Tariff price for 10mg tablets.¹⁴⁵⁵
- 4.283. This limited the indirect constraint on Actavis's pricing because the reimbursement price did not decrease as quickly as it would have, had all of Actavis's competitors been Scheme M members (since competitors were pricing at lower levels than Actavis so the average price data informing reimbursement prices would have been lower).
- 4.284. Intas/Accord-UK acknowledged that the way the Drug Tariff price for 10mg hydrocortisone tablets was calculated limited the extent of this constraint in a letter to the DHSC dated 7 December 2017. Intas/Accord-UK wrote to the DHSC suggesting that it request information on supply prices from non-Scheme M members on a voluntary basis, to use in formulating the Drug

¹⁴⁵⁴ However, the direct constraint was limited by the orphan designation, which provided Actavis with an assured customer base, as explained in section 4.C.II.c.iii below.

¹⁴⁵⁵ The DHSC has since revised the method it uses to calculate the Drug Tariff, and now takes all suppliers' prices into account.

Tariff price for 10mg hydrocortisone tablets, which '*would quickly lower the latter and reinforce the competitive process*'.¹⁴⁵⁶

- 4.285. By making this suggestion, Intas/Accord-UK acknowledged the limitations of Scheme M to reflect competition for 10mg hydrocortisone tablets and that the extent of the constraint on Actavis from the Drug Tariff price was limited.
- 4.286. Intas/Accord-UK's suggestion to the DHSC further shows that Actavis's conduct was not, at the time, sufficiently constrained by its competitors. If competition from competing suppliers of 10mg hydrocortisone tablets was effective in constraining Actavis's price it would not have been necessary for Intas/Accord-UK to suggest that the DHSC take action to '*reinforce*' the '*competitive process*' to make the constraint from the Drug Tariff price more effective.
- 4.287. It was also the case that Actavis did not need to rely on the Drug Tariff price to lower its price – it could have simply decided to lower its price, which would have acted to lower the Drug Tariff price (given that Actavis was a Scheme M member and its selling price fed into the Drug Tariff price calculations, and in fact, would have had a significant impact since its price had a large weight due to its volume market share). Actavis not taking unilateral action and instead suggesting that the DHSC take action reflected the fact that Actavis was even at that stage able to act appreciably independently of its customers and the end consumer and that the extent of the constraint coming from the Drug Tariff price was limited.

iii. Market context – the barrier created by the orphan designation and Actavis's assured customer base

- 4.288. As set out in section 3.B.III above, when a drug is in the third stage of the drug lifecycle, independent entry can usually be expected to lead to significant erosion of an incumbent's market power.¹⁴⁵⁷ However, as explained in sections 4.C.II.c.i and 4.C.II.c.ii above, following independent entry in the markets for 10mg and 20mg hydrocortisone tablets, Actavis retained its preponderant market position, holding substantial market shares and charging prices significantly above its costs and its competitors' prices. The CMA has concluded that the orphan designation granted in respect of

¹⁴⁵⁶ Document 02194, Intas letter to the DHSC dated 7 December 2017.

¹⁴⁵⁷ In fact, the erosion of Actavis's premium (and market share) is not, however, analogous to the process of competition following the loss of exclusivity of a patented product: in the hydrocortisone tablets markets, all suppliers are generic, which would suggest that a faster erosion of prices and market shares could be expected than where a branded product is competing with generic equivalents.

Plenadren was a key factor contributing to this ability because it formed a barrier to expansion and provided Actavis with an assured customer base.

- 4.289. As explained in section 3.D.III.c above, the orphan designation for Plenadren meant that:
- a. For 10mg hydrocortisone tablets, only Auden/Actavis had a full label MA and was, therefore, the only option for those customers who purchased only (or only material quantities of) full label tablets.
 - b. For 20mg hydrocortisone tablets, only Auden/Actavis and Waymade had full label MAs.
- 4.290. Despite full and skinny label hydrocortisone tablets being bioequivalent (see section 3.D.I above) and the vast majority of prescriptions being open (see section 3.E.III.a above), the effect of the orphan designation was to create two differentiated versions of hydrocortisone tablets: full and skinny label tablets.
- 4.291. While many customers viewed full label and skinny label tablets as substitutes,¹⁴⁵⁸ the regulatory circumstance of the orphan designation granted to Plenadren meant that a significant proportion of the market had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets (see section 3.E.IV.c.i.). This meant that, as a result of regulatory circumstance and the decisions of pharmacies and wholesalers, Actavis had an assured customer base accounting for a significant proportion of 10mg hydrocortisone tablets sales in the UK.¹⁴⁵⁹
- 4.292. As explained in section 4.B.II.c.ii above, a significant number of customers,¹⁴⁶⁰ accounting for a substantial portion of demand (around 50% of total purchases by volume), continued to purchase Actavis's product. Eight of the ten largest pharmacy groups – Asda, Boots, Lloyds, Morrisons, Rowlands, Sainsbury's, Superdrug and Well – all purchased only, or to a material extent only, full label hydrocortisone tablets during the Post-Entry Period. These customers continued to purchase Actavis's product despite its much higher price (a price difference of 145% on average above skinny label prices during the Post-Entry Period) and in doing so, those customers were foregoing a significant amount of profit.

¹⁴⁵⁸ See section 4.A.III above.

¹⁴⁵⁹ See figure 4.4 above.

¹⁴⁶⁰ Intas/Accord-UK submitted that Accord-UK's position was [X] (Document 205212, Intas/Accord-UK's RSSO paragraphs 74). Intas/Accord-UK's assertion that Accord-UK's share would be [X] amounts to a hypothetical scenario and which is not supported by evidence. On the evidence, these customers did not switch.

- 4.293. Therefore, the orphan designation's key impact on the 10mg hydrocortisone tablets market in the Post-Entry Period was as a barrier to expansion because competitors could only compete for and supply customers that were prepared to purchase skinny label tablets, but not those who had no choice but to purchase full label tablets. The orphan designation therefore rendered a significant portion of the 10mg hydrocortisone tablets market *de facto* incontestable for skinny label tablet suppliers during the Post-Entry Period and provided Actavis with an assured customer base.
- 4.294. The assured customer base that Actavis enjoyed as a result of regulatory circumstance effectively provided a floor to the erosion of its sales volumes. This resulted in a significant market impact: as the only supplier of full label 10mg hydrocortisone tablets (with 10mg tablets accounting for 96% of the total volumes of hydrocortisone tablets dispensed) and one of only two suppliers of full label 20mg tablets (the other being Waymade), Actavis was able to retain [✂] significant price premium above its competitors'.
- 4.295. The fact that customers continued to purchase full label tablets from Actavis despite its substantial price premium (see figure 4.19 above) is a strong demonstration that Actavis retained dominance in the Post-Entry Period. As explained in section 4.B.I.b.ii above, where '*customers continue to buy more goods from [the undertaking] which is the dearest vendor*', this is '*a particular feature of the dominant position*' which is more significant than its overall profit margin and may, in context, be '*determinative*' of the question of dominance.¹⁴⁶¹ In this case, customers' continued purchasing of the dearest product by quite some margin is cogent evidence of Actavis's dominance.¹⁴⁶²
- 4.296. The fact that Actavis's hydrocortisone tablets were full label was therefore a critical factor in its ability to maintain a substantial price premium over competitors during the Post-Entry Period. This advantage resulted not from any innovation by Auden/Actavis (see section 5.D.II.b.ii), but as a result of regulatory circumstance. Auden/Actavis derived a competitive advantage simply because it happened to have existing MAs when Plenadren was granted MAs.
- 4.297. The size or existence of Auden/Actavis's assured base may have been strengthened by Project Guardian – in which it sought to ensure customers would purchase only full label tablets (see section 3.F.III.h above). This

¹⁴⁶¹ Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 126 to 128.

¹⁴⁶² Compare T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 217 to 219: this means that neither the possibility that Actavis may sell lower volumes to other large customers, nor fluctuations in its total market share, call into question a finding of dominance, since it had an assured base of demand.

project had some limited success with certain customers, but was unsuccessful with others (see section 3.F.III.i above).

4.298. In relation to 20mg tablets, although Waymade also supplied a full label product and therefore provided customers with an alternative full label supplier, Actavis retained a substantial premium over competitors, including Waymade, during the Post-Entry Period. The evidence shows that while some customers, notably AAH and Alliance (see paragraph 4.346), were able to use the threat to switch to Waymade to negotiate a lower supply price from Actavis, and on one occasion did switch purchases to Waymade,¹⁴⁶³ this did not provide enough competitive constraint to undermine Actavis's position of dominance in the Post-Entry Period. Moreover, Waymade itself never obtained a sufficient market share in the 20mg tablets market to materially challenge Actavis's market power (its share by volume did not exceed 31% during the Post-Entry Period and was often substantially below this level).

iv. Representations on dominance in the Post-Entry Period

'There was widespread market entry'

4.299. Intas/Accord-UK¹⁴⁶⁴ submitted that widespread market entry of skinny label suppliers during the Post-Entry Period shows there were no effective barriers to entry¹⁴⁶⁵ in the supply of hydrocortisone tablets, and new entrants took a market share which prevented Actavis from maintaining its prices.¹⁴⁶⁶ Intas/Accord-UK further submitted that market shares do not establish dominance, and in particular, submitted that:¹⁴⁶⁷

- a. Recent market entry should rebut any presumption of dominance as it provides evidence of the competitive process that occurred with new entry and sharp falls in prices.
- b. Although Actavis's share by volume remained constant, its share by value fell as revenues were in constant decline.

¹⁴⁶³ For example, from October 2016 to January 2017, AAH switched its supply of 20mg hydrocortisone tablets to Waymade, after Actavis refused to match Waymade's price. Document 02707, AAH response to the CMA's section 26 notice of 7 February 2018, response to question 2.

¹⁴⁶⁴ All of Intas/Accord-UK's representations focussed on the 10mg hydrocortisone tablet market (as the 20mg Unfair Pricing Abuse ended prior to Intas/Accord-UK's ownership period).

¹⁴⁶⁵ Auden/Accord similarly submitted that *'a high market share cannot be indicative of dominance in the absence of insurmountable barriers to entry'*. Document 205217, Auden/Accord's RSSO, paragraph 3.75.

¹⁴⁶⁶ Document 205212, Intas/Accord-UK's RSSO, paragraphs 42-46. Auden/Accord also submitted that *'Auden, and later Accord-UK, has lost significant market share in the face of entry from multiple participants'*, Document 205217, Auden/Accord's RSSO, paragraph 3.75. See also Document 206676, Intas/Accord-UK's RLOF, paragraph 7 and pages 5-6.

¹⁴⁶⁷ Document 205212, Intas/Accord-UK's RSSO, paragraphs 60-67.

- 4.300. Despite the market entry of skinny label suppliers, the CMA finds that Auden/Actavis's 10mg shares remained high, reasonably stable, and much higher than competitors' (see section 4.C.II.c.i above). The presumption of dominance continues to apply even in circumstances where market shares are decreasing (as explained in section 4.C.I.a.i above).
- 4.301. In any event, that presumption is corroborated by additional evidence. Though overall values declined, Actavis was still able to maintain a price premium above competitors. As set out at section 3.E.IV.c.i, a significant proportion of the larger pharmacy chains (accounting for around 50% of total volumes) had no choice but to purchase Auden/Actavis's tablets and were not able to switch to skinny label tablets. This acted as a barrier to expansion for skinny label tablet suppliers and gave Auden/Actavis an assured customer base that enabled it to maintain prices significantly in excess of those charged by its competitors (a substantial premium of **five times** competitors' prices at the end of the Post-Entry Period) while maintaining significant market shares.

'Falling prices demonstrate Auden/Actavis was not dominant'

- 4.302. Intas/Accord-UK submitted that prices fell by almost 65% during the '*Intas Period*' (ie the period from 9 January 2017, when Accord-UK was owned by Intas) which, it submitted, is contrary to the fundamental hallmark of dominance which is the ability to maintain prices for a sustained period of time. Intas/Accord-UK further stated that this pricing trend is consistent with a normal competitive process in pharmaceutical markets where prices and volumes of the incumbent fall following generic entry, and that prices were on an irreversible trajectory of constant and significant decline, with market forces self-correcting.¹⁴⁶⁸ Similarly, Auden/Actavis submitted that the persistent reductions in Actavis's prices during the period following entry are indicative that Actavis was not in a position to act independently of its competitors and customers (beyond March 2016).¹⁴⁶⁹
- 4.303. However, one indication of dominance is the ability to profitably sustain prices above competitive levels: Actavis's ability to do so was demonstrated by its price premium above competitors. The legal test requires **appreciable** freedom from constraint and does not require monopoly or the absence of any competition or complete pricing freedom to raise prices entirely unconstrained.

¹⁴⁶⁸ Document 205212, Intas/Accord-UK's RSSO, paragraphs 47-52 and 87-92, and 100. See also Document 206676, Intas/Accord-UK's RLOF, paragraph 7 and page 7.

¹⁴⁶⁹ Document 205217, Auden/Actavis's RSSO, paragraphs 3.74-3.78. See also Document 206667, Auden/Actavis's RLOF, paragraphs 3.42-3.46.

- 4.304. Despite falling prices and volumes, Actavis retained the ability to price at a substantial premium above competitors and at a profit, demonstrating market power. Although both prices and the absolute premium above skinny label prices were falling during the Post-Entry Period, this erosion did not prevent Actavis from charging **five times** its competitors' prices by the end of that period.
- 4.305. Further, the CMA does not consider that the development of the relevant markets is consistent with normal generic entry (as set out in section 3.B above). This is because the orphan designation granted to Plenadren gave rise to differentiation between full and skinny label tablets, thereby providing Auden/Actavis with an assured base and the ability to exercise market power (as set out at in section 4.C.II.c.iii above).
- 4.306. Moreover, the question of whether the market was self-correcting and would eventually have reached equilibrium after the Unfair Pricing Abuses ended is not relevant for establishing, or disproving, dominance during the Unfair Pricing Abuses. The evidence demonstrates that Auden/Actavis's market shares remained high and stable and it retained a substantial price premium above its competitors throughout the Post-Entry Period. The persistence of these features throughout the relevant period provides compelling evidence of Auden/Actavis's ability to behave to an appreciable extent independently of its competitors, its customers and ultimately of consumers.

'The Drug Tariff mechanism was a further constraint on prices'

- 4.307. Intas/Accord-UK submitted that the Drug Tariff ratchet provided an additional constraint, on top of competition from its competitors, on Actavis's freedom to set prices. Intas/Accord-UK submitted that the drug tariff ratchet '*worked*' and produced significant declines in prices, by January 2019 at the latest.¹⁴⁷⁰
- 4.308. Whilst the CMA agrees, as set out at paragraphs 4.278 to 4.287 above, that there was an indirect constraint on pricing arising from the Drug Tariff to some extent, the presence of this indirect constraint was not sufficient to remove the market power which Actavis enjoyed. In particular, a sizeable price premium to competitors' prices remained (during the period in which the CMA finds Auden/Actavis to be dominant): Actavis's prices were still **five times** those of its skinny label competitors by the end of the Post-Entry Period.

¹⁴⁷⁰ Document 205212, Intas/Accord-UK's RSSO, paragraphs 53-55, 66 and 93-98.

- 4.309. Moreover, one reason that the indirect constraint from the Drug Tariff did not undermine Auden/Actavis's dominance during the Post-Entry Period¹⁴⁷¹ is because the Scheme M calculation meant that Actavis faced a more limited constraint than had the Drug Tariff price taken whole market prices into account¹⁴⁷² (as explained in paragraphs 4.278 to 4.287 above). Indeed, Intas/Accord-UK acknowledged this when it wrote a letter to the DHSC which highlighted that the Drug Tariff did not provide a sufficient constraint on its pricing (it suggested that the DHSC request information on supply prices from all suppliers to use in formulating the Drug Tariff price for 10mg hydrocortisone tablets, which '*would quickly lower the latter and reinforce the competitive process*').¹⁴⁷³
- 4.310. Intas/Accord-UK submitted that the '*free choice*' of customers to continue to purchase from Actavis and to pay a (declining) premium for full label product does not establish dominance. Intas/Accord-UK noted that the same regulatory regime applied to all customers, and that '*a choice made "at discretion" does not give rise to dominance, either in fact or in law*'.¹⁴⁷⁴
- 4.311. As set out in section 3.E.IV.c.i above, the CMA considers that full label tablets are a differentiated product for which some customers had no choice but to purchase. Those customers were not able to switch to skinny label tablets, and so for those customers there were no alternatives. That sustained Auden/Actavis's market power because it was the only supplier of 10mg full label tablets. Further, the facts that the same regulatory regime applies to all customers or that dispensing is at the '*discretion*' of pharmacies does not undermine this position: it is evident that pharmacies reached differing positions on whether to dispense full or skinny label tablets, but both are reasonable positions to take and, once taken, do not imply an element of choice where there is only one supplier of the type of product in question (as was the case for full label 10mg hydrocortisone tablets, which only Auden/Actavis was able to supply due to the orphan designation granted to Plenadren).

¹⁴⁷¹ Further, the Drug Tariff mechanism itself will have disincentivised Actavis from making aggressive price reductions. This is because reductions in Actavis's own prices would lead to lower future Drug Tariff prices (especially since its prices had a substantial weight in the Drug Tariff price calculation given its overall share of volumes, and even greater share of the volumes being taken into account by the Scheme M calculation). Therefore, to avoid having to price too low in the future, it was in Actavis's interests to not reduce prices more than necessary in any given month.

¹⁴⁷² Document 205212, Intas/Accord-UK's RSSO states that Intas/Accord-UK assumes that Waymade and Bristol Laboratories (as BGMA members) were supplying prices to the DHSC (Document 205212, Intas/Accord-UK's RSSO, footnote 59). However, Waymade and Bristol Laboratories were not members of Scheme M at the relevant time so did not supply prices to the DHSC.

¹⁴⁷³ Document 02194, Intas letter to the DHSC dated 7 December 2017.

¹⁴⁷⁴ Document 205212, Intas/Accord-UK's RSSO paragraphs 68-76. See also paragraphs 107-111. See also Document 206676, Intas/Accord-UK's RLOF, paragraph 8 and page 6.

d. The absence of countervailing buyer power

- 4.312. The CMA has concluded that throughout the Infringements, Auden/Actavis was not effectively constrained by countervailing buyer power.
- 4.313. As explained in paragraphs 4.212 to 4.214 above, the Court of Appeal when refusing permission for Pfizer to appeal the CAT's *Phenytoin* judgment confirmed that when considering countervailing buyer power and specifically the issue of whether the DHSC had such power, as a matter of '[b]oth the case law and common sense' the focus should be on whether there is '**an effective constraint rather than the theoretical position**' (emphasis in original).¹⁴⁷⁵
- 4.314. The absence of an **effective** constraint – whether from the DHSC/NHS or from Auden/Actavis's intermediate customers – is clear from Auden/Actavis's pricing behaviour.¹⁴⁷⁶
- 4.315. As explained above:
- a. Auden/Actavis was able to increase its prices for hydrocortisone tablets by over 200%¹⁴⁷⁷ during the Infringements, despite low and stable costs and without losing volumes during the Pre-Entry Period.
 - b. Actavis was also able to maintain its prices significantly in excess of its competitors' during the Post-Entry Period (an average of 145% (for 10mg tablets) and 23% (for 20mg tablets) above competitors) and retain significant volume shares. This is not consistent with it facing a sufficient or effective countervailing constraint from the prospect of its customers switching supplier.¹⁴⁷⁸

¹⁴⁷⁵ Document PAD172, *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey, dated 12 December 2018. See also *National Grid v GEMA* [2009] CAT 14, paragraph 60; *Hutchison 3G v Ofcom* [2005] CAT 39, paragraphs 105(i), 100(c) and 126.

¹⁴⁷⁶ Compare Case IV.30.787 *Eurofix-Bauco v Hilti*, paragraph 71. See also Commission Decision in Case IV/30.178 *Napier Brown – British Sugar*, paragraph 55: British Sugar's ability to maintain price rises indicated its ability to behave to an appreciable extent independently of its competitors and customers. Compare the CAT's observation in *Genzyme* that: '*the very state of affairs which forms the subject matter of the present case itself indicates the ability of Genzyme to disregard the wishes of its customers and consumers*': *Genzyme v OFT* [2004] CAT 4, paragraph 257.

¹⁴⁷⁷ For 10mg tablets: an increase of 224% (or £49.86) from £22.28 in October 2008 (the month the 10mg Unfair Pricing Abuse started) to a peak of £72.14 in March 2016. For 20mg tablets: an increase of 204% (or £48.45) from £23.74 in October 2008 (the month the 20mg Unfair Pricing Abuse started) to a peak of £72.19 in October 2015.

¹⁴⁷⁸ Compare Case T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 266: '*the ability of AZ to maintain higher prices than those of its competitors, while retaining a much higher market share, shows that it was able to exercise market power in respect of price, since neither competing producers, nor social security systems, which bore the cost of the medicines, nor indeed patients, were able to force AZ to bring its prices into line with those of competing products.*' In this case the fact that Auden/Actavis's customers did not exert a sufficient degree of buyer power to countervail Auden/Actavis's market power in the supply of hydrocortisone

4.316. In the remainder of this section, the CMA further examines the factors that explain the absence of countervailing buyer power during the Infringements, considering (i) the NHS and the DHSC, and (ii) Auden/Actavis's intermediate customers.

i. The NHS and the DHSC

4.317. The end customer of Auden/Actavis's hydrocortisone tablets is generally the NHS – specifically CCGs, which must pay for the medicines prescribed to patients via the reimbursement price. The DHSC, which is responsible for the NHS, has certain reserve powers to intervene in generic drug pricing.

4.318. The CMA has concluded that Auden/Actavis's market power was not effectively constrained by the NHS or the DHSC during the Infringements. This is explained by the following factors:

- a. the fragmented composition of the NHS;
- b. the inability of the NHS to exercise choice; and
- c. the absence of an effective constraint from the powers available to the DHSC.

The fragmented composition of the NHS

4.319. The CAT pointed out in *Genzyme v OFT* that:

*'The "NHS" does not, however, exist as a corporate entity. In practice, the operation of the NHS is devolved to numerous executive or advisory bodies or agencies.'*¹⁴⁷⁹

4.320. The CAT went on to note that '*the largely decentralised structure of the NHS*' was a relevant factor in its conclusion that Genzyme held a dominant position.¹⁴⁸⁰

tablets is demonstrated by Auden/Actavis's ability to maintain prices significantly above costs and those of its competitors, while retaining a high market share. Compare the OFT's decision in *Reckitt Benckiser*, in which the fact that the undertaking's value market share remained above 70-80%, despite a competitor product being available at a significantly cheaper price, demonstrated that '*in reality the NHS has failed to exert countervailing buyer power*'. OFT decision in *Reckitt Benckiser* (CE/8931/08), paragraph 5.52.

¹⁴⁷⁹ *Genzyme v OFT* [2004] CAT 4, paragraphs 246-247. Compare the OFT decision in *Reckitt Benckiser* (Decision No. CA98/02/2011): '*the NHS is not in fact a single, large corporate entity*' (paragraph 5.51, noting that the CAT's observations in *Genzyme* apply more generally). Compare also the Competition Commission decision in the *Bournemouth/Poole* merger, in which the CC observed (in relation to hospital services) that in light of the '*split between those exercising choice and the commissioners that pay*', no party exercised a sufficient constraint to offset market power (*Final report on the anticipated merger of The Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust and Poole Hospital HS Foundation Trust*, paragraphs 7.2-7.5).

¹⁴⁸⁰ *Genzyme v OFT* [2004] CAT 4, paragraph 251.

- 4.321. The NHS comprises multiple different entities, which together form a fragmented and diffuse system that significantly limits the NHS's ability to exercise buyer power. For example:
- a. decisions as to the selection (prescribers) and dispensing (pharmacists) of drugs are not made by the entities responsible for paying for the drugs (CCGs);
 - b. the entities responsible for paying (CCGs) have no choice over whether to purchase or pay for drugs; and
 - c. the price payable by CCGs is not determined or agreed by CCGs, even though they are responsible for paying.
- 4.322. It is therefore overly simplistic to refer to '*the NHS*' as a '*customer*': it is a collection of many individual customers and organisations, particularly CCGs, each of which has its own budget and priorities. Indeed, NHS Clinical Commissioners ('**NHSCC**'), the membership organisation of CCGs, informed the CMA that:
- a. while there is a great deal of information on drug pricing available to CCGs, it is practically very difficult for them to collate and use it, meaning CCGs generally do not track when individual drug prices change;
 - b. because of the incremental nature of the price increases for hydrocortisone tablets, individual CCGs were unaware of them (notwithstanding that press coverage may have brought them to the attention of other individuals within the NHS); and
 - c. NHSCC has separate bilateral relationships with NICE, the DHSC and NHS England, but none of these relates to drug pricing.¹⁴⁸¹

The inability of the NHS to exercise choice

- 4.323. Even in circumstances where a buyer is a single, large corporate entity (which, as explained above, the NHS is not), this is not usually in itself sufficient for a purchaser to have buyer power. In order **effectively** to constrain an undertaking from exercising its market power, the buyer also typically has to have a choice as to whether to continue buying from the seller.¹⁴⁸²

¹⁴⁸¹ Document 01936, Note of call between CMA and NHSCC, 3 May 2017, paragraphs 10, 11, 13, and 37.

¹⁴⁸² OFT415 *Assessment of market power*, paragraph 6.1.

4.324. Neither the NHS, nor any of its constituent parts, was able to exercise such a choice during the Infringements. For the majority of the Infringements (around seven years), Auden was the sole supplier of hydrocortisone tablets. Although a number of other suppliers entered from July 2015 onwards, the introduction of competition did not give the NHS a choice: CCGs continued to have no option but to fund the hydrocortisone tablets dispensed, regardless of which supplier's product was dispensed.

4.325. In addition to its fragmented and diffuse structure, the NHS does not operate on a purely commercial basis. It has a duty to continue the promotion of a comprehensive health service designed to treat physical and mental illness.¹⁴⁸³ The scope of this role serves further to reduce the extent of any buyer power the NHS might otherwise possess if its priorities were commercial.

4.326. In *Genzyme v OFT*, the CAT observed that:

'in practice, once the prescribing decision is taken by the clinician, the NHS – in the form of the patient's local PCT [now CCG] – has little option but to fund the product.

*In those circumstances, in our view, even though the NHS is the only purchaser of Cerezyme, its bargaining position is relatively weak in the face of Genzyme's monopoly in the supply of that drug. If the NHS wishes to treat the highly vulnerable patients concerned, it has no alternative but to deal with Genzyme.'*¹⁴⁸⁴

4.327. In this case, CCGs are responsible for funding prescriptions for hydrocortisone tablets out of their prescribing budgets. However, CCGs have no choice as to which hydrocortisone tablets are dispensed or funded.

4.328. Once a particular medicine has been prescribed, pharmacies are bound to dispense it. Though pharmacies have discretion over which product to dispense against an open prescription, CCGs are bound to compensate pharmacies for whatever product they dispense, provided that the product dispensed is within the parameters of the prescription. CCGs do not negotiate the prices of hydrocortisone tablets with pharmaceutical suppliers or purchase the medicines directly from them.¹⁴⁸⁵ Moreover, CCGs have no formal powers enabling them to limit the price they pay for pharmaceutical

¹⁴⁸³ See section 1 of the National Health Service Act 2006.

¹⁴⁸⁴ *Genzyme v OFT* [2004] CAT 4, paragraphs 249-250.

¹⁴⁸⁵ Moreover, as the Drug Tariff does not distinguish between different hydrocortisone tablets of the same strength, both full and skinny label tablets are reimbursed at the same price.

products, nor are they able to influence the Drug Tariff price (ie the price they have to pay).

- 4.329. Given its legal duty, and the importance of hydrocortisone tablets as the first-line treatment for adrenal insufficiency, the NHS could not stop purchasing hydrocortisone tablets in favour of an alternative drug. In any event, there was no feasible alternative to hydrocortisone tablets during the Infringements.¹⁴⁸⁶
- 4.330. CCGs (and hence the NHS) therefore had no choice but to pay for Auden/Actavis's hydrocortisone tablets where they were dispensed.¹⁴⁸⁷

The absence of an effective constraint from the powers available to the DHSC

- 4.331. As explained in section 3.E.I.d above, the Secretary of State has certain powers to monitor and intervene in drug pricing in specific circumstances, in sections 261 to 266 of the NHS Act and arrangements entered into with industry pursuant to the NHS Act. These powers are discussed in this section on countervailing buyer power, because if he were to exercise these powers, the Secretary of State would be acting on behalf of the NHS as the organisation that ultimately pays for hydrocortisone tablets.
- 4.332. For the reasons set out below, the CMA has concluded that these powers – or the prospect of the DHSC using them, whether ‘*formally*’ or ‘*informally*’ – did not confer countervailing buyer power on the DHSC.
- 4.333. First, as explained in section 4.C.I.c.iii above, the CAT, the Court of Appeal, the European Commission and the European Courts have consistently held, in the pharmaceutical sector and in other sectors, that the prospect of ‘*regulatory*’ intervention does not negate the possibility of dominance.¹⁴⁸⁸

¹⁴⁸⁶ As explained in section 4.B.II.C.i above, Plenadren was not routinely prescribed as an alternative to hydrocortisone tablets due to its cost. Moreover, prescribers do not consider either prednisolone or other corticosteroids to be feasible alternatives to hydrocortisone tablets either. Instead, they are prescribed only in exceptional circumstances, usually when the patient is not able to tolerate hydrocortisone tablets.

¹⁴⁸⁷ This was confirmed by the CCGs from whom the CMA requested information (Coastal West Sussex, Gloucestershire and South Devon and Torbay, see Document 01604, Document 01612 and Document 01638A). Spending on prescribed medicines is not discretionary, such that increases in the price of prescribed medicines led to decreases in discretionary spending. For example, Coastal West Sussex CCG and Gloucestershire CCG incurred very substantial additional costs as a result of the increasing price of hydrocortisone tablets, despite receiving no additional funding to cover these costs.

¹⁴⁸⁸ See, for example, *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, paragraphs 98 to 99 and 138(b); *Hutchison 3G UK Limited v Office of Communications* [2008] CAT 11, paragraph 122, upheld in *Hutchison 3G (UK) Limited v Ofcom* [2009] EWCA Civ 683, paragraphs 60-61 and 66. See also *National Grid v Ofgem* [2009] CAT 14, paragraph 80; *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* (Case No. 1001/1/1/01), paragraphs 153 to 155 and 165 to 168. Compare Case AT.39612 *Perindopril (Servier)*, footnote 3356 and the case cited. See also C-280/08 P *Deutsche Telekom AG v Commission*, EU:C:2010:603, paragraphs 84 and 92.

- 4.334. As a matter of principle, therefore, an argument that Auden/Actavis would behave in a way that would comply with ‘regulatory’ controls that could in theory have been imposed on it cannot call into question the evidence of its dominance from its market shares, pricing behaviour and financial performance. The Court of Appeal has confirmed, in the context of dominance, that *‘the failure of the Department to exercise any powers it may have had could not have absolved the appellants from their “special responsibility not to allow their conduct to impair genuine undistorted competition”’*.¹⁴⁸⁹
- 4.335. Secondly, as explained in section 4.C.I.c.iii above, the assessment of buyer power is one of degree; the relevant question is to what extent any such power *‘operated as a constraint on [the undertaking]’s ability to exert market power’*,¹⁴⁹⁰ in the context of *‘the actual relationship’* between supplier and buyer in practice, taking into account *‘how the market actually operates (or is likely to operate) on the true facts, not on artificial “facts” or partial facts’*. Any potential constraint *‘must be viewed realistically and for what it is’*.¹⁴⁹¹
- 4.336. For example, as explained above, in refusing Pfizer permission to appeal the CAT’s findings on dominance in *Phenytoin* the Court of Appeal found that the CAT, and by extension the CMA,¹⁴⁹² *‘was clearly entitled to conclude that it did not need to decide the precise extent of the Department of Health’s powers and to find that the Department had no effective means to limiting the appellants’ prices’*. The Court of Appeal found the argument that the DHSC’s powers gave it countervailing buyer power, in the absence of evidence of an effective constraint in reality, to have no reasonable prospect of success.¹⁴⁹³
- 4.337. The DHSC did not exercise its powers in relation to hydrocortisone tablets during the Infringements.¹⁴⁹⁴ A hypothetical exercise of the DHSC’s powers

¹⁴⁸⁹ *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey, dated 17 December 2018.

¹⁴⁹⁰ *National Grid v GEMA* [2009] CAT 14, paragraph 60.

¹⁴⁹¹ *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, paragraphs 105(i), 110(c) and 126.

¹⁴⁹² The CAT expressly held that *‘We agree with the CMA’* in relation to the relevance of the DHSC’s powers: *Flynn Pharma and Pfizer v CMA* [2018] CAT 11, paragraph 207.

¹⁴⁹³ *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey dated 17 December 2018. See also *CMA v Flynn Pharma and Pfizer Inc.* [2020] EWCA Civ 339, paragraphs 192 and 217; and *Flynn Pharma and Pfizer v CMA* [2018] CAT 11, paragraphs 203 and 207.

¹⁴⁹⁴ Indeed, it appears that the DHSC did not begin to monitor the prices of hydrocortisone tablets in any detail until the CMA commenced its investigation, by which point prices had begun to decrease. Document 02664.B, DHSC response to Intas’ letter of 8 December 2017: *‘The Department has been monitoring the reimbursement price of hydrocortisone 10mg tablets since the Competition and Markets Authority launched its investigation in April 2016’*.

would therefore only be relevant if it could be shown that Auden/Actavis was effectively constrained in practice by this prospect.¹⁴⁹⁵

4.338. Auden/Actavis's pricing behaviour in itself demonstrates that the prospect of the DHSC exercising its powers did not effectively constrain its market power during the Infringements. The CMA is also not aware of any contemporaneous evidence that Auden/Actavis was effectively constrained by the prospect of DHSC intervention. It is clear that the DHSC was not, as a matter of fact in this case, able to exercise buyer power in the form of regulatory power materially to influence Auden/Actavis's pricing.¹⁴⁹⁶

4.339. Auden/Actavis's representations on the DHSC/NHS powers are addressed in Annex B to this Decision.

ii. Auden/Actavis's intermediate customers (wholesalers and pharmacies)

4.340. The CMA has concluded in relation to both 10mg and 20mg hydrocortisone tablets that Actavis was not effectively constrained by countervailing buyer power at the level of its intermediate customers during the Unfair Pricing Abuses.

4.341. During the Pre-Entry Period, which accounts for the majority of the Infringements, as the sole supplier of hydrocortisone tablets, Auden was the only choice for all of its intermediate customers. Pharmacies did not have a choice but to dispense hydrocortisone tablets upon receipt of a prescription for hydrocortisone tablets, and therefore had to stock Auden's products.

4.342. During the Post-Entry Period, because of the additional choice that existed on the 20mg strength – where Waymade provided an alternative full label product – Actavis may have faced a different degree of demand-side constraint in relation to 20mg hydrocortisone tablets.¹⁴⁹⁷ The CMA has therefore assessed the position of Actavis's intermediate customers during the Post-Entry Period separately for 10mg and 20mg hydrocortisone tablets.

4.343. During the Post-Entry Period, Actavis was able to profitably maintain its prices significantly in excess of its competitors' prices (see paragraphs 4.267 to 4.275 above). This is not consistent with Actavis facing a countervailing constraint from the prospect of its customers switching supplier.

4.344. This can be explained in part by the fact that certain customers had no choice but to purchase Auden/Actavis's tablets and were not able to switch

¹⁴⁹⁵ Compare the Court of Justice's finding in C-280/08 P *Deutsche Telekom AG v Commission*, EU:C:2010:603, paragraphs 80 to 85.

¹⁴⁹⁶ Compare *Flynn Pharma and Pfizer v CMA* [2018] CAT 11, paragraph 207.

¹⁴⁹⁷ The CMA notes that some pharmacies do not negotiate individual drug prices directly. For example, [X].

to skinny label tablets (see section 3.E.IV.c.i above). As explained in section 4.C.II.c.iii above, Actavis benefited from an assured customer base accounting for a substantial proportion of 10mg hydrocortisone tablets sales in the UK. This made Actavis their only possible supplier and therefore those customers could not exercise buyer power by threatening to switch.

4.345. Consistent with the existence of its assured base, it is clear that Actavis was not effectively constrained by countervailing buyer power in the context of the actual relationship between Actavis and its customers for 10mg hydrocortisone tablets:

- a. The limited evidence of attempts to negotiate with Actavis shows these were not successful for 10mg tablets. In particular, Alliance referred to a number of price increases by Actavis, which it considered it had no option but to accept.¹⁴⁹⁸ Though Alliance attempted on occasion to secure a greater discount than that offered by Actavis, it was unsuccessful. Alliance explained that, during the Post-Entry Period, in relation to 10mg hydrocortisone tablets it was *'not aware of any alternative suppliers of the full label product'*, so that *'the only leverage to be used in price negotiations was the margin available against the Drug Tariff'*.¹⁴⁹⁹
- b. The evidence shows that Actavis did not face realistic threats from customers to switch purchases to an alternative supplier if it did not reduce its price: Intas stated that it was [✂].¹⁵⁰⁰ Consistent with this, Boots and AAH (on behalf of Lloyds) confirmed that they did not threaten to switch their business away from Actavis's hydrocortisone tablets.¹⁵⁰¹
- c. There is also evidence that Actavis did not negotiate on price with its customers. For example, DE Pharma (one of Auden/Actavis's customers, a short-line wholesaler) told the CMA that *'Actavis/Accord refused to compete on price with skinny label tablet entrants'*.¹⁵⁰²

¹⁴⁹⁸ Alliance considered that Actavis was *'able to take this stance as they too were aware that there were no alternative suppliers of the full label product.'* Document 02202, Alliance's response to the CMA's section 26 notice dated 19 December 2017, response to question 2.

¹⁴⁹⁹ Document 02202, Alliance's response to the CMA's section 26 notice dated 19 December 2017, response to question 2.

¹⁵⁰⁰ Document 02238, Intas' response to the CMA's section 26 notice dated 20 December 2017, response to question 2.

¹⁵⁰¹ Document 02175, Boots response to the CMA's section 26 notice of 19 December 2017, response to questions 2 and 4(c). Document 00522, Boots response to the CMA's section 26 notice of 16 June 2016, response to question 2. Document 02267, AAH response to the CMA's section 26 notice of 19 December 2017, response to question 3. Document 02198, Lloyds response to the CMA's section 26 notice of 19 December 2017, response to question 4.

¹⁵⁰² Document 206579, note of call with DE Pharma on 23 February 2021.

4.346. There is limited evidence suggesting that some of Actavis's customers used the threat to switch to Waymade as an alternative supplier of full label 20mg hydrocortisone tablets to exert comparatively greater leverage in discrete price negotiations than on 10mg tablets. For example:

- a. AAH used comparative market prices, or Waymade's prices directly, as leverage to renegotiate prices with Actavis during the Post-Entry Period:
 - i. In June 2016, AAH challenged Actavis to match a competitor's price for 20mg hydrocortisone tablets. The new price was £41, compared to the existing price of £44. Actavis agreed to match the price in July.¹⁵⁰³
 - ii. From October 2016 to January 2017, AAH switched its supply of 20mg hydrocortisone tablets to Waymade, after Actavis refused to lower its price to match Waymade's price.¹⁵⁰⁴
 - iii. Actavis matched (or nearly matched) Waymade's prices on two further occasions when prompted by AAH: in February 2017 and May 2017.¹⁵⁰⁵
- b. During the first few months of the Post-Entry Period, Alliance was notified of a price increase by Actavis. Alliance explained that '*As Alliance were not aware of any alternative suppliers of the full label product that could be used as leverage in price negotiations, the increase was accepted*'.¹⁵⁰⁶ However, Alliance later succeeded in negotiating a lower price from Actavis on one occasion during the Post-Entry Period: in July 2016.¹⁵⁰⁷

4.347. This limited evidence of customer switching and price negotiations shows that the presence of an alternative supplier of full label 20mg hydrocortisone tablets during the Post-Entry Period increased the competitive constraint that Actavis faced. It does not, however, indicate that Actavis was subject to countervailing buyer power in relation to 20mg hydrocortisone tablets during the Post-Entry Period because it had only limited success.

¹⁵⁰³ Document 02712, email from [X] to [X] dated 1 July 2016 and Document 02714, attachment. AAH also stated in this context that Actavis had offered a significantly reduced price for its 20mg hydrocortisone tablets in March 2016, though did not provide documentary evidence of associated negotiations (Document 02267, AAH's response to the CMA's section 26 notice of 19 December 2017, response to question 2).

¹⁵⁰⁴ Document 02707, AAH response to the CMA's section 26 notice of 7 February 2018, response to question 2.

¹⁵⁰⁵ Document 02707, AAH response to the CMA's section 26 notice of 7 February 2018, response to question 2.

¹⁵⁰⁶ Document 02202, Alliance response to the CMA's section 26 notice of 19 December 2017, response to question 2.

¹⁵⁰⁷ See Document 02202, Alliance response to the CMA's section 26 notice of 19 December 2017, response to question 2.

- 4.348. As explained above, buyer power is not a binary question. The important question is what degree of power the buyer may have, and whether it operates to a sufficient extent so as to mean that there is no significant market power.¹⁵⁰⁸ Despite the negotiations that took place at specific points between AAH, Alliance and Actavis in relation to the 20mg strength, Actavis retained the ability to behave appreciably independently from its competitors, customers and ultimately consumers during the Post-Entry Period, as its pricing behaviour and financial performance demonstrate.¹⁵⁰⁹ As explained in paragraphs 4.267 to 4.275 above, Actavis retained the ability to maintain significantly higher prices than its competitors (including, from April 2016, Waymade) throughout the Post-Entry Period.
- 4.349. The CMA has therefore concluded that, notwithstanding the limited evidence of (to some extent) successful price negotiations on 20mg hydrocortisone tablets that took place at the intermediate customer level, Actavis was not subject to countervailing buyer power for either 10mg or 20mg hydrocortisone tablets during the Post-Entry Period.

¹⁵⁰⁸ *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, para. 110(c); *National Grid v GEMA* [2009] CAT 14, paragraph 60.

¹⁵⁰⁹ Compare the CAT's treatment of buyer power in *National Grid v Ofgem* [2009] CAT 14: despite considerable evidence of active negotiations between National Grid and British Gas, with significant concessions made to British Gas (which even at one point walked away from negotiations, prompting a revised offer from National Grid), the CAT found that the evidence '*falls far short of demonstrating that British Gas had sufficient CBP to negate National Grid's market power to a significant extent*' (paragraphs 66-67).

5. THE UNFAIR PRICING ABUSES

A. Conclusions

- 5.1. The CMA finds that Auden/Actavis abused its dominant position in the market(s) for the supply of 10mg and 20mg hydrocortisone tablets in the UK by imposing unfair selling prices and in so doing infringed the Chapter II prohibition. The relevant periods for these infringements are:
- a. In relation to the 10mg Unfair Pricing Abuse, from 1 October 2008 until 31 July 2018.
 - b. In relation to the 20mg Unfair Pricing Abuse, from 1 October 2008 until 8 January 2017.
- 5.2. The 10mg Unfair Pricing Abuse and the 20mg Unfair Pricing Abuse are together referred to as the Unfair Pricing Abuses.
- 5.3. The CMA finds that Auden/Actavis's prices for 10mg and 20mg hydrocortisone tablets throughout the Unfair Pricing Abuses were excessive and unfair.
- 5.4. The CMA finds, first, that Auden/Actavis's prices were excessive (see section 5.C below). This is because when Auden/Actavis's prices are compared to its costs plus a reasonable rate of return ('**Cost Plus**'), the resulting differences are material, ie sufficiently large to be deemed excessive,¹⁵¹⁰ particularly at the peak of Auden/Actavis's prices (around £72 per pack for both 10mg and 20mg hydrocortisone tablets).
- 5.5. The CMA's calculation of Cost Plus for hydrocortisone tablets is:
- a. For 10mg tablets, between **£2.17** and **£4.45** per pack.
 - b. For 20mg tablets, between **£2.91** and **£5.20** per pack.
- 5.6. In calculating Cost Plus the CMA has made a number of assumptions which are favourable to Auden/Actavis in terms of an excessive pricing analysis; these assumptions have increased the levels of Cost Plus and therefore reduced the level of any excesses identified.
- 5.7. The CMA then finds that Auden/Actavis's prices were also unfair (see section 5.D below), both in themselves (see section 5.D.II) and when

¹⁵¹⁰ *Albion Water II* [2008] CAT 31, paragraph 199.

compared to competing products (see section 5.D.III). Either would be a sufficient basis for a finding of unfairness in law.¹⁵¹¹

- 5.8. The CMA then finds that the economic value of both 10mg and 20mg hydrocortisone tablets is no greater than the CMA's calculation of Cost Plus. This is because there are no non-cost related factors associated with hydrocortisone tablets that increase their economic value beyond that already reflected in the CMA's calculation of Cost Plus (see section 5.D.IV below).
- 5.9. The CMA therefore finds that Auden/Actavis's prices during the Unfair Pricing Abuses bore no reasonable relation to the economic value of hydrocortisone tablets.
- 5.10. In reaching its conclusions, the CMA has had regard to a substantial volume of evidence, the mutually corroborative nature of which assures confidence in the CMA's findings.
- 5.11. In April 2008, when Auden entered the market with generic hydrocortisone tablets after buying the MAs from MSD and de-branding the product, its initial prices were **£4.54** for 10mg tablets and **£5.14** for 20mg: prices consistent with the CMA's calculation of Cost Plus (see sections 5.C.IV.a.i and 5.D.II.c.i).
- 5.12. In January 2015, after nearly seven years of increasing prices as a monopolist, Auden's prices were £51.79 (10mg) and £60.64 (20mg). In that month, as part of its due diligence on the business of AM Pharma, Allergan modelled what would happen if competitors entered the market in 2015 and projected that Auden would experience '*price erosion of 90% over 3 yrs*',¹⁵¹² leading it to agree a £220 million reduction in the price it was prepared to pay for AM Pharma and an earn-out on the product in order to provide a '*total and complete de risking of hydrocortisone tablets for Actavis*'.¹⁵¹³ Allergan's projections would have left Auden/Actavis's prices at levels only slightly above Cost Plus (see section 5.C.IV.a.iv).
- 5.13. In fact, competitors entered from July 2015 onwards. After more than five years of competition in the market(s):

¹⁵¹¹ C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255; *Phenytoin* [2018] CAT 11, paragraph 366; and *Phenytoin CoA*, paragraphs 97(vii), 257 and 259.

¹⁵¹² Document 00706, Project Apple presentation dated January 2015, slide 6.

¹⁵¹³ Document 302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

- a. the current prices charged by the numerous suppliers of competing skinny label hydrocortisone tablets are **£1.34** for 10mg and **£1.85** for 20mg (see sections 5.C.IV.a.ii and 5.D.III.a);¹⁵¹⁴
- b. the current price charged by Waymade, Auden/Actavis's only competing supplier of full label tablets, for 20mg hydrocortisone tablets is **[£1-£4]** (see sections 5.C.IV.a.ii and 5.D.III.a);¹⁵¹⁵ and
- c. the current prices charged by Auden/Actavis are **[£1-£4]** for 10mg and **[£1-£4]** for 20mg (see section 5.C.IV.a.iii and 5.D.II.c.ii).¹⁵¹⁶

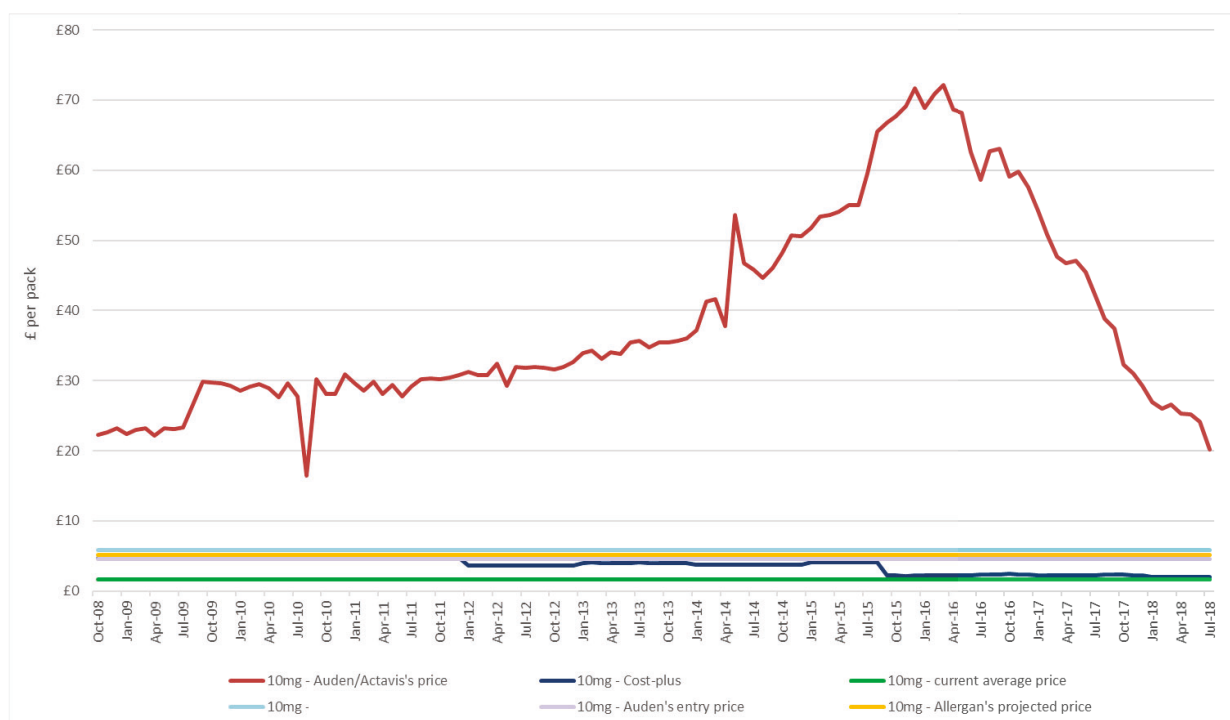
5.14. This evidence is set out in the figures and table below.

¹⁵¹⁴ Weighted average over the period February to April 2021.

¹⁵¹⁵ Weighted average over the period May to July 2020. [REDACTED], see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

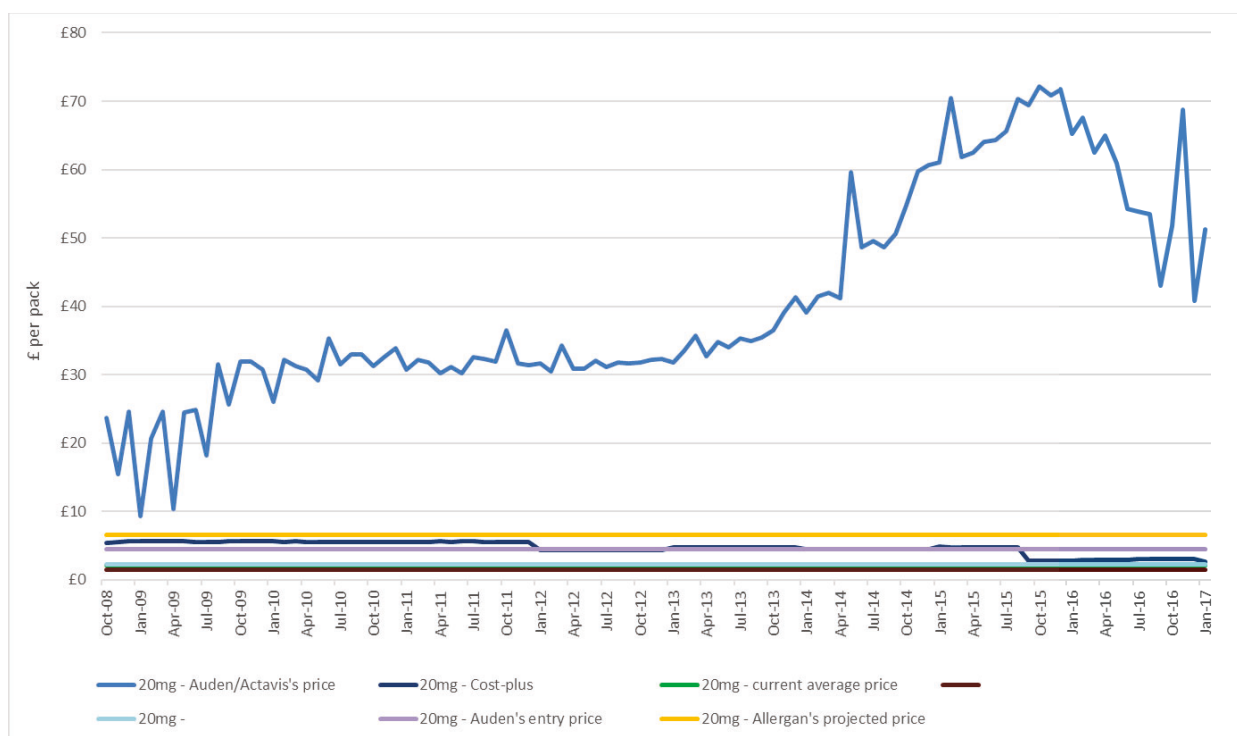
¹⁵¹⁶ Weighted averages over the period February to April 2021.

Figure 5.1: evidence relied on by the CMA in reaching its conclusions that Auden/Actavis's 10mg hydrocortisone tablets prices were excessive and unfair



Source: CMA analysis based on data submitted by relevant parties.

Figure 5.2: evidence relied on by the CMA in reaching its conclusions that Auden/Actavis's 20mg hydrocortisone tablets prices were excessive and unfair



Source: CMA analysis based on data submitted by relevant parties.

Table 5.3: evidence relied on by the CMA in reaching its conclusions that Auden/Actavis's prices were excessive and unfair

	10mg	20mg
Auden/Actavis's prices during the Unfair Pricing Abuses	£20 - £72.14	£20 - £72.19
Cost Plus	£2.17 - £4.45	£2.91 - £5.20
Current average price of skinny label tablets*	£1.34	£1.85
Current price of Waymade's full label tablets**	[£1-£4]	[£1-£4]
Actavis's current prices*	[£1-£4]	[£1-£4]
Auden's entry price	£4.54	£5.14
Allergan's projected prices following competitive entry	£5.20	£6.10

* Weighted average from February to April 2021

** Weighted average from May to July 2020 because [REDACTED], see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

5.15. Each of these measures falls within a relatively narrow range: between £1.34 and £5.20 for 10mg tablets and between [£1-£4] and £6.10 for 20mg tablets. This demonstrates:

- a. First, that the CMA's calculation of Cost Plus is an appropriate measure against which to assess whether Auden/Actavis's prices were excessive.
- b. Second, that the CMA's calculation of Cost Plus is in fact a measure that is likely to understate how excessive Auden/Actavis's prices were and overstate the economic value of hydrocortisone tablets. This is because the average prices of all of Auden/Actavis's competitors (including its only full label competitor, Waymade) are now substantially [REDACTED]. Further, Actavis's 20mg tablet price has itself fallen [REDACTED], while its 10mg tablet price has fallen [REDACTED] and has continued to fall.

5.16. The evidence the CMA has relied on is not a hypothetical 'benchmark range'. The appropriateness of the CMA's calculation of Cost Plus as a measure of excessiveness and economic value is demonstrated by mutually corroborative, real-world measures.¹⁵¹⁷

5.17. These measures show that after a prolonged period of competition prices tended towards Cost Plus and that prior to that point Auden/Actavis's prices were in excess of Cost Plus by up to:

¹⁵¹⁷ Compare *Phenytoin CoA*, paragraph 254; see also paragraphs 120-125 and 249-250.

- a. **3,100%** (£70 per pack) for 10mg hydrocortisone tablets; and
 - b. **2,400%** (£69 per pack) for 20mg hydrocortisone tablets (see section 5.C.IV).
- 5.18. Cost Plus already includes a reasonable rate of return. However, notwithstanding that the CMA's calculation of Cost Plus is a generous measure, the CMA has prioritised its enforcement activity in this case at levels which are substantially above Cost Plus. In this respect, the CMA has not reached a conclusion regarding at what level above Cost Plus but below **£20 per pack** Auden/Actavis's prices became excessive or unfair as a matter of law. Therefore, although it is possible that prices somewhere above Cost Plus but below £20 per pack could be excessive and unfair, the CMA has limited itself in this case to finding only that Auden/Actavis's prices were excessive and unfair when they were at least £20 per pack. This means that the **lowest** price at which the CMA has made a finding that Auden/Actavis's prices were excessive and unfair (ie £20 per pack) itself exceeds the upper bound of Cost Plus by **285%**.¹⁵¹⁸
- 5.19. This prioritisation decision determined the start dates of both Unfair Pricing Abuses and the end date of the 10mg Unfair Pricing Abuse.¹⁵¹⁹ For the avoidance of doubt, the CMA makes no findings in relation to whether Auden/Actavis's prices were excessive and unfair prior to, or after, these dates.
- 5.20. The CMA does not stipulate what a 'fair' price for hydrocortisone tablets would be. It finds that the economic value of hydrocortisone tablets is no greater than Cost Plus. Given the nature of hydrocortisone tablets and the context in which their prices were set during the period covered by this Decision, any price exceeding £20 per pack is clearly excessive and unfair.

B. Legal framework

I. Overview

- 5.21. Section 18(1) of the Act prohibits any conduct on the part of one or more undertakings which amounts to an abuse of a dominant position in a market if it may affect trade within the UK. Article 102 TFEU prohibits the same

¹⁵¹⁸ Although Auden's prices fell below £20 in a few individual months during the Unfair Pricing Abuses (its 10mg price in a single month, August 2010, and its 20mg price in November 2008 and January, April and July 2009), these were single-month fluctuations in the context of sustained price increases over the period from 2008 to 2015; see figure 5.6 below.

¹⁵¹⁹ In relation to the end date of the 20mg Unfair Pricing Abuse, as explained in section 4.B above, the CMA has deprioritised investigating whether Actavis continued to hold a dominant position after 8 January 2017, and therefore has made no finding as to whether the 20mg Unfair Pricing Abuse continued after that date.

conduct within the internal market or in a substantial part thereof in so far as it may affect trade between EU Member States.¹⁵²⁰

- 5.22. The concept of abuse is an objective one relating to the behaviour of an undertaking in a dominant position. The existence of an anti-competitive intent on the part of the dominant undertaking is not a requirement for a finding of abuse.¹⁵²¹ However, evidence of such an intent, while it cannot be sufficient in itself, constitutes a fact that may be taken into account in order to determine that a dominant position has been abused.¹⁵²²
- 5.23. Section 18(2)(a) of the Act and Article 102(a) state that, directly or indirectly, imposing unfair selling prices constitutes an abuse.¹⁵²³
- 5.24. It is well established that the ‘*seminal*’¹⁵²⁴ judgment on unfair pricing is *United Brands v Commission*¹⁵²⁵ which provides that:

‘248 The imposition by an undertaking in a dominant position directly or indirectly of unfair purchase or selling prices is an abuse to which exception can be taken under Article [102] of the Treaty.

249 It is advisable therefore to ascertain whether the dominant undertaking has made use of the opportunities arising out of its dominant position in such a way as to reap trading benefits which it would not have reaped if there had been normal and sufficiently effective competition.

250 In this case charging a price which is excessive because it has no reasonable relation to the economic value of the product supplied would be such an abuse.

251 This excess could, inter alia, be determined objectively if it were possible for it to be calculated by making a comparison between the

¹⁵²⁰ Section 60 of the Act aims to ensure that, so far as possible, the provisions of the Chapter II prohibition are interpreted and applied consistently with the EU Courts’ jurisprudence on the application of Article 102 TFEU. Under the European Union (Withdrawal Agreement) Act 2020, section 2(1) of the European Communities Act 1972 (under which EU law has effect in the UK’s national law) is preserved until the end of the Transition Period (section 1A, Withdrawal Act (as introduced by section 1, Withdrawal Agreement Act)). This means that directly applicable EU law, including Article 101(1) and Article 102 and Council Regulation (EC) No 1/2003, will continue to apply in the UK during the Transition Period. Section 60 of the Competition Act 1998 also remains in force during the Transition Period.

¹⁵²¹ C-549/10 P *Tomra v European Commission*, EU:C:2012:221, paragraph 21. See also *Hoffmann-La Roche*, EU:C:1979:36, paragraph 91.

¹⁵²² C-307/18 *Generics (UK) Ltd and others v Competition and Markets Authority*, EU:C:2020:52, paragraph 162. See also C-549/10 P *Tomra v European Commission*, EU:C:2012:221, paragraphs 20, 21 and 24.

¹⁵²³ Section 18(2) of the Act; Article 102(a) TFEU; and *United Brands*, EU:C:1978:22, paragraph 248.

¹⁵²⁴ See *CMA v Flynn Pharma and Pfizer Inc.* [2020] EWCA Civ 339 (*‘Phenytoin CoA’*), paragraphs 56 and 219. See also *Albion Water and Another v Water Services Regulation Authority and Others (‘Albion Water II’)* [2008] CAT 31, paragraph 14; *Phenytoin* [2018] CAT 11, paragraph 285.

¹⁵²⁵ *United Brands*, EU:C:1978:22.

selling price of the product in question and its cost of production, which would disclose the amount of the profit margin; however the Commission has not done this since it has not analysed [United Brands'] costs structure.

252 *The questions therefore to be determined are whether the difference between the costs actually incurred and the price actually charged is excessive, and, if the answer to this question is in the affirmative, whether a price has been imposed which is either unfair in itself or when compared to competing products.*

253 *Other ways may be devised – and economic theorists have not failed to think up several – of selecting the rules for determining whether the price of a product is unfair’.*

- 5.25. As is clear from paragraph 253 of *United Brands*, there is no single method or ‘way’ in which an unfair pricing abuse can be established.¹⁵²⁶ Competition authorities have a ‘margin of manoeuvre’ or ‘discretion’ in deciding which methodology to use.¹⁵²⁷
- 5.26. One possible method for determining whether or not a price is unfair is set out in paragraphs 251 and 252 of *United Brands*, and is commonly referred to as the ‘**United Brands Test**’. The *United Brands Test* involves comparing the selling price of the relevant product and its cost of production, which discloses the amount of the profit margin.¹⁵²⁸ Under this method a price will be abusively high where the following cumulative, two limb test is met:
- a. *‘the difference between the costs actually incurred and the price actually charged is excessive’* (Excessive Limb); and, if yes
 - b. *‘a price has been imposed which is either unfair in itself or when compared to competing products’* (Unfair Limb).¹⁵²⁹
- 5.27. This two-limb test has been consistently reiterated by the European Commission,¹⁵³⁰ competition authorities of Member States of the EU,¹⁵³¹ the

¹⁵²⁶ *Phenytoin CoA*, paragraphs 84–86, 97(iii)–(iv) and 251.

¹⁵²⁷ *Phenytoin CoA*, paragraphs 97(iii), 107, 120, 121, 246 and 251.

¹⁵²⁸ *United Brands*, EU:C:1978:22, paragraph 251.

¹⁵²⁹ *United Brands*, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 7; *Attheraces Limited v the British Horseracing Board Limited* (**‘Attheraces High Court’**) [2005] EWHC 3015 (Ch), paragraph 294; and 36568 *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, (**‘Scandlines’**) paragraphs 102, 149, 150 and 215.

¹⁵³⁰ *Scandlines*, paragraphs 98–103 and 145–152.

¹⁵³¹ See e.g. *Aspen Italian NCA* (Case A480, Autorità Garante della Concorrenza e del Mercato) decision of 29 September 2016; and *CD Pharma Danish NCA* (Konkurrence- og Forbrugerstyrelsen) decision of 31 January 2018.

EU Court of Justice,¹⁵³² the High Court,¹⁵³³ the CAT,¹⁵³⁴ and the Court of Appeal¹⁵³⁵ (most recently in its *Phenytoin* judgment dated 10 March 2020).¹⁵³⁶

- 5.28. Whilst the authority bears the legal burden of proof and must take a rigorous reasoned approach to the legal and factual questions,¹⁵³⁷ it is not required to apply an approach or methodology that is so complex and time-consuming that the relevant authority has neither the time nor the resources to deal with cases of alleged unfair pricing.¹⁵³⁸

II. The Excessive Limb of the *United Brands* Test: is the price 'excessive'?

- 5.29. The first limb of the *United Brands* Test is to establish '*whether the difference between the costs actually incurred and the price actually charged is excessive*'.¹⁵³⁹ This has been confirmed by the Court of Appeal which made clear that, under the Excessive Limb, the competition authority may compare the cost of production with the selling price in order to disclose the profit margin.¹⁵⁴⁰ Then the authority should determine whether the margin is 'excessive'.¹⁵⁴¹ This can be done by comparing the selling price to the cost of production plus a reasonable rate of return (usually referred to as 'Cost Plus').¹⁵⁴²
- 5.30. There is no need to establish a benchmark price or a range of prices, beyond a Cost Plus calculation, in order to determine whether the prices charged are excessive.¹⁵⁴³
- 5.31. In each of *Ineos Vinyls v Huntsman Petrochemicals*,¹⁵⁴⁴ *Attheraces v British Horseracing Board*,¹⁵⁴⁵ *Albion Water I*¹⁵⁴⁶ and *Albion Water II*¹⁵⁴⁷ a price/cost

¹⁵³² For the most recent example see *Latvian Copyright*, EU:C:2017:689, paragraph 36.

¹⁵³³ *Ineos Vinyls Ltd v Huntsman Petrochemicals* (UK) Ltd [2006] EWHC 1241 (Ch), paragraphs 217-218.

¹⁵³⁴ *Albion Water I* [2006] CAT 23, paragraphs 308 and 314; *Albion Water II* [2008] CAT 31, paragraphs 14-15 and 20-21; *Napp* [2002] CAT 1, paragraph 387. In *Phenytoin* [2018] CAT 11 the CAT summarised the two limb *United Brands* test at paragraphs 285 and 288 but, when applying it, it set out at paragraph 443 an eight-pronged test for cases where the only alleged infringement is one of excessive pricing.

¹⁵³⁵ *Attheraces Limited v British Horse Racing Board Limited* ('**Attheraces Court of Appeal**') [2007] EWCA Civ 38, paragraphs 114-119.

¹⁵³⁶ *Phenytoin CoA*, paragraphs 97(v)-(viii).

¹⁵³⁷ *Phenytoin CoA*, paragraphs 243 and 246.

¹⁵³⁸ *Phenytoin CoA*, paragraph 244.

¹⁵³⁹ *United Brands* EU:C:1978:22, paragraph 252; *Latvian Copyright*, EU:C:2017:689, paragraph 36 *Phenytoin CoA*, paragraphs 97(v) and 249.

¹⁵⁴⁰ *Phenytoin CoA*, paragraph 97(v).

¹⁵⁴¹ *Phenytoin CoA*, paragraph 97(v).

¹⁵⁴² *Phenytoin CoA*, paragraphs 97(v) and 252.

¹⁵⁴³ *Phenytoin CoA*, paragraph 254; see also *ibid* paragraphs 120-125, 185 and 249-250.

¹⁵⁴⁴ [2006] EWHC 1241 (Ch), paragraphs 217.

¹⁵⁴⁵ [2007] EWCA Civ 38, paragraphs 116 and 209.

¹⁵⁴⁶ [2006] CAT 23, paragraph 314.

¹⁵⁴⁷ [2008] CAT 31, paragraphs 20 and 194.

comparison was considered to be sufficient to satisfy the Excessive Limb and it was not considered necessary to apply more than one method.

a. Cost Plus

i. Costs

- 5.32. The measurement of '*the costs actually incurred*'¹⁵⁴⁸ in, or '*reasonably attributable*'¹⁵⁴⁹ to, supplying the product in question will include:
- a. The costs *directly* incurred in supplying the product or service;¹⁵⁵⁰ and
 - b. An appropriate apportionment of the *indirect* costs that are reasonably attributable to the product or service.¹⁵⁵¹
- 5.33. The excessive pricing case law does not prescribe a particular methodology for measuring cost. In *Albion Water II*, the CAT stated that, rather, '*it is a matter of fact, accounting technique and economic assessment*'¹⁵⁵² and went on to state that:
- 'Because there may be times when a competition authority or court needs the flexibility to examine more than one measure of cost in order to evaluate an allegedly excessive price, we do not prescribe a cost measure that would apply in all cases. The use of more than one credible methodology, even if only as a cross-check, helps to minimise the risk of false positives and to assure confidence in the results obtained.'*¹⁵⁵³
- 5.34. The EU Court of Justice in *United Brands* recognised the need for flexibility in the methods used for calculating costs because of '*the considerable and at times very great difficulties in working out production costs which may sometimes include a discretionary apportionment of indirect costs and general expenditure and which may vary significantly according to the size of the undertaking, its object, the complex nature of its set up, its territorial area of operations, whether it manufactures one or several products, the number of subsidiaries and their relationship with each other*'.¹⁵⁵⁴

¹⁵⁴⁸ *United Brands*, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 20.

¹⁵⁴⁹ *Albion Water II* [2008] CAT 31, paragraph 198.

¹⁵⁵⁰ *Albion Water I* [2006] CAT 23, paragraph 314; *Albion Water II* [2008] CAT 31, paragraph 89.

¹⁵⁵¹ *United Brands*, EU:C:1978:22, paragraph 254.

¹⁵⁵² *Albion Water II* [2008] CAT 31, paragraph 88.

¹⁵⁵³ *Albion Water II* [2008] CAT 31, paragraph 93.

¹⁵⁵⁴ *United Brands*, EU:C:1978:22, paragraph 254. See also *Scandlines*, paragraph 117.

- 5.35. Further, it is well-established that any costs must be reasonably and efficiently incurred.¹⁵⁵⁵ As the CAT explained in *Albion Water II*: ‘*Community jurisprudence only permits the inclusion of efficiently incurred costs*’.¹⁵⁵⁶

ii. Reasonable rate of return

- 5.36. The judgment in *United Brands* only refers to the costs of production, without further definition.¹⁵⁵⁷
- 5.37. As the European Commission recognised in *Scandlines*¹⁵⁵⁸ it is legitimate that a company may want to cover its cost of capital. Similarly, the CAT recognised in *Albion Water II*¹⁵⁵⁹ that the relevant components of costs should ordinarily include a return on capital. Therefore, when establishing the ‘*costs actually incurred*’ it will normally be necessary to allocate a reasonable rate of return to cover the cost of capital.
- 5.38. It is not necessary to adopt any particular approach to the determination of the ‘*plus*’ part of the Cost Plus calculation.¹⁵⁶⁰ The identification of a reasonable rate of return is not a matter of ‘*precise mathematics*’.¹⁵⁶¹ It is a question of judgement and appreciation on which experts may well take differing views.¹⁵⁶² In exercising that judgement, regard may be had to the interests of patients and the NHS.¹⁵⁶³

b. Differential

- 5.39. Having established the ‘*costs actually incurred*’ plus a reasonable rate of return, it is then necessary to compare it with the selling price and determine whether the margin is excessive.¹⁵⁶⁴
- 5.40. In *Albion Water II*, the CAT stated that:

‘The term “excessive” is an ordinary English word, which may be applied in accordance with its ordinary meaning, having regard to the overall purpose of the Chapter II prohibition. We note that the Authority submitted that a price may not be “excessive” within the meaning of the first United Brands question where the price exceeds costs but not by a

¹⁵⁵⁵ C-395/87 *Ministère Public v Tournier*, EU:C:1989:319, paragraph 42.

¹⁵⁵⁶ *Albion Water II* [2008] CAT 31, paragraph 88.

¹⁵⁵⁷ *United Brands*, EU:C:1978:22, paragraphs 251 and 254. See also *Albion Water II* [2008] CAT 31, paragraph 89.

¹⁵⁵⁸ *Scandlines*, paragraph 224.

¹⁵⁵⁹ *Albion Water II* [2008] CAT 31, paragraph 89.

¹⁵⁶⁰ See *Phenytoin CoA*, para 253.

¹⁵⁶¹ *Genzyme Limited v Office of Fair Trading* (‘*Genzyme Remedy*’) [2005] CAT 32, paragraph 279.

¹⁵⁶² *Genzyme Remedy* [2005] CAT 32, paragraph 255.

¹⁵⁶³ *Genzyme Remedy* [2005] CAT 32, paragraph 256.

¹⁵⁶⁴ *Phenytoin CoA*, paragraph 97(v).

*material extent (see paragraph 11.3 of the Report). While we are prepared to accept that a material difference between price and cost must be shown, we see no need to specify, in this case, when a particular difference is sufficiently large to be deemed excessive’.*¹⁵⁶⁵

- 5.41. The assessment of whether the differential is excessive requires the exercise of judgement as it *‘involves a proper degree of discretionary judgment by the decision-maker.’*¹⁵⁶⁶

III. The Unfair Limb of the *United Brands* Test: is the price unfair?

- 5.42. An excessive price may be unfair either:

- a. *‘in itself’*; or
- b. *‘when compared to competing products’.*¹⁵⁶⁷

- 5.43. This is an alternative rather than a cumulative test.¹⁵⁶⁸ Accordingly, it is sufficient to demonstrate that one of the unfairness limbs is satisfied to establish an infringement.¹⁵⁶⁹

- 5.44. It is therefore possible to use either alternative 1 (unfair in itself) or alternative 2 (unfair when compared to competing products) to determine unfairness.¹⁵⁷⁰ If the relevant undertaking does not adduce other methods or evidence, competition authorities may proceed to a conclusion upon the basis of that method and evidence alone.¹⁵⁷¹ There is no fixed list of categories of evidence relevant to unfairness.¹⁵⁷²

- 5.45. However, irrespective of which alternative is chosen, *‘...the competition authority will always need, at least as part of its duty of good administration, to give some consideration to prima facie valid comparators advanced evidentially’*¹⁵⁷³ *by the undertakings.*¹⁵⁷⁴ As to that duty:

¹⁵⁶⁵ *Albion Water II* [2008] CAT 31, paragraph 199.

¹⁵⁶⁶ *Albion Water II* [2008] CAT 31, paragraphs 193 to 194.

¹⁵⁶⁷ *United Brands*, EU:C:1978:22, paragraph 252. See confirmation of this test in *Latvian Copyright*, EU:C:2017:689, paragraph 36.

¹⁵⁶⁸ C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255, where the CAT also held that the test was alternative in nature; and *Phenytoin CoA*, paragraph 259.

¹⁵⁶⁹ *Phenytoin* [2018] CAT 11, paragraph 366.

¹⁵⁷⁰ *Phenytoin CoA*, paragraphs 259 and 269.

¹⁵⁷¹ *Phenytoin CoA*, paragraph 97(vii).

¹⁵⁷² *Phenytoin CoA*, paragraph 97(vi).

¹⁵⁷³ See *Phenytoin CoA*, paragraphs 114 and 116: *‘There is an important evidential burden upon an undertaking being investigated.’*

¹⁵⁷⁴ See *Phenytoin CoA*, paragraph 259 and 260. See also *ibid* paragraph 97(viii): *‘If an undertaking relies, in its defence, upon other methods or types of evidence to that relied upon by the competition authority then the authority must fairly evaluate it.’*

- a. The law does not predetermine how intensive any particular evaluation by the authority will be. The extent of the duty on an authority to evaluate evidence adduced by an undertaking will be fact and context specific and is affected by the nature, extent and quality of that evidence. There is an important evidential burden upon an undertaking being investigated.¹⁵⁷⁵
- b. The authority has a margin of manoeuvre or discretion as to how it performs that duty of fair evaluation, including with regard to the depth and intensity of the inquiry, and there is no general duty to perform a '*full*' investigation in all cases.¹⁵⁷⁶ The competition authority '*...does not have any duty actively to investigate in every case, in the sense of obtaining evidence about, any comparators put forward by the undertakings*'. It may be prudent for the competition authority to make its own investigations, but it is not under a legal duty to do so.¹⁵⁷⁷ Rather, the authority is obliged to evaluate the arguments and evidence advanced by undertakings fairly and impartially. It may reject comparators so advanced, but should give reasons for doing so.¹⁵⁷⁸

a. Assessing whether a price is unfair in itself

- 5.46. The authority has a considerable margin of appreciation when assessing whether an excessive price is also unfair.¹⁵⁷⁹
- 5.47. A price which '*significantly exceeds*' the economic value of the product supplied '*will be prima facie excessive and unfair*'.¹⁵⁸⁰ However, other factors are relevant to that determination.
- 5.48. The CAT held in *Albion Water II* that, when assessing the potential unfairness of a price, it is necessary to '*take into account the competitive conditions and any related abusive conduct that may enable the undertaking concerned to fulfil its pricing ambitions*'.¹⁵⁸¹
- 5.49. In this respect, the CAT found that factors establishing a dominant position may be relevant to assessing whether an excessive price is unfair:

¹⁵⁷⁵ *Phenytoin CoA*, paragraphs 112, 114 and 116.

¹⁵⁷⁶ *Phenytoin CoA*, paragraphs 113, 116 and 270.

¹⁵⁷⁷ *Phenytoin CoA*, paragraphs 270 and 273.

¹⁵⁷⁸ *Phenytoin CoA*, paragraph 270.

¹⁵⁷⁹ *Phenytoin CoA*, paragraph 135 and *Albion Water II* [2008] CAT 31, paragraphs 216, 261 and 263.

¹⁵⁸⁰ *Attheraces CoA*, paragraph 204. See also *Albion Water II* [2008] CAT 31, paragraph 265.

¹⁵⁸¹ *Albion Water II* [2008] CAT 31, paragraph 266. See also the following judgments on the importance of taking into account the competitive conditions prevailing in the market when assessing whether an abuse of a dominant position has been committed: *Napp* [2002] CAT 1, paragraph 400; and C-23/14 *Post Danmark*, EU:C:2015:651, paragraph 30.

‘factors that establish a dominant position, notably barriers to entry, may well be relevant to determining whether a price is so high as to amount to an abuse by an undertaking of its dominant position. This is particularly true in excessive pricing cases, in which it is important to distinguish excessive prices shielded from effective competitive pressure from temporarily high prices that are the subject of normal market forces in a competitive market.’¹⁵⁸²

- 5.50. Such factors are naturally case-specific and the CAT found that, where present, they *‘suggest that the Tribunal should review with care the lawfulness of a price which was unconstrained by any competitive considerations whatsoever’*.¹⁵⁸³ For instance, in *Albion Water II*, the CAT looked at *‘whether the relevant market is capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value of the services to be supplied’*.¹⁵⁸⁴
- 5.51. In *Albion Water II*, the CAT recognised the importance of taking end customers’ interests into account and looking beyond the immediate interests of competitors,¹⁵⁸⁵ on the basis that *‘the primary interest to be protected under the Chapter II prohibition is that of the consumer, rather than the private interest of a particular competitor’*.¹⁵⁸⁶
- 5.52. The value added by a firm and the risks and activities it undertakes may also be relevant for assessing whether a price is unfair in itself.¹⁵⁸⁷ For example, a dominant undertaking may have taken risks, made investments, improved a product or innovated in a way that could render high profits, partially or entirely, a legitimate reward for pro-competitive efforts.¹⁵⁸⁸
- 5.53. All other factors taken into account by the CMA in the 2016 Infringement Decision in *Phenytoin* could be relevant for the assessment of *‘unfair in itself’*:

‘...such factors as: the increase in price; the selective change of prices in the UK but not elsewhere; the impact on the buyer; the lack of any independent or objective justification; the commercial purpose of the

¹⁵⁸² *Albion Water II* [2008] CAT 31, paragraph 213.

¹⁵⁸³ *Albion Water II* [2008] CAT 31, paragraph 268. See also Opinion of Advocate General Jacobs in C-395/87 *Ministère Public v Tournier*, EU:C:1989:215, paragraph 43.

¹⁵⁸⁴ *Albion Water II* [2008] CAT 31, paragraph 268.

¹⁵⁸⁵ *Albion Water II* [2008] CAT 31, paragraph 271.

¹⁵⁸⁶ *Albion Water II* [2008] CAT 31, paragraph 218. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 215.

¹⁵⁸⁷ See, to that effect, *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 215 and *Phenytoin* [2018] CAT 11, paragraphs 404 and 346. See also AT.40394 *Aspen*, Commission decision of 10 February 2021, paragraph 163.

¹⁵⁸⁸ AT.40394 *Aspen*, Commission decision of 10 February 2021, paragraph 163.

*arrangements and the approach of the parties to them; could all be factors which it was relevant for [the CMA] to weigh when considering the application of the “unfair in itself” test...*¹⁵⁸⁹

b. Assessing whether a price is unfair when compared to competing products

5.54. Alternatively, an excessive price can be unfair when compared to competing products.¹⁵⁹⁰

5.55. Any comparison must be '*made on a consistent basis*' and comparators must be '*selected in accordance with objective, appropriate and verifiable criteria*' according to the circumstances of the case, allowing for the differing economic conditions in which the prices of comparators may have been set.¹⁵⁹¹

5.56. Comparators do not have to be identical¹⁵⁹² or on the same relevant market as the product at issue.¹⁵⁹³ However, it is necessary to ensure in every case that the comparator is sufficiently similar to the product concerned to allow for a '*meaningful*' comparison.¹⁵⁹⁴ Comparisons must be made on a consistent basis and the figures that are compared must be comparable.¹⁵⁹⁵

5.57. A comparator cannot be considered meaningful simply on the basis that the customer is paying the price imposed.¹⁵⁹⁶ Comparisons should not be drawn with other products the price of which may also have been inflated by the exercise of substantial market power.¹⁵⁹⁷

5.58. As the CAT has noted:

'If the [price under consideration] is not cost-justified, and since the evidence strongly suggests that that price was excessive, it does not in

¹⁵⁸⁹ *Phenytoin* [2018] CAT 11, paragraph 369.

¹⁵⁹⁰ *United Brands*, EU:C:1978:22, paragraph 252.

¹⁵⁹¹ *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 41, 44-46 and 51. See also *Phenytoin* [2018] CAT 11, paragraphs 392 and 444.

¹⁵⁹² C-372-19 *SABAM v Weareone.World, Wecandance*, EU:C:2020:959, paragraph 32 and *Albion Water II* [2008] CAT 31, paragraph 252.

¹⁵⁹³ C-372-19 *SABAM v Weareone.World, Wecandance*, EU:C:2020:959, paragraph 32 and *Phenytoin* [2018] CAT 11, paragraph 373.

¹⁵⁹⁴ See for example *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

¹⁵⁹⁵ See for example *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 44-46 and 51; *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin* [2018] CAT 11, paragraph 373.

¹⁵⁹⁶ See for example *Albion Water I* [2006] CAT 23, paragraphs 754 to 756.

¹⁵⁹⁷ This is consistent with the CAT's findings in *Albion Water I* [2006] CAT 23, paragraph 757; and *Albion Water II* [2008] CAT 31, paragraph 257. It is also consistent with the submission from the European Union to the Roundtable on Excessive Prices held by the OECD Competition Committee (Working Party No. 2 on Competition and Regulation) in October 2011, paragraphs 49 and 50.

*our view assist that that price is based on a comparison with other prices which are not cost justified either.*¹⁵⁹⁸

- 5.59. These concerns are similarly reflected in the CAT's conclusion that even where a number of other companies providing the same service engage in similar pricing practices, this will *'not, in itself, show that the [price in question] is not unfair'*.¹⁵⁹⁹

c. Economic value

- 5.60. In *Phenytoin* the Court of Appeal held that economic value *'is an economic concept which describes what it is that users and customers value and will reasonably pay for and it arose in the United Brands judgment as an economic description of the abuse of unfair pricing'*.¹⁶⁰⁰
- 5.61. The Court of Appeal set out that *'the reference in United Brands to 'economic value' is as part of the overall descriptor of the abuse; it is not the test itself.*¹⁶⁰¹ Rather *'economic value needs to be factored in and fairly evaluated, somewhere, but it is properly a matter which falls to the judgment of the competition authority as to where in the analysis this should occur.'*¹⁶⁰² Competition authorities are not required to adopt any particular approach to the determination of economic value.¹⁶⁰³
- 5.62. Determining the *'economic value'* of a product involves a considerable margin of appreciation¹⁶⁰⁴ with appropriate weight being given to factors on both the supply and demand side.¹⁶⁰⁵
- 5.63. The economic value of a product may exceed Cost Plus as a result of non-cost related factors including,¹⁶⁰⁶ where applicable, *'additional benefits not reflected in the costs of supply'*¹⁶⁰⁷ or any *'particular enhanced value from the customer's perspective'*.¹⁶⁰⁸

¹⁵⁹⁸ *Albion Water I* [2006] CAT 23, paragraph 757.

¹⁵⁹⁹ *Albion Water II* [2008] CAT 31, paragraph 257.

¹⁶⁰⁰ *Phenytoin CoA*, paragraph 171.

¹⁶⁰¹ *Phenytoin CoA*, paragraph 172.

¹⁶⁰² *Phenytoin CoA*, paragraph 172 (emphasis in original).

¹⁶⁰³ *Phenytoin CoA*, paragraph 253.

¹⁶⁰⁴ *Albion Water I* [2006] CAT 23, paragraph 310 and *Albion Water II* [2008] CAT 31, paragraphs 216 and 263. See also *Phenytoin* [2018] CAT 11, paragraphs 407 and 425.

¹⁶⁰⁵ *Albion Water II* [2008] CAT 31, paragraph 225. See also *Phenytoin* [2018] CAT 11, paragraph 411.

¹⁶⁰⁶ See *Albion Water II* [2008] CAT 31, paragraph 222; and *Scandlines*, paragraph 226. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 218.

¹⁶⁰⁷ *Albion Water II* [2008] CAT 31, paragraph 7.

¹⁶⁰⁸ *Albion Water II* [2008] CAT 31, paragraph 222.

- 5.64. This was, for instance, the case in *Scandlines*¹⁶⁰⁹ and *Attheraces*¹⁶¹⁰ where the European Commission and the Court of Appeal found, respectively, that the '*unique location close to Elsinore*' of the port of Helsingborg and '*the relevance of the value of the pre-race data to ATR*' increased the economic value of the product and services concerned beyond their costs of production.
- 5.65. This is consistent with the CAT's analysis of *Attheraces* in *Albion Water II*, where the CAT concluded that in that case, the economic value was greater than the cost of production because the customer was '*readily willing to pay a premium*' for the product.¹⁶¹¹
- 5.66. The existence and scale of any '*non-cost related factors*' vary on a case by case basis. Some products may have '*non-cost related factors*' which increase the economic value above production costs. Others may have no, or few, '*non-cost-related factors*' meaning the economic value of the product or service in question is either '*not more, or not significantly more, than*' the production costs.¹⁶¹²
- 5.67. For example, in *Albion Water II*, the CAT found that there was no additional economic value beyond the cost of providing the service in question.¹⁶¹³ The European Commission reached the same conclusion in *Deutsche Post*.¹⁶¹⁴ In those circumstances, the CAT has held in *Albion Water II* that neither *Scandlines* nor *Attheraces* '*excludes the possibility that, in the absence of relevant non-cost-related factors, the very excessiveness of a price could be sufficient to establish that the price bears no reasonable relation to the economic value of the product/service being provided.*'¹⁶¹⁵
- 5.68. Economic value is not simply whatever price a product or service will fetch or '*the market will reasonably bear*'.¹⁶¹⁶ That was confirmed by the Court of Appeal in *Attheraces*¹⁶¹⁷ and *Phenytoin*:

¹⁶⁰⁹ *Scandlines*, paragraph 241.

¹⁶¹⁰ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 218.

¹⁶¹¹ *Albion Water II* [2008] CAT 31, paragraph 226.

¹⁶¹² *Albion Water II* [2008] CAT 31, paragraphs 225 and 249.

¹⁶¹³ *Albion Water II* [2008] CAT 31, paragraph 249.

¹⁶¹⁴ *Deutsche Post*, paragraph 162.

¹⁶¹⁵ *Albion Water II* [2008] CAT 31, paragraph 225. See also paragraph 264.

¹⁶¹⁶ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraphs 210 to 211. The Court of Appeal rejected this argument even when '*reasonably*' was added to the proposition (see paragraph 211). See also *Albion Water II* [2008] CAT 31, paragraph 226, where the CAT distinguished between cases where the customer was '*readily willing to pay a premium*' and ones where the customer was not. The CAT found that while Albion was paying the price charged, it was only doing so under protest. Consequently, the CAT held that Albion was '*not a willing purchaser*' for the purposes of assessing economic value.

¹⁶¹⁷ *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 205.

‘But [what the customer is willing to pay] cannot serve as an adequate definition in an abuse case since otherwise true value would be defined as anything that an exploitative and abusive dominant undertaking could get away with. It would equate proper value with an unfair price. This is a well-known conundrum in international competition law...

‘The simple fact that a consumer will or must pay the price that a dominant undertaking demands is not therefore an indication it reflects a reasonable relationship with economic value.’¹⁶¹⁸

5.69. The Advocate General in SABAM also noted that:

‘...it is not always the case that there is a maximum price that the consumer is willing to pay for a product, with a result that, in those situations, there are no obstacles to the introduction of excessive prices. In the case of a life-saving medicine, for example, the only spending limit is the financial capacity of the purchaser (whether the patient or the national health service).’¹⁶¹⁹

5.70. This is particularly relevant where the customer has no real choice when purchasing the product in question. In *Hoffmann-La Roche* the Court of Justice recognised that being an ‘*unavoidable trading partner*’ necessarily gives a dominant undertaking ‘*freedom of action*’ as to how it prices.¹⁶²⁰ The potential for abuse in such situations was also recognised by Advocate General Jacobs in his Opinion in *Ministère Public v Tournier*. When assessing the fairness of a product’s price, the Advocate General stated that it could be ‘*superficially attractive*’ to do so by reference to the product’s importance to the customer, but that ‘*the usefulness of the criterion breaks down where a given category of users is completely dependent for its functioning on the supply of [the product] and where because of the absence of competition [those users] must, in effect, pay whatever price is required*’.¹⁶²¹

5.71. However, the Court of Appeal has set out that:

‘... dependency and the inferences to be drawn from its existence are indeed matters of fact and degree. Even if there is dependency there

¹⁶¹⁸ *Phenytoin CoA*, paragraphs 154-155.

¹⁶¹⁹ Opinion of Advocate General Pitruzzella in C-372/19 *SABAM v Weareone World*, EU:C:2020:598, paragraph 25.

¹⁶²⁰ *Hoffmann-La Roche*, EU:C:1979:36, paragraph 41.

¹⁶²¹ Opinion of Advocate General Jacobs in C-395/87 *Ministère Public v Tournier*, EU:C:1989:215, paragraph 65.

*might still be some economic value but not necessarily reflecting the full price demanded.*¹⁶²²

- 5.72. In circumstances where it is possible to ascertain what consumers are prepared to pay for the relevant good or service in an effectively competitive market, this may provide a proxy for the economic value of the product or service concerned.¹⁶²³

IV. Other methodologies

- 5.73. Methods other than the *United Brands* Test that have been used by EU and domestic courts for determining whether a price is unfair¹⁶²⁴ include for example comparisons with prices charged by: (i) the dominant firm at a different point in time;¹⁶²⁵ (ii) non-dominant firms;¹⁶²⁶ and (iii) the dominant firm or other firms in different geographical markets.¹⁶²⁷
- 5.74. For instance, in cases involving IP rights a comparison across different geographic markets has been the method most often used. In such cases, when an undertaking holding a dominant position imposes fees for its services which are appreciably higher than those charged in other Member States, and where a comparison of the fee levels has been made on a consistent basis, that difference must be regarded as indicative of an abuse of a dominant position. In those circumstances it is for the undertaking in question to justify the difference by reference to objective dissimilarities between the situation in the Member State concerned and the situation prevailing in all other Member States.¹⁶²⁸
- 5.75. There is, however, no rule of law requiring competition authorities to use more than one test or method to assess an unfair pricing abuse.¹⁶²⁹

¹⁶²² *Phenytoin CoA*, paragraph 167.

¹⁶²³ *Phenytoin CoA*, paragraphs 155 and 172.

¹⁶²⁴ *United Brands*, EU:C:1978:22, paragraph 253, and C-177/16 *Autortiesību un komunikēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome ('Latvian Copyright')*, EU:C:2017:689, paragraph 37. See also *Napp* [2002] CAT 1, paragraph 391.

¹⁶²⁵ C-226/84 *British Leyland v Commission*, EU:C:1986:421, paragraphs 27–30.

¹⁶²⁶ C-30/87 *Bodson v SA Pompes funèbres des régions libérées*, EU:C:1988:225, paragraph 31; *Napp* [2002] CAT 1, paragraph 392.

¹⁶²⁷ C-395/87 *Ministère Public v Tournier*, EU:C:1989:319, paragraph 38; cases 110/88, 241/88 and 242/88 *Lucazeau*, EU:C:1989:326, paragraph 25; *Latvian Copyright*, EU:C:2017:689, paragraph 38.

¹⁶²⁸ C-395/87 *Ministère Public v Tournier*, EU:C:1989:319, paragraph 38; cases 110/88 and 242/88 *Lucazeau*, EU:C:1989:326, paragraph 25; *Latvian Copyright*, EU:C:2017:689, paragraphs 38 and 57.

¹⁶²⁹ *Phenytoin CoA*, paragraph 97(iv).

C. Auden/Actavis's prices were excessive

I. Conclusion

- 5.76. The CMA finds that throughout the Unfair Pricing Abuses, Auden/Actavis's prices for hydrocortisone tablets were excessive by reference to the *United Brands* Test. This is because when Auden/Actavis's prices are compared to Cost Plus, the resulting differences are material and hence excessive. In fact, the resulting differences are substantial, particularly at the peak of Auden/Actavis's prices.
- 5.77. The CMA compared Auden/Actavis's prices with Cost Plus because Auden/Actavis's costs actually incurred in relation to hydrocortisone tablets, and a reasonable rate of return for the product, can be ascertained.¹⁶³⁰
- 5.78. When required to make assumptions in calculating Cost Plus the CMA has erred in favour of Auden/Actavis at a number of points. For example:
- The CMA's approach to allocating Auden's tangible assets assigns hydrocortisone tablets a weight of 10% and includes a portion of manufacturing assets, notwithstanding that hydrocortisone tablets represented two out of over 80 products supplied by Auden and it did not manufacture them. See paragraphs 5.174 to 5.175 below.
 - The CMA's approach to calculating Auden's working capital prior to 2015 overestimates Auden's asset base (because it necessarily relies on less accurate data). See paragraphs 5.195 to 5.196 below.
- 5.79. Table 5.4 below summarises the amount by which Auden/Actavis's prices exceeded Cost Plus during the Unfair Pricing Abuses, showing the Differentials per pack as an average during the Unfair Pricing Abuses and the Differentials by revenue as totals throughout the Unfair Pricing Abuses.

Table 5.4: Amount by which Auden/Actavis's prices exceeded Cost Plus during the Unfair Pricing Abuses

	10mg tablets	20mg tablets
Excess per pack (£)	£34.00	£33.78
Excess per pack (%)	879%	702%
Excess by revenue (£)	£262.6m	£13.1m

¹⁶³⁰ *Phenytoin CoA*, paragraph 252.

- 5.80. Costs remained low during the period of the CMA's analysis, reducing from approximately £5 per pack at the beginning of the Unfair Pricing Abuses to less than [£] per pack following AM Pharma's, and later Accord-UK's, acquisition by larger scale pharmaceutical businesses.¹⁶³¹
- 5.81. A Cost Plus of £2-£5 per pack for 10mg and £3-£6 per pack for 20mg compares with prices which increased to as much as approximately £72 per pack at their height, before beginning to fall from 2015 onwards following independent entry.

II. Auden/Actavis's prices

- 5.82. The prices used in this section are based on Auden/Actavis's average selling prices. These are calculated using actual sales data and therefore provide an accurate representation of the revenue that Auden/Actavis made from its sales of hydrocortisone tablets.
- 5.83. As explained in section 3.E.V above, Auden/Actavis imposed frequent price increases. Accordingly, it would not be representative to present one price throughout the whole period for the Unfair Pricing Abuses. Instead, the CMA has presented prices over four time periods:
- a. **1 October 2008 to 31 December 2013.** The CMA selected 31 December 2013 as the end date of this period because of the very significant price increases implemented by Auden after that date. Between October 2008 and December 2013, Auden's price of 10mg and 20mg hydrocortisone tablets rose by 62% (by £13.75, from £22.28 in October 2008 to £36.03 in December 2013) and 74% (by £17.65, from £23.74 in October 2008 to £41.39 in December 2013) respectively.
 - b. **1 January 2014 to 31 August 2015.** Although AM Pharma became part of the Allergan group on 29 May 2015, it continued to supply 10mg and 20mg hydrocortisone tablets in the UK until 31 August 2015.¹⁶³² Therefore, all costs relating to those supply activities were incurred by Auden until 31 August 2015, after which Actavis (Accord-UK) began supplying 10mg and 20mg hydrocortisone tablets in the UK. Between January 2014 and August 2015, Auden's price of 10mg and 20mg hydrocortisone tablets rose by 76% (by £28.30, from £37.20 in January

¹⁶³¹ The decline in common costs per pack appears to be the result of two factors: first, the acquisition of hydrocortisone tablets by larger businesses resulted in significant economies of scale, with dramatic reductions in the level of common costs per pack allocated to hydrocortisone; second, it seems likely that part of this decline in costs resulted from the availability and use of more accurate/reliable information, which is available for the later part of the period but not for the earlier part of the Unfair Pricing Abuses.

¹⁶³² Document 00670, Auden/Actavis's response to question 3 of section 26 notice of 23 June 2016.

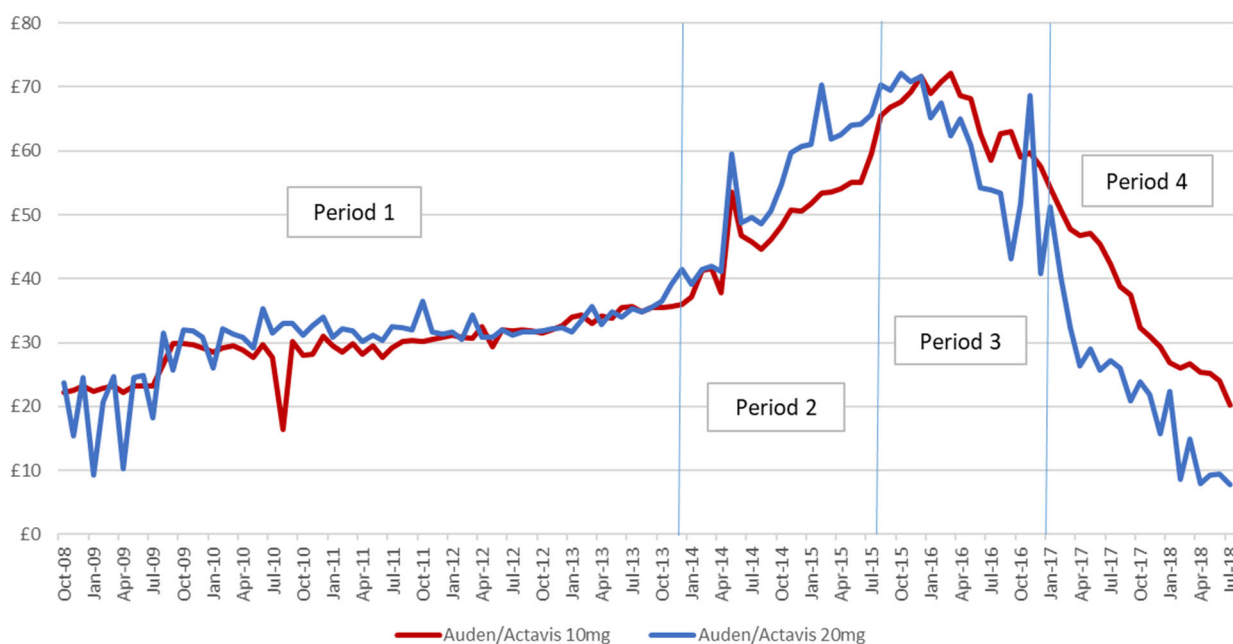
2014 to £65.50 in August 2015) and 80% (by £31.14, from £39.13 in January 2014 to £70.27 in August 2015) respectively compared with 31 December 2013.

- c. **1 September 2015 to 8 January 2017.** This period represents the point at which Actavis (Accord-UK) replaced Auden (AM Pharma) as the supplier of 10mg and 20mg hydrocortisone tablets in the UK following the acquisition of AM Pharma by Allergan, when Actavis began incurring costs relating to those activities. Actavis's prices fluctuated frequently over this period. From 1 September 2015, Actavis's prices of 10mg and 20mg hydrocortisone tablets continued to grow, reaching their peaks in March 2016 (£72.14) and October 2015 (£72.19) respectively. However, by December 2016, Actavis's prices of 10mg and 20mg hydrocortisone tablets were 12% and 42% lower than their respective prices at 31 August 2015, that is £57.57 in December 2016 as compared to £65.50 in August 2015 for 10mg tablets and £40.76 in December 2016 as compared to £70.27 in August 2015 for 20mg tablets. The end of this period coincides with the end of the 20mg Unfair Pricing Abuse.
 - d. **9 January 2017 to 31 July 2018.** This period begins with the acquisition of Accord-UK by Intas. The end date for this period is 31 July 2018, which is the date at which the CMA deprioritised further enforcement action in relation to the 10mg Unfair Pricing Abuse (see paragraph 5.19 above). Actavis's price of 10mg hydrocortisone tablets fell by almost 65% during this period (£37.34, from £57.57 in December 2016 to £20.23 in July 2018), although its price remained only marginally lower in December 2017 (£29.33) than its average price from October 2008 to December 2013 (£29.53).
- 5.84. The CMA considers that breaking its assessment into these four periods allows for a meaningful assessment of Auden/Actavis's pricing conduct over the period covered by this Decision. In particular, shorter periods might give a misleading picture given the short-term price fluctuations, especially in the early part of Unfair Pricing Abuses.
- 5.85. Breaking down the CMA's assessment into these periods, some of which reflect changes in Auden/Actavis's ownership structure, is also helpful in understanding how the costs incurred in the supply of hydrocortisone tablets may have changed over time.
- 5.86. Auden/Actavis's prices are outlined in table 5.5 and figure 5.6 below.

Table 5.5: Auden/Actavis's prices for 10mg and 20mg hydrocortisone tablets

	October 2008-December 2013	January 2014-August 2015	September 2015-January 2017	January 2017-July 2018
10mg	£29.53	£49.57	£65.31	£35.26
20mg	£29.81	£56.81	£60.77	N/A

Figure 5.6: Auden/Actavis's prices for 10mg and 20mg hydrocortisone tablets



III. Costs plus a reasonable rate of return (Cost Plus)

5.87. The CMA has concluded that Auden/Actavis's Cost Plus was between **£2.17 and £4.45** for 10mg hydrocortisone tablets and between **£2.91 and £5.20** for 20mg hydrocortisone tablets.¹⁶³³

5.88. In this case, the CMA has found that Cost Plus is the most appropriate measure by which to determine whether Auden/Actavis's prices were excessive under the Excessive Limb. As explained in section 5.B.II.a above, the calculation of Cost Plus requires the identification of:

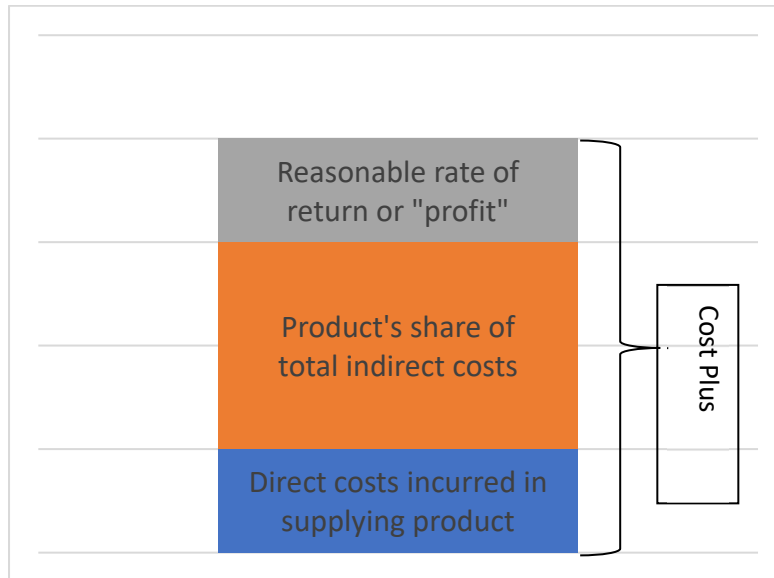
- a. the costs that Auden/Actavis actually incurred in supplying 10mg and 20mg hydrocortisone tablets, including:
 - i. direct costs (see section 5.C.III.a.i below); and

¹⁶³³ These figures show the range of the average Cost Plus in each of the four periods, as shown in figures 5.14 and 5.15 below. Taking the average annual Cost Plus in figures 5.22 and 5.23, the corresponding ranges would be between £1.98 - £4.88 for 10mg hydrocortisone tablets and £2.66 - £5.62 for 20mg hydrocortisone tablets.

- ii. an appropriate apportionment of indirect costs (see section 5.C.II.a.ii below); and
- b. a reasonable rate of return for Auden/Actavis in respect of 10mg and 20mg hydrocortisone tablets (see section 5.C.III.b below).

5.89. Figure 5.7 shows the three key components of Cost Plus.

Figure 5.7: Components of Cost Plus



- 5.90. A substantial volume of real-world evidence corroborates the CMA's finding that Cost Plus is an appropriate measure by which to assess whether Auden/Actavis's prices were excessive (see section 5.C.IV.a below).
- 5.91. In measuring Cost Plus in this case, the CMA has also applied a number of sensitivities as a cross-check to assure confidence in the results (see section 5.C.IV.b below).¹⁶³⁴
- 5.92. The CMA's calculations of Cost Plus and the data underlying those calculations are being provided to Auden/Actavis alongside this Decision.

a. Costs

- 5.93. The CMA has calculated the costs for Auden/Actavis's 10mg and 20mg hydrocortisone tablets by considering:
- a. direct costs (section 5.C.III.a.i below); and

¹⁶³⁴ Compare *Albion Water II* [2008] CAT 31, paragraph 93.

- b. indirect costs, including joint and common costs attributable to the relevant product (section 5.C.III.a.ii below).
- 5.94. This approach to cost identification makes allowance for direct and indirect costs, both variable and fixed (including administrative overheads), attributable to hydrocortisone tablets.
- 5.95. The CMA's assessment is from 1 October 2008 (the date on which the CMA has decided, based on its administrative priorities, that the 10mg and 20mg Unfair Pricing Abuses began, see paragraph 5.19 above) and is based on costs incurred by Auden until 31 August 2015, and incurred by Actavis from 1 September 2015 (when Actavis took over Auden's supply of 10mg and 20mg hydrocortisone tablets in the UK).
- 5.96. Consequently, the CMA has based its analysis on the costs incurred by Actavis from 1 September 2015 until January 2017 in respect of 20mg tablets (the date on which the CMA has decided, based on its administrative priorities, not to continue investigating the 20mg Unfair Pricing Abuse, see paragraph 4.228 above) and until July 2018 in respect of 10mg tablets (the date on which the CMA has decided, based on its administrative priorities, not to continue investigating the 10mg Unfair Pricing Abuse, see paragraph 5.19 above).

i. Direct costs

- 5.97. Direct costs are those costs that can be directly attributed to the purchase, distribution and sale of hydrocortisone tablets in the UK. Auden/Actavis's direct costs for hydrocortisone tablets are those costs that it directly incurred from supplying hydrocortisone tablets to its customers. Direct costs comprise:
- a. cost of goods (that is, purchasing hydrocortisone tablets); and
 - b. warehousing and distribution costs.
- 5.98. Auden/Actavis sourced both 10mg and 20mg hydrocortisone tablets from its CMO, Tiofarma, throughout the Unfair Pricing Abuses. Initially, the prices Auden/Actavis paid to Tiofarma were **[€1-€4]** and **[€1-€4]** per pack of 10mg and 20mg tablets respectively. This increased to **[€1-€4]** for 10mg tablets and **[€1-€4]** for 20mg tablets per pack in September 2008 and to **[€1-€4]** for 10mg tablets and **[€1-€4]** for 20mg tablets in February 2018.¹⁶³⁵ Given that

¹⁶³⁵ Document 00452, response to question 5, Tiofarma's response to the CMA's section 26 notice dated 4 April 2016. See also Document 02669 and Document 03954, Intas/Accord-UK's responses to the CMA's section 26 notices dated 2 February 2018 and 27 August 2019.

Auden/Actavis recorded its expenses in pounds sterling, the first component of direct costs – cost of goods – fluctuated due to changes in exchange rates.¹⁶³⁶

- 5.99. Once delivered to Auden/Actavis, hydrocortisone tablets were then stored by Auden/Actavis until they were delivered to customers by third-party couriers. Auden/Actavis submitted that the delivered consignments comprised several products, including 10mg and 20mg hydrocortisone tablets, such that only total warehousing and distribution costs could be provided.¹⁶³⁷ Given that this expense was likely to be driven by volumes, the CMA considers that sales volumes are the most appropriate method for allocating warehousing and distribution costs to 10mg and 20mg hydrocortisone tablets.^{1638,1639}
- 5.100. Table 5.8 sets out Auden/Actavis's direct costs for 10mg hydrocortisone tablets from October 2008 to July 2018 and table 5.9 sets out those costs for 20mg hydrocortisone tablets from October 2008 to January 2017. Auden/Actavis's direct costs remained below [REDACTED] per pack for both 10mg and 20mg hydrocortisone tablets throughout the Unfair Pricing Abuses.

Table 5.8: Auden/Actavis's direct costs per pack of 10mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	January 2017 – July 2018
Cost of Goods	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Storage and distribution costs	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Total direct costs	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]

Source: CMA calculation based on Document 00452, Tiofarma's response to the CMA's section 26 notice dated 4 April 2016; Document 00639 and Document 00733, AM Pharma's and Accord-UK's responses to the CMA's section 26 notices dated 18 March 2016 and 18 October 2016; and Document 03954 Intas/Accord-UK's responses to the CMA's section 26 notice dated 27 August 2019.

Table 5.9: Auden/Actavis's direct costs per pack of 20mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017
Cost of Goods	[REDACTED]	[REDACTED]	[REDACTED]
Storage and distribution costs	[REDACTED]	[REDACTED]	[REDACTED]
Total direct costs	[REDACTED]	[REDACTED]	[REDACTED]

Source: CMA calculation based on Document 00452, Tiofarma's response to the CMA's section 26 notice dated 4 April 2016; Document 00639 and Document 00733, AM Pharma's and Accord-UK's responses to the CMA's section 26 notices dated 18

¹⁶³⁶ The Bank of England's average monthly exchange rates were applied to the euro denominated purchase prices to convert these costs into pounds sterling.

¹⁶³⁷ Document 00639, response to question 11, Auden/Actavis's response to the CMA's section 26 notice dated 18 March 2016.

¹⁶³⁸ Although these costs are shared across a portfolio of products and will need to be allocated to 10mg and 20mg hydrocortisone tablets, the CMA treats these expenses as direct costs.

¹⁶³⁹ The oldest reliable warehousing and distribution costs data cover the year ending 31 December 2011. Therefore, the CMA has treated this data as representative of the pre-January 2011 period.

ii. Indirect costs

Approach

- 5.101. In addition to direct costs, businesses incur costs that are not directly related to the supply of individual products or product groups. These costs are 'indirect costs' and a proportion of these costs needs to be allocated to hydrocortisone tablets to reflect fully the total costs actually incurred by Auden/Actavis.
- 5.102. Indirect costs may include:
- a. joint costs that arise when two or more products are necessarily purchased or produced together; and
 - b. costs which are common across a number of products.
- 5.103. Auden/Actavis did not have any joint costs in relation to either 10mg or 20mg hydrocortisone tablets because no costs attributable to other products were incurred as a direct result of the procurement of 10mg or 20mg hydrocortisone tablets. Accordingly, only common costs are relevant.
- 5.104. Common costs are those costs that are incurred in the supply of more than one product.¹⁶⁴⁰ Typically, they include costs related to matters such as administrative employees (eg finance and legal departments) and head office overheads (eg utilities, rent and rates). In order to determine the relevant common costs for a particular product, a portion of the total attributable common costs should be allocated to each of the products that a company supplies.
- 5.105. In this case, the CMA identified the common costs partly attributable to the supply of hydrocortisone tablets. It then used an allocation methodology to allocate part of these costs to 10mg and 20mg hydrocortisone tablets. The same approach was used when allocating common costs to both 10mg and 20mg tablets for Auden/Actavis as the CMA has not identified any reasons for adopting different approaches for either of these products.
- 5.106. The CAT has recognised that there are a number of different methodologies that can be used to allocate common costs and has also stated that *'[e]stimates and allocations of costs will always have a degree of*

¹⁶⁴⁰ In this case, Auden/Actavis incurred costs related to the supply of all medicines that it sold into the UK. This included, but was not limited to, hydrocortisone tablets.

arbitrariness'.¹⁶⁴¹ In this context, the CMA has identified a preferred, primary approach to (indirect) cost allocation and has cross-checked this with two alternative approaches to ensure that the Cost Plus estimates are robust to a range of cost allocation approaches.

- 5.107. The OFT's report, *Assessing profitability in competition policy analysis* (the '**Profitability Assessment Report**'), also notes that there is no single correct method for cost allocation but various different methods that depend on the circumstances,¹⁶⁴² and that there are essentially three types of cost drivers that can be used separately or in combination:
- a. **output-based cost drivers**, where indirect costs are allocated using output indicators, such as production or sales volumes;
 - b. **input-based cost drivers**, where indirect costs are allocated to a particular line of business based on other known inputs employed in the production of that line of business, such as labour employed, raw material, or costs of floor space used; and
 - c. **value-based cost drivers**, where indirect costs are allocated based on demand factors, such as prices, revenues or consumers' willingness to pay.¹⁶⁴³
- 5.108. The Inter-Regulatory Working Group¹⁶⁴⁴ identified four principles upon which cost allocation approaches should be based.¹⁶⁴⁵ Of these, the following principles are most relevant in the context of this case and have therefore been taken into account when identifying an appropriate cost allocation methodology:¹⁶⁴⁶
- a. **Cost Causality**: costs should be allocated in accordance with the activities that caused them;
 - b. **Objectivity**: costs should be allocated on an objective basis, not unduly benefiting any particular party;

¹⁶⁴¹ *Genzyme Remedy* [2005] CAT 32, paragraph 277.

¹⁶⁴² OFT657 *Assessing profitability in competition policy analysis*, Economic discussion paper 6, July 2003, prepared by OXERA, paragraph 6.15.

¹⁶⁴³ Profitability Assessment Report, paragraph 6.16.

¹⁶⁴⁴ The Inter-Regulatory Working Group was established to identify and develop areas of consistency within published regulatory accounts.

¹⁶⁴⁵ These principles are described in a paper from the Inter-Regulatory Working Group (2001), '*The Role of Regulatory Accounts in Regulated Industries: A Final Proposals Paper*' by the Chief Executive of Ofgem, Director General of Telecommunications, Director General of Water Services, Director General of Electricity and Gas Supply (Northern Ireland), Rail Regulator, Civil Aviation Authority, and Postal Services Commission

¹⁶⁴⁶ The other criterion identified by the inter-regulatory working group, in the Profitability Assessment Report, is 'consistency'. This is less relevant in the context of this case as it relates more specifically to its application in regulatory accounts where it is important to ensure the same method is used from year to year.

- c. **Transparency:** the method should be clear to all interested parties with the underlying data (costs, revenues, asset values etc) all being clearly identifiable.
- 5.109. The CMA has considered the use of each of the different types of cost driver by reference to these principles.
- 5.110. For the reasons set out below, the CMA allocated common costs according to sales volumes and performed a sensitivity analysis on the resulting common cost allocations, using both the equal allocation and the equi-proportional mark-up approaches.

Output-based cost drivers

- 5.111. With respect to output-based measures, allocation by sales volumes (which allocates common costs proportionally to individual products according to their volumes) and equal allocation (which allocates common costs equally to each individual product) are two potential methods.
- 5.112. The sales volumes approach is objective and transparent, and given the difficulty Actavis has encountered in obtaining other sources of historical data, this method is the most practical and reliable since data on the number of packs sold is readily available. Further, the number of packs sold is likely to be linked to activities from procurement to invoicing, all of which require support activities which result in common costs, such as employee costs and office expenses. Therefore, there is likely to be some link between the number of packs sold and common costs incurred and, as such, the CMA considers that this is the most appropriate measure for allocating common costs.
- 5.113. The CMA therefore used the sales volumes approach as its primary methodology for common cost allocation.
- 5.114. The equal allocation method is also a reasonable method for allocating common costs. Although it is unlikely that each product requires the same level of administrative support, which drives common costs (and therefore this approach is likely to be less robust than allocation by sales volumes), this approach is objective, practical and transparent. Therefore, the CMA has adopted it as part of its sensitivity analysis of common costs (see section 5.C.IV.b below).

Input-based cost drivers

- 5.115. Activity-based costing is an input-based driver which aims to trace a company's indirect expenses by identifying how costs arise and attributing them to the relevant products or services.^{1647,1648} This approach is consistent with the principle of cost causality and reflects the underlying business reality. Therefore, the CMA considers that this would, in principle, be the most appropriate allocation method, if suitable data were available.
- 5.116. However, Auden/Actavis did not record the necessary data to allocate indirect costs to particular products.¹⁶⁴⁹ Therefore, activity-based costing is not possible in this case.
- 5.117. Given that cost causation cannot be established, no allocation method will be uniquely correct. Accordingly, to improve the robustness of its findings, the CMA has performed a sensitivity analysis on its common cost allocation results from the sales volumes approach to ensure that its findings are reasonable. This approach is consistent with the CAT's view that the use of more than one credible methodology as a cross-check helps to assure confidence in the results.¹⁶⁵⁰
- 5.118. The input-based sensitivity that the CMA has used is the equi-proportional mark-up ('**EPMU**') method, which allocates common costs in proportion to the directly attributable costs of the product(s) (direct costs) (see section 5.C.IV.b.i below). Although there is no necessary link between the size of direct costs and common costs, this method fulfils a number of common costs principles,¹⁶⁵¹ namely, it is practical, transparent and objective.

Value-based cost drivers

- 5.119. Auden/Actavis submitted that the CMA should use value-based cost drivers, specifically allocation by sales revenues.¹⁶⁵² Auden/Actavis submitted that

¹⁶⁴⁷ Institute of Management Accountants (2006) *Implementing activity-based costing*, page 1.

¹⁶⁴⁸ For example, if electricity charges vary according to the length of time machines operate, then equipment hours per product will be an appropriate basis for apportioning these costs.

¹⁶⁴⁹ Document 00639, response to question 10, Auden/Actavis's response to the CMA's section 26 notice dated 18 March 2016.

¹⁶⁵⁰ Compare *Albion Water II*, [2008] CAT 31, paragraph 93.

¹⁶⁵¹ This allocation method does not fulfil the principle of cost causality. However, as noted above, it is not possible to select an input-based measure which is consistent with cost causality in this case. With regards to consistency, this principle is less relevant in this context than other, regulatory or accounting, settings. Auden/Actavis's direct costs have remained broadly stable in euros since September 2008.

¹⁶⁵² Document 205217, Auden/Actavis's RSSO, paragraph 4.27. See also Document 01454, Auden/Actavis's RSO1, section 5.

this approach would be consistent with industry standard practice as demonstrated by the PPRS.¹⁶⁵³

- 5.120. Value-based cost drivers are usually considered inadequate for the assessment of pricing abuses in competition law. Although the sales value method is practical and transparent, it is inconsistent with the principle of cost causality and is likely to give rise to a circularity problem as indirect costs would be weighted towards the allegedly excessively priced product.
- 5.121. As explained in the Profitability Assessment Report,¹⁶⁵⁴ where some of the underlying prices are potentially excessive, there is a high probability that costs will be misallocated, possibly materially. This could lead to inaccurate profit margins across products by reducing the margin on the highest price products and inflating on the lowest price products, which is not a reasonable outcome.
- 5.122. This problem was recognised by the CAT in *Genzyme Remedy* where it confirmed that the OFT was right to reject *'Healthcare at Home's submission that certain costs should be allocated solely according to turnover: such an approach would allocate an unduly high proportion of overheads to Cerezyme, because of the high cost of the drug'*.¹⁶⁵⁵ The CAT also rejected this approach in *Socrates Training* on the basis that it was *'an unreliable basis for any fair assessment of the profitability of the scheme'*.¹⁶⁵⁶ In *Phenytoin* the CAT upheld the CMA's use of a volume based approach to allocate costs to individual products, noting that it *'was necessary ... for the purpose of the CMA's analysis to ascertain the profitability of individual products'*; and rejected the argument that the CMA was bound to follow PPRS cost allocation methodology.¹⁶⁵⁷
- 5.123. Under the PPRS, the prices of branded drugs were constrained at an overall level, which could mitigate the risk of circularity. A value-based approach, such as allocation by revenue, could therefore be reasonable when considering products subject to the PPRS. However, this is irrelevant to this case. As generic drugs, hydrocortisone tablets were never subject to the

¹⁶⁵³ Document 205217, Auden/Actavis's RSSO, paragraph 4.27. See also Document 01454, Auden/Actavis's RSO1, section 5.

¹⁶⁵⁴ Profitability Assessment Report, paragraph 6.18.

¹⁶⁵⁵ *Genzyme Remedy* [2005] CAT 32, paragraph 268.

¹⁶⁵⁶ *Socrates Training Limited v The Law Society of England and Wales* [2017] CAT 10, paragraph 83.

¹⁶⁵⁷ *Phenytoin* [2018] CAT 11, paragraphs 351-352.

PPRS when under Auden/Actavis's ownership.^{1658, 1659} Further, a revenue-based allocation is effectively a volume-based allocation multiplied by prices, and Auden/Actavis has not sufficiently explained why the inclusion of price data would be likely to generate a more reasonable allocation than a volume-based allocation.

- 5.124. Indeed, given that Auden/Actavis's prices of 10mg and 20mg hydrocortisone tablets were several times greater than the average price of its other products, value-based approaches contain a clear risk that this circularity problem could over-allocate costs to hydrocortisone tablets: attributing costs in this way assumes that prices are cost-justified despite evidence that they may not be and would allow Auden/Actavis to attribute high costs to hydrocortisone tablets purely because it charged high prices for them.
- 5.125. For these reasons, value-based cost allocation is not a credible methodology to measure Auden/Actavis's costs in relation to 10mg or 20mg hydrocortisone tablets and the CMA has therefore not applied this methodology.

Conclusion on method of allocating common costs

- 5.126. In the light of the above analysis, the CMA has decided to use sales volumes as its primary allocation method and to use the equal allocation and EPMU methods as part of its sensitivity analysis (see section 5.C.IV.b.ii below).

Auden/Actavis's common costs data

- 5.127. Auden/Actavis's business changed significantly over the course of the Unfair Pricing Abuses meaning that there are four discrete periods where the methodology for calculating common costs differs. These are:
- a. October 2008 to June 2010;
 - b. July 2010 to 31 August 2015;
 - c. 1 September 2015 to 8 January 2017; and

¹⁶⁵⁸ Auden/Actavis's submission that the PPRS set out '*an agreed basis for cost allocation in the branded pharmaceuticals sector*' (Document 205217, Auden/Actavis RSSO, paragraph 4.27) is therefore irrelevant. In any event, the PPRS simply stated that common costs '*must be reasonably apportioned*' (The Pharmaceutical Price Regulation Scheme 2014, paragraph 8.8).

¹⁶⁵⁹ Auden/Actavis also submitted that the CMA should have adopted a method consistent with its own methodology for allocating common costs (Document 205217, Auden/Actavis RSSO, paragraph 4.27 and Document 01454, Auden/Actavis's RSO1, section 5. However, Auden/Actavis did not explain the nature or identity of its internal approach. If Auden/Actavis adopted a sales revenue approach under the PPRS, this would be for the purposes of complying with its financial reporting obligations, rather than being used by management to assess the profitability of individual products.

d. from 9 January 2017.

October 2008 to June 2010

5.128. In the period up to June 2010, Auden recorded its data by means of accounting software which was subsequently archived. The information stored in this way cannot be checked for accuracy as the software has not been in use since June 2010.¹⁶⁶⁰ In addition, the data provided is incomplete because certain costs – such as staff costs – were not recorded.¹⁶⁶¹ Further, Auden/Actavis informed the CMA that in the period up to June 2010, AM Pharma failed a financial audit, which is believed to have been due to the absence of adequate financial records.¹⁶⁶² Consequently, the CMA cannot place sufficient reliance on this data in order to estimate Auden's common costs prior to June 2010.

July 2010 to 31 August 2015

5.129. From July 2010 up to 31 August 2015, financial data was recorded in new accounting software and greater reliance can therefore be placed on the data provided. This information also appears to be a more complete record of Auden's costs, as all expected categories of costs are accounted for.

5.130. Although it is likely to be more robust, this dataset may also contain inaccuracies because Auden/Actavis has not verified the cost data extracted from this system or linked it to the statutory accounts.¹⁶⁶³ However, to the extent this cost data is incomplete, this will favour Auden in terms of assessing whether it engaged in excessive and unfair pricing. A high-level cross check between the cost data extracted from Auden's accounting system for the period 2010-2014 against AM Pharma's audited financial statements for the corresponding period¹⁶⁶⁴ indicates that Auden's indirect costs extracted from its accounting system are likely to be overstated. This means that the CMA's analysis is likely to have allocated a higher cost base to Auden than it actually incurred during this period, with the consequence that its differentials (the difference between its ASPs and its costs) will be

¹⁶⁶⁰ Document 00639, Auden/Actavis's response to the CMA's section 26 notice dated 18 March 2016. Auden/Actavis advised the CMA that data for the period to June 2010 had been extracted from an archived accounting software system, used by Auden up to and including June 2010, and that it is not possible to validate the accuracy or completeness of the information as the systems had not been in use since that time.

¹⁶⁶¹ Document 00639, paragraph 6(a) of the Introduction and response to question 10, Auden/Actavis's response to the CMA's section 26 notice dated 18 March 2016.

¹⁶⁶² Document 00639, paragraph 6(a) of the introduction, Auden/Actavis's response to the CMA's section 26 notice dated 18 March 2016.

¹⁶⁶³ Document 00639, Auden/Actavis's response to the CMA's section 26 notice dated 18 March 2016.

¹⁶⁶⁴ Review of published statutory financial statements for AM Pharma for the financial years ending 30 September 2010 to 30 March 2015 (Source: Companies House)

lower than was actually the case. This means that Auden's differentials are likely to be even higher than those calculated in section 5.C.IV below.

5.131. The financial year ended 31 December 2011 was the first full year that Auden used this new accounting system. The CMA extrapolated Auden's common costs in that financial year backwards¹⁶⁶⁵ to provide a figure it considers to be broadly representative of Auden's common costs before January 2011.¹⁶⁶⁶

5.132. Under its new accounting system, Auden recorded costs within approximately 50 types of expenses that fit into three general categories:

- a. 'General and Administrative' expenses;
- b. 'Sales and Marketing' expenses; and
- c. 'Other' costs (including 'research and development' expenses).¹⁶⁶⁷

5.133. Each of these costs is recorded for the business as a whole and across the entire portfolio of Auden's products.

1 September 2015 to 8 January 2017

5.134. From 1 September 2015, financial information relating to the sales of hydrocortisone tablets was recorded under Actavis's main accounting system. Accordingly, the CMA used data from this system from 1 September 2015 for the purposes of allocating Actavis's common costs.

5.135. In order to understand how much of each expense line was attributable to hydrocortisone tablets, Actavis estimated the proportion of certain expenses lines that:

- a. relate specifically to 10mg and 20mg hydrocortisone tablets;
- b. relate to products other than hydrocortisone tablets; and
- c. apply across its entire business, including hydrocortisone tablets.¹⁶⁶⁸

¹⁶⁶⁵ This has been extrapolated backwards by applying the level of common cost allocated to each pack of hydrocortisone tablets in 2011 to each pack sold prior to then, between October 2008 and December 2010.

¹⁶⁶⁶ This differs from the rebate data on which reliance cannot be placed until 2012.

¹⁶⁶⁷ Auden did not incur any research and development costs which were specifically attributable to hydrocortisone tablets. However, where 'research and development' costs were general costs that applied across the entire business, a portion of these were allocated to hydrocortisone tablets, following the methodology outlined above. This approach also favours Auden, since some of these entries may not in fact reflect costs actually incurred: see [§].

¹⁶⁶⁸ Document 00670, response to question 1, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016.

5.136. Where costs related specifically to 10mg or 20mg hydrocortisone tablets, these were allocated in full to 10mg or 20mg hydrocortisone tablets. Where indirect costs were attributable to 10mg or 20mg hydrocortisone tablets but were applicable across Actavis's entire business, those costs were allocated to 10mg or 20mg hydrocortisone tablets with the use of sales volumes. On this basis, using the information submitted by Actavis,¹⁶⁶⁹ the CMA was able to perform a detailed allocation exercise of indirect costs to 10mg and 20mg hydrocortisone tablets.¹⁶⁷⁰

From 9 January 2017

5.137. On 9 January 2017 Accord-UK was acquired by Intas/Accord. Since that date, Accord-UK's UK-based regional office has incurred additional indirect costs.¹⁶⁷¹ These are common costs which are not specifically attributable to the sale of individual products which have been applied across its regional business, rather than costs which are specific to the sale of hydrocortisone tablets in the UK.¹⁶⁷²

5.138. Table 5.10 outlines Auden/Actavis's total common costs from January 2011 to July 2018.¹⁶⁷³ As explained above, the financial year ended 31 December 2011 was the first full year that Auden used the new accounting system that the CMA has used to extrapolate common costs before January 2011. The table therefore begins with the year ending 31 December 2011. It also outlines the total amount allocated to hydrocortisone tablets in total and per pack.

¹⁶⁶⁹ Document 00670, response to question 1, Auden/Actavis's response to the CMA's section 26 notice dated 23 June 2016.

¹⁶⁷⁰ This exercise enabled the CMA to exclude costs which were directly attributable to products other than hydrocortisone tablets.

¹⁶⁷¹ None of the regional indirect costs that Intas/Accord-UK has identified as being relevant were specific to the manufacture and sale of hydrocortisone tablets in the UK, but were common costs which are not specifically attributable to the sale of individual products.

¹⁶⁷² Documents 206267 and 206265, Intas/Accord-UK's response to CMA's section 26 notice dated 17 February 2021. Intas's data submission also included certain finance costs. However, these have been excluded from the CMA's common costs allocation. The CMA has allocated these costs on a sales volumes basis consistent with its approach to other indirect costs.

¹⁶⁷³ The CMA does not have common cost data for the three months between 1 June 2015 and 31 August 2015, after which Accord-UK took over AM Pharma's supply of hydrocortisone tablets in the UK. The CMA has applied the higher allocation of common costs to hydrocortisone tablets over this period, which favours Auden/Actavis.

Table 5.10: Auden/Actavis's common costs allocated to hydrocortisone tablets from 1 January 2011 up to July 2018

Period	Total Auden/Actavis costs to be allocated across products ¹	Common costs allocated to hydrocortisone tablets	Common costs allocated to each pack of hydrocortisone tablets
Year ending 31 December 2011 ²	[REDACTED]	[REDACTED]	[REDACTED]
Year ending 31 December 2012 ³	[REDACTED]	[REDACTED]	[REDACTED]
Year ending 31 December 2013	[REDACTED]	[REDACTED]	[REDACTED]
Year ending 31 December 2014	[REDACTED]	[REDACTED]	[REDACTED]
Eight months up to 31 August 2015 ³	[REDACTED]	[REDACTED]	[REDACTED]
September 2015 to 8 January 2017 ⁴	[REDACTED]	[REDACTED]	[REDACTED]
9 January 2017 to 31 July 2018 ⁵	[REDACTED]	[REDACTED]	[REDACTED]

¹ This excludes Warehousing and Distribution costs, which are included in direct costs, and rebates which are included in prices.

² This balance includes particularly high 'research and development' costs of [REDACTED], a proportion of which relates to payments which may have been incorrectly invoiced as research and development costs,¹⁶⁷⁴ the impact of which would have been to overstate the common costs allocated to hydrocortisone tablets for 2011.

³ Following its acquisition of AM Pharma in May 2015, Allergan began to move indirect costs out of AM Pharma into Accord-UK during the second half of 2015 and moved sales of hydrocortisone tablets out of AM Pharma from September 2015. The CMA took a conservative approach and allocated Auden/Actavis's common costs on the basis of hydrocortisone tablets sales in the first half of 2015. However, as sales of hydrocortisone tablets were transferred from Auden to Actavis only from September 2015, this approach is likely to be favourable to Auden/Actavis.

⁴ From September 2015, Auden's hydrocortisone tablets' business was integrated into Actavis's wider UK business (which is a much larger business), therefore explaining the increase in total common costs.

⁵ Comprises £[REDACTED] of UK common costs and regional overheads of £[REDACTED]

- 5.139. As is shown in table 5.10 above, the level of common costs fluctuated over the period from January 2011 to July 2018 and experienced a notable drop following Allergan's acquisition of AM Pharma.
- 5.140. The analysis set out in table 5.10 above shows a decline in the level of common costs per pack that Auden/Actavis incurred following the transfer of Auden's hydrocortisone tablets business to Accord-UK. Efficiently incurred costs will, by definition, exploit economies of scale. Actavis was of greater scale than Auden. To the extent that greater scale reduced indirect costs, the lower level of common costs observed for Auden/Actavis following Allergan's acquisition than for earlier periods is more likely to represent efficiently incurred costs.¹⁶⁷⁵ The CMA considers that the lower common

¹⁶⁷⁴ [REDACTED].

¹⁶⁷⁵ Allergan's due diligence report from the time anticipated 60% operating cost synergies for the acquired business following acquisition, consistent with the expectation that greater scale would reduce costs associated with supply of hydrocortisone tablets. Document 00706: Project Apple presentation dated January 2015, slide 4.

costs per pack which prevailed following Allergan's acquisition of AM Pharma of less than [X] per pack are more representative of efficiently incurred costs than the higher costs earlier in the Unfair Pricing Abuses. Not only are the costs incurred by AM Pharma as a standalone business less likely to reflect efficiently incurred costs due to its significantly lower scale, but the CMA has also erred significantly on the side of caution in its cost allocation for that period due to lack of reliable data.

- 5.141. The CMA has taken a conservative approach of using the costs actually incurred by each firm in supplying hydrocortisone tablets, during its respective period of supplying hydrocortisone tablets. This approach means that there is no risk of the Cost Plus calculation being based on a level of common costs that was not available to an owner of the business of supplying hydrocortisone tablets in an earlier period.
- 5.142. However, it also results in common costs changing according to the actual cost base under different periods of ownership, even though some of those costs may not reflect efficiently incurred costs.¹⁶⁷⁶
- 5.143. In order to assure confidence in the results obtained from the CMA's primary allocation method (the sales volume method),¹⁶⁷⁷ the CMA assessed whether adopting either the **EPMU** or the **equal allocation method** would affect the level of common costs allocated to hydrocortisone tablets (see section 5.C.IV.b.ii below).
- 5.144. As compared to the sales volume method, the **EPMU** method led to a similar level of common costs being allocated to both 10mg and 20mg hydrocortisone tablets, which assures confidence in the CMA's preferred method.
- 5.145. As compared to the sales volume method, the **equal allocation** method led to:
- a. a significantly lower level of common costs being allocated to 10mg hydrocortisone tablets; and
 - b. a higher level of common costs being allocated to 20mg hydrocortisone tablets.

¹⁶⁷⁶ Intas/Accord-UK submitted that a change in ownership should not change the CMA's allocation of costs or its Cost Plus assessment; see Document 205212, Intas/Accord-UK's RSSO, paragraph 137(i) (compare Document 205217, Auden/Actavis's RSSO, paragraphs 4.82-4.84). However, as already explained above, the significant changes in cost relate to actual costs incurred by each party during each period of ownership, which may not necessarily represent efficiently incurred costs.

¹⁶⁷⁷ *Albion Water II* [2008] CAT 31, paragraph 93.

5.146. As explained in paragraph 5.114 above, the CMA considers equal allocation method to be less reliable than the sales volume method. Nonetheless, the CMA has considered the results of the equal allocation method within its sensitivity analysis in section 5.C.IV.b.ii below.

b. Auden/Actavis's reasonable rate of return

5.147. In addition to calculating the total costs incurred by Auden/Actavis in selling 10mg and 20mg hydrocortisone tablets, it is necessary to also establish a **reasonable return** for it to make in respect of its sales of those tablets.¹⁶⁷⁸

5.148. The purpose of a reasonable rate of return is to acknowledge that a firm should receive a sufficient financial incentive for engaging in the activity of supplying a good or service. This return serves as compensation for investing capital and for taking on any risks associated with these activities.

5.149. In order to establish a reasonable return for Auden/Actavis, it is necessary to determine:

- a. the appropriate measure of return to use (see section 5.C.III.b.i below); and
- b. what would be a reasonable rate using that measure (see section 5.C.III.b.ii below).

i. The appropriate measure of the rate of return

5.150. In this case, the CMA has used return on capital employed ('**ROCE**') as the primary basis for assessing Auden/Actavis's rate of return. ROCE is measured by assessing profits against the level of capital employed.¹⁶⁷⁹

5.151. The CMA has used ROCE in this case because it is a well-known profitability metric, based on the risk and capital employed by a business, and its use is accepted within the pharmaceutical industry.¹⁶⁸⁰

5.152. In order to calculate ROCE, the CMA has calculated capital employed and determined what it considers to be an appropriate return on that capital. Auden/Actavis's capital employed with regards to hydrocortisone tablets was composed of both working capital and fixed assets. Auden/Actavis provided

¹⁶⁷⁸ The need to take into account, in appropriate circumstances, not only the costs of production but also a reasonable rate of return was acknowledged by the CAT in *Albion Water II* [2008] CAT 31, paragraph 89. The same general point was made by *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 209.

¹⁶⁷⁹ ROCE is measured by dividing total profits by capital employed, defined as total assets less current liabilities or fixed assets plus working capital.

¹⁶⁸⁰ For instance, return on capital was a profitability measure used in the PPRS: see section 8 of the Pharmaceutical Price Regulatory Scheme 2014.

the CMA with specific figures regarding its working capital requirements for hydrocortisone tablets and the CMA obtained fixed asset information from Auden/Actavis's financial statements.

- 5.153. As a result, the CMA has been able to estimate the level of capital Auden/Actavis employed in the supply of 10mg and 20mg hydrocortisone tablets in the UK and has used ROCE in order to calculate a reasonable return for the purposes of calculating Auden/Actavis's Cost Plus.

Capital employed

- 5.154. Auden/Actavis's capital employed with regards to hydrocortisone tablets was composed of both working capital and fixed assets, and the CMA has considered each of these in turn.

The CMA's approach to working capital

- 5.155. Working capital is the capital used by a business to fund its day to day activities and to finance its short-term debts. To the extent that it is efficiently employed, Auden/Actavis should be allowed a return on this capital when calculating Auden/Actavis's Cost Plus.
- 5.156. Prior to May 2015, the most reliable source of Auden's working capital balances is the due diligence report¹⁶⁸¹ which was completed prior to Allergan's acquisition of AM Pharma.
- 5.157. This report provided an independent estimate of the business's total working capital requirements, namely debtors, creditors and stock. Given that the components of working capital which relate directly to this product are driven by sales and purchases, the CMA has concluded that these metrics provide reasonable bases on which these assets and liabilities should be allocated to 10mg and 20mg hydrocortisone tablets.¹⁶⁸²
- 5.158. From September 2015, sales of hydrocortisone tablets were managed by Actavis. Accordingly, in order to determine a reasonable rate of return for Auden/Actavis in the period from September 2015 it is necessary to determine the level of capital employed by Actavis.
- 5.159. Actavis recorded specific inventory, debtors and creditors data with respect to hydrocortisone tablets meaning that from September 2015 onwards it is

¹⁶⁸¹ This due diligence report was prepared by independent advisers (PwC) to inform Allergan and Accord-UK about AM Pharma's financial position (Document 00681, Annex 11, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016: Project Apple Financial and Tax Due Diligence – Key Issues Report, 11 December 2014).

¹⁶⁸² For example, the CMA has applied a revenue-based, rather than volume-based allocation for debtors, as debtors represent the amount of sales which have not yet been paid for by customers.

only necessary to conduct a limited allocation exercise in order to establish Actavis's working capital.¹⁶⁸³

5.160. A comparison of Auden's working capital balances before and after Allergan's acquisition of AM Pharma indicates that the figure for earlier periods may be inflated. Total working capital requirements are likely to change in line with revenues. This can be seen in historical data showing that Auden's working capital balance in 2015 was significantly greater than in prior years. However, as shown in tables 5.11 and 5.12 below, the working capital balance allocated in the period from January to September 2015 is almost double the [REDACTED] balance allocated from September 2015 onwards, using more accurate data. Given that there is no reason for Auden/Actavis's working capital balance, which is specific to 10mg and 20mg hydrocortisone tablets, to have fallen so significantly since Allergan's acquisition of AM Pharma, this indicates that the pre-September figure used by the CMA is very likely to be a highly inflated one when considering what Auden's working capital is likely to have been. Accordingly, by using this figure the CMA has taken an approach which is favourable to Auden/Actavis when assessing whether its prices were excessively high. This is because by using this figure, the CMA will establish a higher reasonable rate of return figure for Auden/Actavis than would have been the case with more accurate data thereby reducing the level of any differentials (the gap between Auden/Actavis's ASPs and its Cost Plus). In other words, taking this approach will reduce the chances of establishing that Auden/Actavis's prices were excessive under the *United Brands* Test.

Table 5.11: Working capital employed by Auden (January-September 2015)

	Attributable to 10mg hydrocortisone tablets	Attributable to 20mg hydrocortisone tablets
	£'000	£'000
<u>Working capital</u>		
Trade debtors	[REDACTED]	[REDACTED]
Trade creditors	[REDACTED]	[REDACTED]
Stock	[REDACTED]	[REDACTED]
Total Working capital	[REDACTED]	[REDACTED]

¹⁶⁸³ Creditor balances are only recorded for hydrocortisone tablets as a whole and therefore the CMA has allocated this balance using the average sales volumes ratio of 10mg to 20mg hydrocortisone tablets, and adjusted for the difference in purchase price Accord-UK faces for each product.

Table 5.12: Working capital employed by Actavis (September 2015-December 2016)

	Attributable to 10mg hydrocortisone tablets	Attributable to 20mg hydrocortisone tablets
	£'000	£'000
<u>Working capital</u>		
Trade debtors	[X]	[X]
Trade creditors	[X]	[X]
Stock	[X]	[X]
Total Working capital	[X]	[X]

- 5.161. In addition, the approach the CMA has adopted of using Auden/Actavis's actual receivables balance also errs significantly in Auden/Actavis's favour when determining whether its prices were excessive. This is because the debtors balance resulting from a product being sold at an excessive price does not represent an efficient level of capital employed by the business, since the high price distorts and inflates the trade debtor balance proportionately.¹⁶⁸⁴
- 5.162. In effect, the high prices charged increase the capital employed and therefore the reasonable return on capital, increasing Cost Plus and reducing the scale of the measured differentials. In other words, in using these inflated figures in the CMA's analysis will reduce the chances of establishing that Auden/Actavis's prices were excessive under the *United Brands* Test.
- 5.163. Although the CMA considers that the working capital balance should, in theory, be reduced, it has decided not to do so in this case. This is because despite clearly inflating the reasonable rate of return figure attributed to Auden/Actavis for the sale of hydrocortisone tablets during the Unfair Pricing Abuses, the impact of using the inflated working capital figure is not determinative in this case. In other words, if the CMA was to use a lower figure which would be more reflective of Auden/Actavis's working capital costs, this would not materially affect the scale of the differentials, such was the scale of Auden/Actavis's prices.
- 5.164. Given that the use of Auden/Actavis's actual working capital leads to an overestimate of capital employed, the CMA has used the resultant figure as the upper bound for the level of capital employed in the CMA's assessment

¹⁶⁸⁴ Were the product not sold at an excessive price, the debtors balance would represent the total of costs (including cost of capital) which the business has incurred. Until such time as the debtor is received, capital is required to fund the timing difference.

and decided that a range of capital employed balances is not necessary in this case.¹⁶⁸⁵

The CMA's approach to fixed assets

- 5.165. Auden/Actavis's capital base also includes fixed assets. To the extent that they are efficiently employed in the supply of 10mg and 20mg hydrocortisone tablets, Auden/Actavis should be allowed a return on these assets when calculating Auden/Actavis's Cost Plus.
- 5.166. For the period to September 2015 the CMA has relied on Auden's fixed asset balances in its financial statements for the financial year ending 31 March. From September 2015 onwards, it has relied on data submissions from the parties.
- 5.167. For the purpose of its accounts,¹⁶⁸⁶ Auden broke down its fixed assets into the following three categories, and the CMA has applied the same categories for the purpose of its analysis:
- a. tangible;
 - b. intangible; and
 - c. investments.

Tangible assets

- 5.168. Tangible assets include land and buildings, plant and machinery, fixtures and fittings and motor vehicles. The CMA has included these categories of tangible assets in its assessment of Auden/Actavis's fixed asset base, because Auden/Actavis will have used each of them to supply 10mg and 20mg hydrocortisone tablets in the UK.
- 5.169. In determining the value of capital employed, the CMA considers the relevant benchmark to be the 'value to the business' ('**VTB**') of the assets. The VTB is given by the lower of the assets' (depreciated) replacement cost and their net realisable value.¹⁶⁸⁷ Where assets are being actively used by a business, the VTB will usually be the (depreciated) replacement cost of the

¹⁶⁸⁵ The effect of including a higher working capital asset value is to increase the capital base used by Auden/Actavis in selling hydrocortisone tablets, meaning it will be provided with a higher reasonable return for the supply of the tablets than would otherwise have been granted. This higher return means that the difference between Auden/Actavis's prices and its Cost Plus allocation will be lower than would have genuinely been the case meaning its prices are also less likely to be excessive.

¹⁶⁸⁶ For subsequent periods, the breakdown of those assets would have reflected the reporting structure of its subsequent owners.

¹⁶⁸⁷ The net realisable value of an asset is the higher of its value in use and the value that could have been achieved by selling the asset.

asset. In this case, the CMA has used the net book value ('**NBV**') of these tangible assets as the best estimate of the (depreciated) replacement cost. This value is readily available, reflects the cost incurred by the business to acquire the relevant assets, and the extent to which the business considers their value to have depreciated since acquisition.

- 5.170. The NBV of land and buildings were revalued in the year ending 31 March 2015. As this approximates to the period of the data which the CMA has relied upon, the CMA has reached its conclusions based on the NBV of these assets being likely to be a fair reflection of their (depreciated) replacement cost.¹⁶⁸⁸
- 5.171. Therefore, the CMA has relied on the NBV of land and buildings as at 31 March 2015 for the period to September 2015. From September 2015 onwards, it has relied on data submissions from the parties.
- 5.172. As the tangible asset data Auden/Actavis has provided to the CMA relates to Auden/Actavis's business as a whole and was not allocated to specific products, the CMA has used an allocation method to allocate them to individual products. The CMA has allocated a proportion of the NBV of these assets to 10mg and 20mg hydrocortisone tablets on the basis of sales volumes data, on a per pack basis. This is consistent with the approach that was taken in respect of the allocation of common costs. As outlined above, a sales volumes approach is objective and transparent, and the CMA considers this method to be practical and reliable in the context of cost allocation for 10mg and 20mg hydrocortisone tablets.
- 5.173. Depreciation is a cost associated with spreading the costs of capital assets over the lifetime of the assets, and is already included as an expense within the CMA's common cost assessment. As a result, the CMA has allocated depreciation according to sales volumes, consistent with its approach to fixed asset allocation for 10mg and 20mg hydrocortisone tablets.
- 5.174. In considering whether its asset allocation method is appropriate, the CMA has considered whether it produces a reasonable outcome. Under the CMA's chosen method, 10% of Auden's tangible assets in 2015 were allocated to 10mg and 20mg hydrocortisone tablets. Given that 10mg and

¹⁶⁸⁸ Auden/Actavis submitted that the CMA should have recognised that accounting depreciation may not be equivalent to economic depreciation (Document 01454, paragraph 5.32 Auden/Actavis's RSO1), and Intas/Accord-UK submitted that there is no reason to assume no value beyond book value at historical cost (Document 205212, Intas/Accord-UK's RSSO, paragraph 137(iv)). Whilst there is potential for the NBV of land and buildings to diverge from their replacement value, these assets were revalued in the year ending 31 March 2015 which is approximate to the period of the data on which the CMA has relied. Directors also have a responsibility to choose an appropriate depreciation schedule for assets and the CMA considers that it is appropriate to rely on the schedules they have chosen in the absence of clear evidence that these are inappropriate. Therefore, the NBV of these assets is likely to be a fair reflection of their market value.

20mg hydrocortisone tablets represented just two of over 80 products supplied by Auden with the support of these assets, the CMA considers that this is a reasonable approach.

- 5.175. Further, the CMA has allocated a portion of all of Auden/Actavis's tangible assets to 10mg and 20mg hydrocortisone tablets, even though manufacturing assets are not applicable to those products as Auden/Actavis purchased hydrocortisone tablets from a CMO.¹⁶⁸⁹ This is favourable to Auden/Actavis in the context of considering whether or not its prices for 10 and 20mg hydrocortisone tablets were excessive.¹⁶⁹⁰

Intangible assets

- 5.176. Auden/Actavis's intangible assets were composed of product licences and goodwill. The CMA has included product rights relating to hydrocortisone tablets in its estimate of capital employed, but excluded goodwill and other intangible assets for reasons explained below.
- 5.177. In order to manufacture 10mg and 20mg hydrocortisone tablets Auden/Actavis required intangible product rights¹⁶⁹¹ in the form of MAs.
- 5.178. Auden purchased the trademarks and MAs for 10mg and 20mg hydrocortisone tablets in 2008 for a total of £200,000.^{1692,1693} As this transaction took place at a time where there was no concern that the prices charged for these products were excessive and unfair, the CMA considers the figure reflects the reasonable value of the intellectual property itself (unaffected by potential capitalisation of future profits).
- 5.179. Auden's accounting policy was to fully amortise any purchased licence costs over an estimated useful life of five years from the date of purchase,¹⁶⁹⁴ and Actavis amortised its MAs over a 10-year period.
- 5.180. However, as there is no evidence that the value of these product rights follows such accounting treatment (ie their value does not decline over time

¹⁶⁸⁹ Document 02050.A, Intas/Accord-UK's response to the CMA's section 26 notice dated 10 November 2017, response to question 2. This point is equally relevant to earlier ownership periods.

¹⁶⁹⁰ The effect of including additional assets is to increase the capital base used by Auden/Actavis in selling hydrocortisone tablets, meaning it will be provided with a higher reasonable return for the supply of the tablets than would otherwise have been granted.

¹⁶⁹¹ A product right is a term used to describe an intangible asset relating specifically to the regulatory approval (in this case an MA) and the technical know-how required for the supply of 10mg and 20mg hydrocortisone tablets.

¹⁶⁹² See section 3.F.I above.

¹⁶⁹³ Auden/Actavis submitted that the product licences of all its pharmaceutical products should have been incorporated into the CMA's assessment (Document 11454, Auden/Actavis's RS01, paragraph 5.50. However, these assets are fully attributable to products other than hydrocortisone tablets. Therefore, it would be inappropriate to include these assets in the CMA's assessment.

¹⁶⁹⁴ Auden McKenzie Holdings Limited Consolidated Report and Accounts 31 March 2015, page 11.

in the same way as physical assets such as plant and machinery), the CMA has used the unamortised value of the acquired product rights (ie a constant asset value of £200,000 throughout the Unfair Pricing Abuses). The CMA considers this a conservative approach, which is more favourable to the parties than using the amortised book value.

- 5.181. Goodwill is a further category of intangible asset. Goodwill materialises when a firm acquires another business and is calculated by deducting the fair market value of the acquired, identifiable net assets from the purchase price. As such, it does not represent an asset that is required to produce or supply specific goods or services, hence cannot be considered a cost that is efficiently incurred in supplying such goods or services. Moreover, given that the purchase price of a business is likely to reflect the value of the expected future profits of the business, goodwill balances will capitalise any excessive returns where they are present.
- 5.182. In this case, given that Auden acquired the MAs for 10mg and 20mg hydrocortisone tablets directly from MSD rather than through a corporate acquisition there is no goodwill to consider for Auden's period of ownership. Allergan's valuation of Auden¹⁶⁹⁵ was determined through the net present value of future expected profits on the various products sold by Auden, including 10mg and 20mg hydrocortisone tablets. Consequently, the inclusion of any such balances in capital employed would serve to mask the excessiveness of prices.
- 5.183. The CMA has therefore not included a value for goodwill in its assessment of fixed assets.

Investments

- 5.184. Auden's investments balance related to the acquisition of companies which were not involved in its supply of 10mg or 20mg hydrocortisone tablets. The financial statements of Auden Mckenzie Holdings Limited defined this class of assets as 'Investments in subsidiary undertakings' or 'unlisted investments'.¹⁶⁹⁶ Accordingly, the CMA has not included this type of investment balance in its estimate of capital employed in the supply of 10mg and 20mg hydrocortisone tablets for Auden/Actavis.

¹⁶⁹⁵ Document 00670, Auden/Actavis's response to the CMA's section 26 notice dated 23 June 2016, response to question 14; and Document 00682, Annex 12.

¹⁶⁹⁶ Auden Mckenzie Holdings Limited Consolidated Report and Accounts 31 March 2015, page 16.

Capital employed by Auden to 2015

5.185. Table 5.13 outlines the level of capital employed by Auden in 2015 which the CMA has attributed to 10mg and 20mg hydrocortisone tablets, and that the CMA has adopted as being representative for the period between October 2008 and August 2015, due to the lack of reliable data before then.

Table 5.13: Capital employed by Auden in 2015¹⁶⁹⁷

	Auden	Allocated to 10mg hydrocortisone tablets	Allocated to 20mg hydrocortisone tablets
	£'000	£'000	£'000
Working capital			
Trade debtors ¹	[X]	[X]	[X]
Trade creditors ²	[X]	[X]	[X]
Stock ²	[X]	[X]	[X]
Tax and Social Security ¹	[X]	[X]	[X]
Other assets ¹	[X]	[X]	[X]
Other liabilities ²	[X]	[X]	[X]
Total Net Working Capital	[X]	[X]	[X]
Fixed Assets ³		[X]	[X]
	[X]	[X]	[X]
Total Capital Employed		[X]	[X]

¹ Allocated based on the ratio of hydrocortisone tablets revenue sales against total revenue.

² Allocated based on the ratio of cost of hydrocortisone tablets against the total cost of goods sold.

³ Allocated based on sales volume of hydrocortisone tablets against total sales volumes.

¹⁶⁹⁷ Document 00681, Annex 11, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016.

- 5.186. The CMA allocated Auden's working capital balances using its sales revenue and purchasing data and allocated fixed assets using sales volumes data.
- 5.187. With regard to fixed asset allocation, Auden/Actavis submitted that the CMA should adopt a '*stand-alone*' approach, in which Auden/Actavis is assumed to sell only hydrocortisone tablets and hence all fixed assets are allocated to hydrocortisone tablets. Auden/Actavis submitted that this approach would reflect the costs faced by a new entrant and therefore represent the '*free entry price*'.¹⁶⁹⁸
- 5.188. Such a 'stand-alone' approach is not appropriate in this case for two reasons.
- 5.189. First, such an approach would be completely divorced from reality. The lack of single product suppliers in the pharmaceuticals sector indicates that entering without any pre-existing assets or infrastructure is not realistic or efficient. This is illustrated by looking at the current prices of hydrocortisone tablets which, have declined to levels at or below the CMA's estimate of Cost Plus. This demonstrates that the efficient costs of production are not those of a stand-alone, single product firm.
- 5.190. Secondly and in any event, it would not produce reliable results when applied to Auden/Actavis. A single product company would operate on a smaller scale than Auden/Actavis and so its asset base would have to be adjusted downwards.
- 5.191. Auden/Actavis also submitted that the CMA's approach of using capital employed as of 2015 as being representative of the 2008 to 2015 period led to '*at least one material error*'.¹⁶⁹⁹ Auden/Actavis considered that, '*because over this period, the relative importance of Hydrocortisone Tablets in terms of both volume and value has sharply decreased*', allocation based on asset values would be likely to underestimate the average level of capital employed that should be allocated to hydrocortisone tablets.
- 5.192. The CMA considered whether its approach could distort the calculation of Cost Plus in this case. In this respect, the CMA noted that since the proportion of 10mg and 20mg hydrocortisone tablets sales volumes as a proportion of total sales volumes declined over this period, it could be appropriate to allocate a higher proportion of total capital employed to 10mg and 20mg hydrocortisone tablets in earlier years.

¹⁶⁹⁸ Document 205217, Auden/Actavis's RSSO, paragraph 4.27. See also Document 01454, Auden/Actavis's RSO1, section 5, paragraph 5.36.

¹⁶⁹⁹ Document 01454, Auden/Actavis's RSO1, paragraph 5.29.

- 5.193. However, if the CMA took this approach, it would also need to take into account Auden's lower asset base during that same period (Auden's fixed tangible assets grew from [X] in 2008 to [X] in 2015).
- 5.194. The net effect of applying the historically higher sales volume share of 10mg and 20mg hydrocortisone tablets of [X] to the lower asset base of [X], and the fixed asset allocation, would be an allocation approximately [X] lower than under the CMA's chosen approach. The current approach is therefore slightly favourable to Auden/Actavis in determining whether or not its prices were excessive.
- 5.195. Further, as explained in paragraph 5.78 above the CMA's approach is generous to Auden/Actavis in other ways. Auden's working capital balance in 2015 was significantly greater than in prior years. The working capital balance allocated in 2015 was almost double the [X] balance allocated from September 2015 onwards, using more accurate data. Given that there is no reason for Auden/Actavis's working capital balance, which is specific to hydrocortisone tablets, to have fallen so significantly since Allergan's acquisition of AM Pharma, this is a further indication that the pre-September figure used by the CMA is inflated and favourable to Auden/Actavis.
- 5.196. The CMA therefore considers that any errors in its approach would favour Auden/Actavis.

Capital employed by Actavis from September 2015 onwards

- 5.197. For the period from September 2015 onwards, the CMA has allocated Actavis's working capital balances based on working capital balances recorded for hydrocortisone tablets as a whole,¹⁷⁰⁰ and allocated fixed assets using sales volumes data.
- 5.198. Table 5.14 below outlines the level of capital employed by Actavis between September 2015 and December 2016 and table 5.15 below outlines the level of capital employed by Actavis between January 2017 and July 2018 that the CMA has attributed to 10mg and 20mg hydrocortisone tablets.

¹⁷⁰⁰ As credit balances are only recorded for hydrocortisone tablets as a whole, the CMA has allocated this balance using the average sales volumes ratio of 10mg to 20mg hydrocortisone tablets, and adjusted the difference in purchase price Actavis faces for each product

Table 5.14: Capital employed by Actavis between September 2015 and December 2016

	Attributable to 10mg hydrocortisone tablets	Attributable to 20mg hydrocortisone tablets
	£'000	£'000
<u>Working capital</u>		
Trade debtors	[X]	[X]
Trade creditors	[X]	[X]
Inventory	[X]	[X]
Total Working capital	[X]	[X]
	[X]	[X]
Fixed Assets	[X]	[X]
Total capital employed	[X]	[X]

Table 5.15: Capital employed by Actavis between January 2017 and July 2018

	Attributable to 10mg hydrocortisone tablets	Attributable to 20mg hydrocortisone tablets
	£'000	£'000
<u>Working capital</u>		
Trade debtors	[X]	[X]
Trade creditors	[X]	[X]
Inventory	[X]	[X]
Total Working capital	[X]	[X]
	[X]	[X]
Fixed Assets	[X]	[X]
Total capital employed	[X]	[X]

5.199. Auden/Actavis submitted that the discrepancy between the CMA's estimates of the level of capital employed before and after the change in ownership in January 2017, which fell by over [X], highlights '*obvious errors*' in the CMA's analysis.¹⁷⁰¹ However, it is right that Auden/Actavis is assessed on the basis of the capital which it actually employed efficiently. As the tables above show, the fall was driven by working capital, which is due to more accurate working capital data specific to hydrocortisone tablets being available to the CMA after the change in ownership.

5.200. This fall is therefore a further indication of the ways in which the CMA's approach to calculating Cost Plus favours Auden/Actavis. The unavoidable use of less accurate data in the earlier period is favourable to Auden/Actavis:

¹⁷⁰¹ Document 01454, Auden/Actavis's RSO1, paragraph 5.38.

the implication of more accurate data from the later period is once again that the level of capital employed in the earlier period is overstated.

ii. The reasonable rate of return

- 5.201. The CMA has concluded that a return of **[5%-15%]** is reasonable for Auden/Actavis's 10mg and 20mg hydrocortisone tablets. This return represents the reasonable level of profit that the firms may expect to earn from undertaking the relevant activity: in this case the supply of hydrocortisone tablets. In particular, the CMA considers that the reasonable rate of return in this case is most appropriately informed by the rate used by Actavis when valuing Auden's business. That valuation included 10mg and 20mg hydrocortisone tablets, which were collectively Auden's most significant products in terms of revenue at the time.
- 5.202. Actavis provided the CMA with the valuation model used in connection with Allergan's acquisition of AM Pharma.¹⁷⁰² That model included projections of profitability and discounted future revenues and profits using a weighted average cost of capital ('WACC') of **[5%-15%]**. According to Allergan, that figure was *'based on Actavis's experience and knowledge concerning the generic pharmaceutical sector generally and also based on a review of the information that Auden McKenzie provided to Actavis during the diligence process, including the fact that Auden McKenzie was an established and ongoing business and that it would be combined with Actavis' existing UK business'*.¹⁷⁰³
- 5.203. Actavis itself applied this figure on an individual product basis, including against sales of hydrocortisone tablets, in order to discount its expected future profits of Auden's products for the purposes of valuing that business. Given that it represents Actavis's contemporaneous assessment of Auden's risk profile, the CMA considers that the **[5%-15%]** WACC used by Actavis provides an appropriate level of ROCE to use in the CMA's assessment of what is a reasonable rate of return in this case in relation to both 10mg and 20mg hydrocortisone tablets.
- 5.204. Auden/Actavis submitted that the **[5%-15%]** WACC figure used was likely to have reflected a *'cautious'* approach focusing on the minimum required return on Allergan's acquisition of AM Pharma.¹⁷⁰⁴

¹⁷⁰² Document 00670, Auden/Actavis's response to the CMA's section 26 notice dated 23 June 2016, response to question 14; and Document 00682, Annex 12.

¹⁷⁰³ Document 02045.A, Allergan's response to the CMA's section 26 notice dated 10 November 2017, email to the CMA dated 24 November 2017.

¹⁷⁰⁴ Document 205217, Auden/Actavis's RSSO paragraph 4.32.

- 5.205. However, given that adopting a higher WACC would have led to a lower valuation of AM Pharma, a '*cautious*' approach would actually have been to adopt a higher than ordinary WACC, in order to minimise the risk that Allergan was placing too high a value on the business. This suggests that **[5%-15%]** may already be a generous rate of return for Auden/Actavis.¹⁷⁰⁵
- 5.206. It is important to note that WACC represents a **reasonable** return for investors rather than a minimum required return, because it represents the weighted average cost of debt and equity to the firm.¹⁷⁰⁶ The cost of debt will be based on three key elements: a risk-free rate, a total market return and a beta value. All of these elements are estimated from actual market values, with the total market return reflecting the average actual returns earned by investors in the market in the past. While, *ex ante*, investors will not provide funds unless they expect to earn a return at least equivalent to the WACC, they do so in the knowledge that (*ex post*) actual returns may be above or below this level. As explained in paragraph 5.148 above, the purpose of allowing a reasonable rate of return in this assessment is to ensure that Auden/Actavis is sufficiently compensated for the risk and investment undertaken when entering and participating in this market. The CMA considers that the use of WACC achieves this aim in this case.
- 5.207. Intas/Accord-UK submitted that an appropriate pre-tax nominal WACC for Accord-UK under Intas's ownership would be around **[5%-15%]**.¹⁷⁰⁷ A later submission updated this figure to **[5%-15%]**, based on Intas itself.¹⁷⁰⁸ However, a change in ownership should not in itself affect the rate of return reasonably required by Auden/Actavis in relation to 10mg and 20mg hydrocortisone tablets, particularly where there has been no material change to Actavis's role or activities in the market as a result of its acquisition. Following Intas's acquisition of Accord-UK, hydrocortisone tablets remained a low risk product and the CMA finds that a rate of return of **[5%-15%]** for 10mg and 20mg hydrocortisone tablets remained appropriate. In addition, the **[5%-15%]** figure for Intas relies on parameters which are not meaningful

¹⁷⁰⁵ Auden/Actavis also submitted that AM Pharma should be entitled to a '*small company premium*' (Document 205217, Auden/Actavis's RSSO, paragraph 4.27. See also Document 01454, Auden/Actavis's RSO1, section 5, paragraph 5.52). In accounting a small company premium is only applicable to companies that face higher trading costs or higher costs of debt or capital than larger businesses. However, Auden/Actavis submitted no evidence that it faced these barriers or higher costs, and there is no reason to suspect that this may have been the case.

¹⁷⁰⁶ The weighted average cost of capital (WACC) is comprised of two components: the cost of debt and the cost of equity. The cost of debt reflects the return required to compensate debt investors for lending into a business and the cost of equity reflects the return required to compensate equity investors for providing capital to a business.

¹⁷⁰⁷ Document 01568, Intas/Accord-UK's response to the CMA's section 26 notice dated 3 May 2017, response to question 7.

¹⁷⁰⁸ Document 01614B, Intas/Accord-UK's submission to the CMA dated 2 June 2017.

in the context of the supply of hydrocortisone tablets in the UK.¹⁷⁰⁹ However, the CMA has also applied an illustrative sensitivity of a **[5%-15%]** WACC in its sensitivity analysis (see section 5.C.IV.b below).

5.208. As outlined in section 5.C.III.b.i above, the CMA's approach is to apply the ROCE framework to estimate a reasonable return. Under this framework, the allowed return for producing 10mg and 20mg hydrocortisone tablets is calculated by multiplying the capital employed by the WACC:

- a. The capital employed is the estimate of how much capital investors need to provide, in order to obtain the assets needed to supply 10mg and 20mg hydrocortisone tablets.
- b. The WACC is the average return investors expect on the capital provided.

5.209. Table 5.16 below outlines the CMA's estimate of Auden's reasonable return with respect to 10mg and 20mg hydrocortisone tablets for the period to 31 August 2015. Using a WACC of **[5%-15%]** the CMA estimates the reasonable return for 10mg and 20mg tablets to be **[£]** and **[£]** per pack respectively.

Table 5.16: Reasonable return on capital employed for Auden to 31 August 2015

	10mg hydrocortisone tablets	20mg hydrocortisone tablets
	Using NBV	Using NBV
Capital Employed	[£]	[£]
WACC of [5%-15%]		
Total reasonable return	[£]	[£]
Reasonable return by pack	[£]	[£]

5.210. Using a WACC of **[5%-15%]** on Actavis's capital employed estimates, table 5.17 outlines the CMA's estimate of Actavis's reasonable return with respect to 10mg and 20mg hydrocortisone tablets between September 2015 and 8 January 2017. Using the NBV measurement of fixed assets,¹⁷¹⁰ the CMA

¹⁷⁰⁹ For example, the cost of equity component of WACC relies on a risk free rate of **[5%-15%]** which is based on average India government bond yields. Document 01614B, Intas/Accord-UK's submission to the CMA dated 2 June 2017.

¹⁷¹⁰ Document 00690, Annex 4 to AM Pharma's response to the CMA's section 26 notice dated 24 August 2016.

estimates the reasonable return for 10mg and 20mg tablets to be [REDACTED] and [REDACTED] per pack respectively.

Table 5.17: Reasonable return on capital employed for Actavis between September 2015 and January 2017

	10mg hydrocortisone tablets	20mg hydrocortisone tablets
Capital Employed	[REDACTED]	[REDACTED]
WACC of [5%-15%]		
Total reasonable return	[REDACTED]	[REDACTED]
Reasonable return by pack	[REDACTED]	[REDACTED]

5.211. Using a WACC of **[5%-15%]** on Actavis's capital employed from 9 January 2017, table 5.18 below outlines the CMA's estimate of Actavis's reasonable return with respect to 10mg hydrocortisone tablets until 31 July 2018. Using the NBV measurement of fixed assets, the CMA estimates the reasonable return for 10mg tablets to be [REDACTED] per pack.

Table 5.18: Reasonable return on capital employed for Actavis between 9 January 2017 and 31 July 2018

	10mg hydrocortisone tablets
Capital Employed	[REDACTED]
WACC of [5%-15%]	
Total reasonable return	[REDACTED]
Reasonable return by pack	[REDACTED]

5.212. A WACC of **[5%-15%]** would have led to the reasonable returns per pack of 10mg hydrocortisone tablets increasing by up to [REDACTED]. This would not have a material impact on the CMA's finding of excessiveness (see section 5.C.IV.b.iii below).

5.213. Auden/Actavis submitted that the CMA should have considered other appropriate measure of profitability as well as ROCE, including return on sales ('**ROS**').¹⁷¹¹ Auden/Actavis provided an overview of operating profit margins (as a percentage of earnings before interest and tax) for the period 2013-2015 for seven other pharmaceutical companies in the market at that time, '*in order to have a better sense of what would be an appropriate level of operating profit*'.¹⁷¹² The CMA does not consider it necessary to further

¹⁷¹¹ Document 205217, Auden/Actavis's RSSO, paragraph 4.35. Return on Sales is a measure of the return on sales after the deduction of both direct and indirect costs.

¹⁷¹² Document 01454, Auden/Actavis's RSO1, paragraphs 5.66-5.68.

cross-check its findings against ROS, which it considers to be a less appropriate basis than return on capital employed in order to determine a reasonable rate of return for this particular case, or other profit measures. However, the CMA notes that, due to the large working capital employed balance, explained in paragraph 5.163, the return by pack included in its Cost Plus analysis translates into a ROS of approximately [X] during the Unfair Pricing Abuses.

- 5.214. The CMA considers that the size of this return, which is five times the size of the target ROS figure under the PPRS, demonstrates that the CMA has adopted an approach which is favourable to Auden/Actavis in determining a reasonable return per pack of hydrocortisone tablets sold by Auden/Actavis in the UK.¹⁷¹³ This ROS is also broadly consistent with Auden/Actavis's own analysis of operating profit margins,¹⁷¹⁴ which showed its operating profits margins to be between [X] and [X], which is significantly lower than the margins Auden/Actavis was achieving on its sales of hydrocortisone tablets.
- 5.215. The CMA has also compared the reasonable return in its Cost Plus analysis with the current average prices for competing skinny label tablets and with Accord's own average price for generics in the UK. Even in a hypothetical scenario where cost of supply was zero and revenues represented pure profit, this would equate to average returns of no more £1.34 per pack for 10mg hydrocortisone tablets. In reality, the expected return would be significantly lower than this after accounting for costs, and the CMA considers the return included in its Cost Plus analysis to be reasonable, if not generous.

¹⁷¹³ The CMA notes that this ROS is itself broadly consistent with Auden/Actavis's own analysis of operating profit margins in its RSO1 (Document 01454). Auden provided an overview of operating profit margins (as a percentage of earnings before interest and tax) for the period 2013-2015 for seven other pharmaceutical companies in the market at that time, '*in order to have a better sense of what would be an appropriate level of operating profit*' (paragraphs 5.66-5.68), which showed their operating profits margins to be between a range of between 10% and 30%, which is significantly lower than the margins Auden/Actavis was achieving on its sale of hydrocortisone tablets.

¹⁷¹⁴ As set out in Document 01454, Auden/Actavis's RSO1, paragraph 5.66 to 5.68.

Table 5.19: Comparison of reasonable return with real-world comparators

	10mg	20mg
Cost Plus	£2.17-£4.45	£2.90-£5.20
Reasonable return included in Cost Plus	[REDACTED]	[REDACTED]
Current average price of skinny label tablets	£1.34	£1.85
Actavis' current prices	[£1-£4]	[£1-£4]
Accord average UK generic price in 2018 (all products)	£1.19	

c. Summary of results

5.216. The CMA's method for calculating Cost Plus in this case, as set out in sections 5.C.III.a to 5.C.III.b above, results in the following Cost Plus ranges for 10mg and 20mg hydrocortisone tablets throughout each of the periods considered on a per pack basis and for the whole period (ie Auden/Actavis's revenue and costs throughout the whole of the Unfair Pricing abuses).

Table 5.20: Auden/Actavis's Cost Plus per pack of 10mg hydrocortisone tablets during the 10mg Unfair Pricing Abuse based on a ROCE of [5%-15%]

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	January 2017 – July 2018	Whole period
Price / Revenue	£29.53	£49.57	£65.31	£35.26	£292,447,709
Direct costs	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Common cost	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Reasonable return	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Cost Plus	£4.45	£3.90	£2.29	£2.17	£29,877,231

Table 5.21: Auden/Actavis's Cost Plus per pack of 20mg hydrocortisone tablets during the 20mg Unfair Pricing Abuse based on a ROCE of [5%-15%]

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	Whole period
Price / Revenue	£29.81	£56.81	£60.77	£14,957,392
Direct costs	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Common cost	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Reasonable return	[REDACTED]	[REDACTED]	[REDACTED]	[REDACTED]
Cost Plus	£5.20	£4.61	£2.91	£1,865,777

5.217. Cost Plus falls within a range of around £2 to £4.50 per pack for 10mg hydrocortisone tablets and around £3 to £5.50 per pack for 20mg hydrocortisone tablets, declining over the duration of the Unfair Pricing Abuses. As explained in paragraphs 5.140 to 5.141, this is primarily because the CMA has conservatively relied on actual common costs which fell significantly following AM Pharma's and subsequently Accord-UK's acquisition by larger companies, rather than just efficiently incurred costs. The CMA considers that the costs from September 2015 onwards reflect efficiently incurred costs, and the Cost Plus results for this later period are therefore more representative of the efficient level of Cost Plus.

Figure 5.22: Auden/Actavis's annual average Cost Plus per pack of 10mg hydrocortisone tablets during the 10mg Unfair Pricing Abuse



Figure 5.23: Auden/Actavis's annual average Cost plus per pack of 20mg hydrocortisone tablets during the 20mg Unfair Pricing Abuse



IV. Auden/Actavis's prices were excessive

- 5.218. The CMA has concluded that Auden/Actavis's prices were excessive because the differences between its prices and Cost Plus were material, ie sufficiently large to be deemed excessive.¹⁷¹⁵
- a. For 10mg tablets, Auden/Actavis's prices were excessive from 1 October 2008 to 31 July 2018.
 - b. For 20mg tablets, Auden/Actavis's prices were excessive from 1 October 2008 to 8 January 2017.
- 5.219. Throughout this section, the CMA refers to the difference between Auden/Actavis's prices and its Cost Plus as the **Differential**.¹⁷¹⁶ The Differential represents additional profit margin in excess of Cost Plus, which already includes a reasonable return.
- 5.220. Tables 5.24 and 5.27 and figures 5.25, 5.26, 5.28 and 5.29 below set out the Differential per pack in pounds (referred to as the absolute Differential, calculated by subtracting Cost Plus from the price) and percentages

¹⁷¹⁵ *Albion Water II* [2008] CAT 31, paragraph 199.

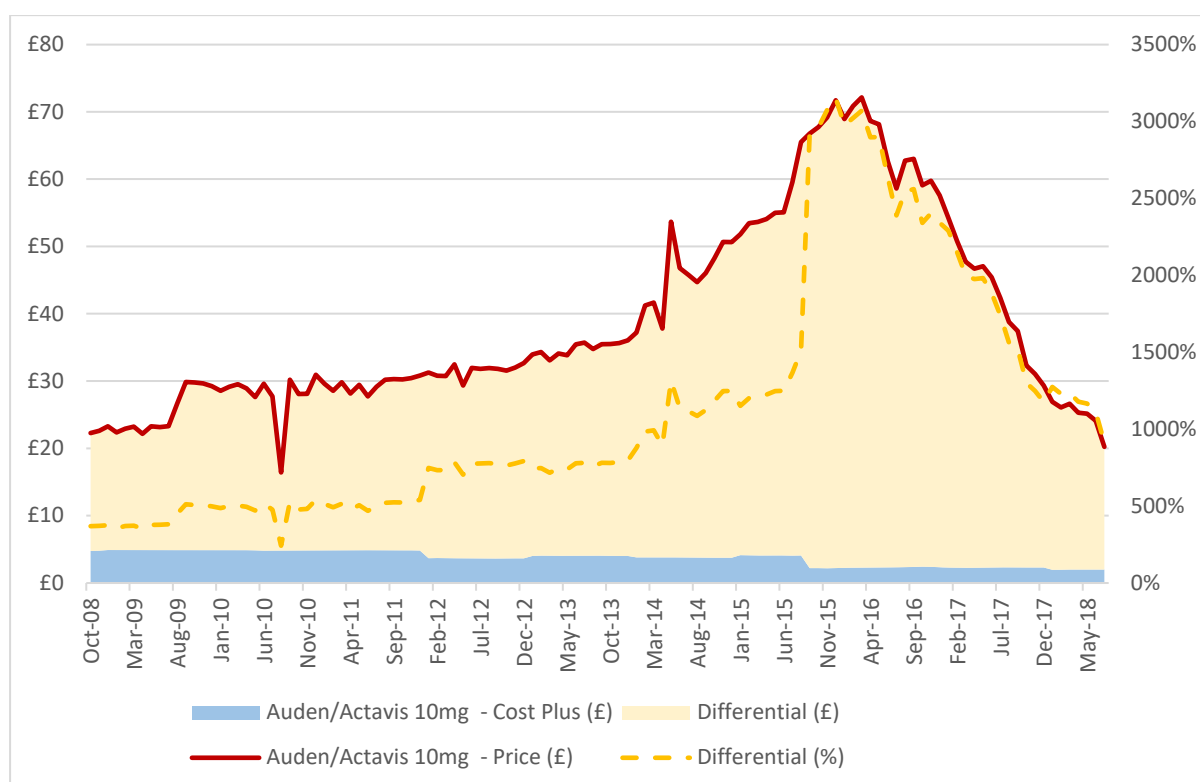
¹⁷¹⁶ In determining the Differentials in this case, the CMA has followed the approach taken in both *Deutsche Post* (see, for example, paragraph 166 of the decision); and *Albion Water II* [2008] CAT 31 (see, for example, paragraph 198 of the judgment).

(referred to as the relative Differential, calculated by subtracting Cost Plus from the price then dividing the result by Cost Plus). Figures 5.24 and 5.29 present the Differential per pack on an annualised basis. The tables also set out the Differential in terms of total revenue.¹⁷¹⁷ These comparisons are done for each of the four representative periods and in total throughout the whole of the 10mg and 20mg Unfair Pricing Abuses. The revenue differentials of £263 million for 10mg hydrocortisone and £11 million for 20mg hydrocortisone tablets are profits earned by Auden/Actavis in excess of Cost Plus.

Table 5.24: Differentials per pack of 10mg hydrocortisone tablets

	October 2008- December 2013	January 2014- August 2015	September 2015- January 2017	January 2017- July 2018	Whole period
Hydrocortisone 10mg - price £	29.53	49.57	65.31	35.26	37.87
Cost Plus £	£4.45	£3.90	£2.29	£2.17	£3.87
Differential - £	£25.08	£45.66	£63.02	£33.09	£34.00
Differential %	563%	1,172%	2,752%	1,524%	879%
Revenue differential (£m)	£115.1	£67.2	£53.2	£27.0	£262.6

Figure 5.25: Differentials per pack of 10mg hydrocortisone tablets



¹⁷¹⁷ In millions of pounds, calculated by multiplying the Differentials per pack by the number of packs sold.

Figure 5.26: Annualised Differentials per pack for 10mg hydrocortisone tablets



Table 5.27: Differentials per pack of 20mg hydrocortisone tablets

	October 2008- December 2013	January 2014- August 2015	September 2015- January 2017	Whole period
Hydrocortisone 20mg - price £	£29.81	£56.81	£60.77	£38.59
Cost Plus £	£5.20	£4.61	£2.91	4.81
Differential - £	£24.61	£52.20	£57.87	33.78
Differential %	474%	1,133%	1,990%	702%
Revenue differential (£m)	£6.6	£3.8	£2.6	£13.1

Figure 5.28: Differentials per pack of 20mg hydrocortisone tablets

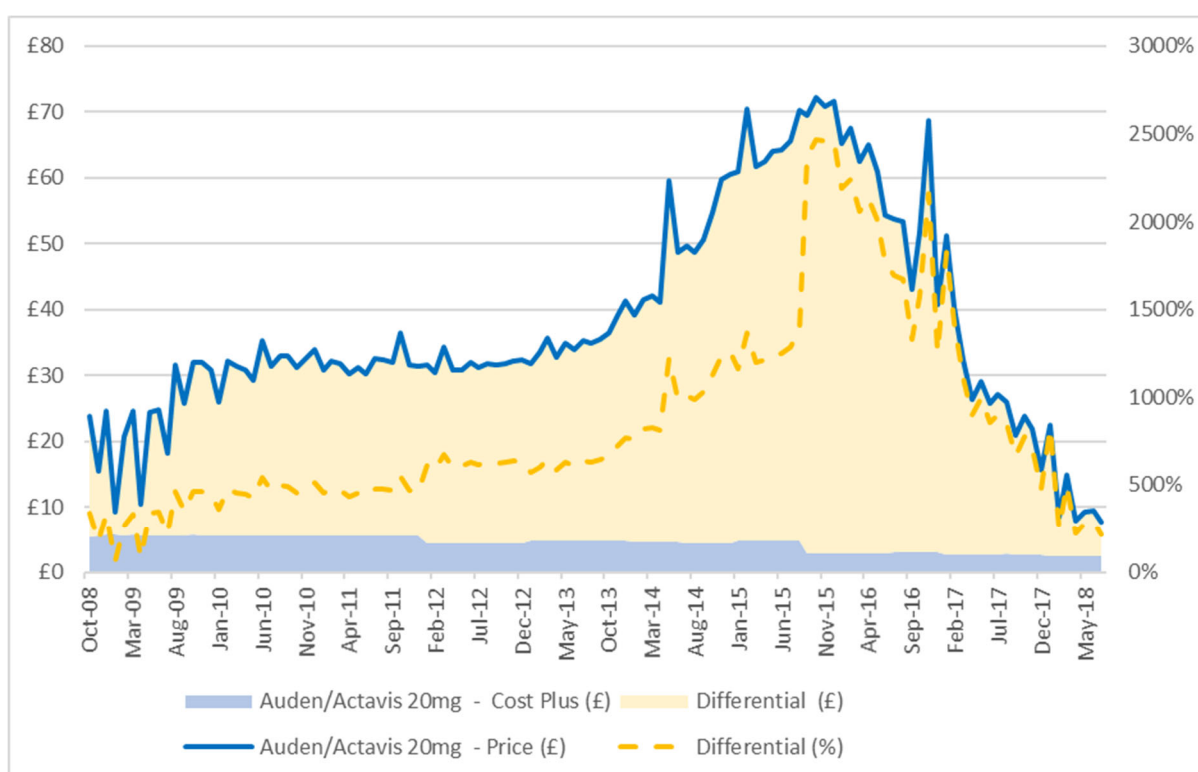


Figure 5.29: Annualised Differential per pack for 20mg hydrocortisone tablets



5.221. The CMA has concluded, applying a '*proper degree of discretionary judgment*',¹⁷¹⁸ that these Differentials were '*material*' and '*sufficiently large to be deemed excessive*'¹⁷¹⁹ by any reasonable measure. That is sufficient for a

¹⁷¹⁸ *Albion Water II* [2008] CAT 31, paragraphs 193 to 194.

¹⁷¹⁹ *Albion Water II* [2008] CAT 31, paragraph 199.

finding of excessiveness under the Excessive Limb of the *United Brands* Test.

5.222. Two points should be borne in mind when considering the Differentials.

5.223. First, Cost Plus in itself already includes a reasonable rate of return. However, the CMA has not made a finding that any price above Cost Plus was excessive. Instead, the CMA has exercised its discretion to determine its administrative priorities in this case and not reached a conclusion regarding at what level above Cost Plus but below **£20 per pack** Auden/Actavis's prices became excessive as a matter of law. This means that the **lowest** price at which the CMA has made a finding that Auden/Actavis's prices were excessive exceeds the upper bound of Cost Plus by **285%**.¹⁷²⁰ This is set out in tables 5.30 and 5.31 below.

Table 5.30: amounts by which the CMA's prioritisation threshold of £20 per pack exceeds Cost Plus for 10mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – 8 January 2017	9 January 2017 – July 2018	Whole period
Cost Plus (£ per pack)	£4.45	£3.90	£2.29	£2.17	£3.87
Amount by which £20 per pack exceeds Cost Plus (£ per pack)	£15.55	£16.10	£17.71	£17.83	£16.13
% by which £20 per pack exceeds Cost Plus	349%	413%	773%	821%	417%

¹⁷²⁰ Although Auden's prices fell below £20 in a few individual months during the Unfair Pricing Abuses (its 10mg price in a single month, August 2010, and its 20mg price in November 2008 and January, April and July 2009), these were single-month fluctuations in the context of sustained price increases over the period from 2008 to 2015. See figure 5.6 above.

Table 5.31: amounts by which the CMA's prioritisation threshold of £20 per pack exceeds Cost Plus for 20mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – 8 January 2017	Whole period
Cost Plus (£ per pack)	£5.20	£4.61	£2.91	£4.81
Amount by which £20 per pack exceeds Cost Plus (£ per pack)	£14.80	£15.39	£17.09	£15.19
% by which £20 per pack exceeds Cost Plus	285%	334%	588%	315%

- 5.224. Secondly, when considering whether the Differentials were material, consideration should also be given to the fact that, at various stages of the Cost Plus calculation, some aspects of the CMA's approach were beneficial to Auden/Actavis in establishing whether or not it priced excessively, such as its decision not to re-state working capital at the efficient level, and the use of available data on common cost in early periods which our later analysis suggests is not an efficient level.¹⁷²¹ These allocations increased the level of Auden/Actavis's Cost Plus meaning that the true scale of the Differentials was reduced. Notwithstanding this, the Differentials were clearly excessive.
- 5.225. Auden/Actavis's prices exceeded Cost Plus to a material extent both in each period considered and throughout the whole of the Unfair Pricing Abuses. That was the case regardless of whether the Differential is considered in absolute or relative terms, for both 10mg and 20mg tablets and for each representative period as well as across the whole of the Unfair Pricing Abuses:
- a. For 10mg hydrocortisone tablets, across the whole of the period for the 10mg Unfair Pricing Abuse, Auden/Actavis had:
 - i. an absolute Differential of £263 million; and
 - ii. a relative Differential of 879% (£34 per pack).
 - b. For 20mg hydrocortisone tablets, across the whole of the period for the 20mg Unfair Pricing Abuse, Auden/Actavis had:

¹⁷²¹ See paragraph 5.78 and section 5.C.I above.

- i. an absolute Differential of £13 million;¹⁷²² and
- ii. a relative Differential of 702% (£34 per pack).

5.226. At their peak, Auden/Actavis's relative Differentials per pack were:

- a. over 3,100% (£70 per pack) for 10mg hydrocortisone tablets; and
- b. over 2,400% (£69 per pack) for 20mg hydrocortisone tablets.

5.227. In terms of total revenue,¹⁷²³ the Differentials for 10mg hydrocortisone tablets were approximately:

- a. £115 million between 1 October 2008 and 31 December 2013;
- b. £67 million between 1 January 2014 and 31 August 2015;
- c. £53 million between 1 September 2015 and 8 January 2017; and
- d. £27 million between 9 January 2017 and 31 July 2018.

5.228. In terms of total revenue, the Differentials for 20mg hydrocortisone tablets were approximately:¹⁷²⁴

- a. £7 million in total between 1 October 2008 and 31 December 2013;
- b. £4 million between 1 January 2014 and 31 August 2015; and
- c. £3 million between 1 September 2015 and 8 January 2017.

a. Real-world evidence corroborating the CMA's finding that Auden/Actavis's prices were excessive

5.229. A substantial volume of real-world evidence corroborates the CMA's finding that Auden/Actavis's prices throughout the Unfair Pricing Abuses were excessive by reference to Cost Plus, namely:

- a. the prices Auden initially set for the sale of its hydrocortisone tablets in April 2008;
- b. the current prices of competing hydrocortisone tablets;

¹⁷²² The lower absolute Differential for 20mg hydrocortisone tablets as compared to that for 10mg hydrocortisone tablets reflects the fact that 10mg tablets account for around 96% of total sales of hydrocortisone tablets.

¹⁷²³ Multiplying the Differential per pack by volumes.

¹⁷²⁴ As explained above, the lower Differential in terms of revenue across the four periods for 20mg hydrocortisone tablets as compared to that for 10mg hydrocortisone tablets reflects the fact that 10mg tablets account for around 96% of total sales of hydrocortisone tablets.

- c. Actavis's current prices for its hydrocortisone tablets; and
- d. Allergan's projected prices following competitive entry.

5.230. This evidence, considered below, demonstrates not only that Cost Plus is an appropriate measure against which to assess whether Auden/Actavis's prices were excessive, but that the CMA's calculation of Cost Plus overestimates Cost Plus and therefore underestimates the extent to which Auden/Actavis's prices were excessive.

i. Auden's initial prices

- 5.231. The first piece of evidence that corroborates the CMA's finding that Auden/Actavis's prices during the Unfair Pricing Abuses were excessive is the prices that Auden initially set for its generic hydrocortisone tablets in April 2008, which were £4.54 per pack of 10mg tablets and £5.14 per pack of 20mg tablets (see section 3.E.V.a.i above).
- 5.232. These were prices that Auden initially determined appropriate for it to profitably sell hydrocortisone tablets in the UK.¹⁷²⁵ These initial prices are within or very close to the upper bounds of the Cost Plus range and are therefore corroborative of the CMA's own independent Cost Plus calculation. In fact, a comparison of Auden's entry prices with the CMA's calculation of Cost Plus for the period between 1 October 2008 and 31 December 2013 (which is the period most relevant to Auden) shows that the two were closely aligned.

Table 5.32: Comparison between Auden's entry prices and Cost Plus

Tablet strength	Auden's entry price	Cost Plus between 1 October 2008 and 31 December 2013
10mg	£4.54	£4.45
20mg	£5.14	£5.20

ii. The current prices of competing hydrocortisone tablets

- 5.233. The second piece of evidence that corroborates the CMA's finding that Auden/Actavis's prices during the Unfair Pricing Abuses were excessive is the current prices of competing hydrocortisone tablets.

¹⁷²⁵ In its representations, Auden/Actavis submitted that it launched its generic versions of hydrocortisone tablets in order for supply to become commercially viable: Document 205217, Auden/Actavis's RSSO, paragraphs 4.43-4.47. As the sole supplier of hydrocortisone tablets and not being constrained by the PPRS in the prices it could set, Auden would not be expected to set launch prices that were unprofitable.

- 5.234. When referring to 'current prices' the CMA is referring to weighted average prices over the period from February to April 2021.¹⁷²⁶
- 5.235. When referring to 'competing hydrocortisone tablets' the CMA is referring to all hydrocortisone tablets, both skinny and full label, supplied by Actavis's competitors, which comprise all skinny label 10mg hydrocortisone tablets,¹⁷²⁷ all skinny label 20mg hydrocortisone tablets,¹⁷²⁸ and Waymade's full label 20mg tablets.
- 5.236. The current prices of competing hydrocortisone tablets are:
- £1.34 per pack of 10mg skinny label tablets;
 - £1.85 per pack of 20mg skinny label tablets; and
 - [X] per pack of Waymade 20mg full label tablets.¹⁷²⁹
- 5.237. This shows that the CMA's Cost Plus figures are consistent with, and in fact higher than, the prices that Actavis's competitors are able to realise for hydrocortisone tablets after a prolonged period of competition between themselves and with Auden/Actavis.

Table 5.33: Comparison between current average price of competing hydrocortisone tablets and Cost Plus

Tablet strength	Current average price of competing hydrocortisone tablets	Cost Plus range
10mg skinny label	£1.34	£2.17 - £4.45
20mg skinny label	£1.85	£2.91 - £5.20
20mg full label (Waymade)	[X]	

Note: Weighted averages over the period from February to April 2021. For Waymade's 20mg full label tablets, from May to July 2020 because [X], see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

iii. Actavis's current prices

- 5.238. The third piece of evidence that corroborates the CMA's finding that Auden/Actavis's prices during the Unfair Pricing Abuses were excessive is Actavis's current prices.

¹⁷²⁶ April 2021 is the most recent sales data on the CMA's file. For Waymade's full label 20mg tablets, the period is May to July 2020 because [X], see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

¹⁷²⁷ Sold by AMCo (Aesica), Alissa, Bristol Laboratories, Genesis, Renata, Resolution Chemicals and Teva.

¹⁷²⁸ Sold by AMCo (Aesica and Focus), Bristol Laboratories, Genesis, Renata, Resolution Chemicals and Teva.

¹⁷²⁹ The prices of competing hydrocortisone tablets are assessed in detail in section 5.D.III.a below.

- 5.239. By 'current prices' the CMA refers to weighted average prices over the period from February to April 2021.
- 5.240. Actavis's current prices are:
- [£1-£4] per pack of 10mg tablets; and
 - [£1-£4] per pack of 20mg tablets.
- 5.241. This shows that the CMA's Cost Plus figures are also consistent with the prices that Actavis itself imposed after a prolonged period of competition from other suppliers, and following changes to how the reimbursement price is calculated for Category M drugs (see section 3.E.I.c above). In fact, Actavis's current price for 20mg tablets is [REDACTED], while its current price for 10mg tablets is [REDACTED] while its price has continued to fall).

Table 5.34: Comparison between Actavis's current prices of hydrocortisone tablets and Cost Plus

Tablet strength	Actavis's current price of hydrocortisone tablets	Cost Plus range
10mg	[£1-£4]	£2.17 - £4.45
20mg	[£1-£4]	£2.91 - £5.20

* Weighted averages over the period February to April 2021

iv. Allergan's projected prices following competitive entry

- 5.242. The fourth piece of evidence that corroborates the CMA's finding that Auden/Actavis's prices during the Unfair Pricing Abuses were excessive is the prices that Allergan projected would prevail if competition emerged. In January 2015 Auden's prices were £51.79 (10mg) and £60.64 (20mg). In that month, as part of its due diligence on the business of AM Pharma, Allergan modelled what would happen if competitors entered the market in 2015 and projected that Auden would experience '*price erosion of 90% over 3 yrs*',¹⁷³⁰ leading it to agree a £220 million reduction in the price it was prepared to pay for AM Pharma and an earn-out on the product in order to provide a '*total and complete de risking of hydrocortisone tablets for Actavis*'¹⁷³¹ (see paragraph 5.12 above). Based on Auden's prices in January 2015, this implied a reduction in the price of 10mg hydrocortisone tablets from approximately £52 per pack to £5.20 per pack and a reduction in the price of 20mg hydrocortisone tablets from approximately £61 per pack to £6.10 per pack. This shows that the CMA's Cost Plus figures are also

¹⁷³⁰ Document 00706, Project Apple presentation dated January 2015, slide 6.

¹⁷³¹ Document 302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

broadly consistent with the prices that Allergan expected would be realised following competitive entry.

Table 5.35: Comparison between Allergan's projected prices for hydrocortisone tablets and Cost Plus

Tablet strength	Allergan's projected prices	Cost Plus range
10mg	£5.20	£2.17 - £4.45
20mg	£6.10	£2.91 - £5.20

b. Sensitivities to Cost Plus

i. Overview

- 5.243. As explained in paragraph 5.91 above, the CMA has modelled sensitivities for two elements of its Cost Plus analysis:
- The first sensitivity involves analysing the effect of using alternative measures for the allocation of common costs.
 - The second sensitivity analyses the effect of changes in the rate of return (using a higher pre-tax nominal WACC than the **[5%-15%]** used, which is favourable to Auden/Actavis).¹⁷³²
- 5.244. The CMA has considered these sensitivities on both an individual and cumulative basis.
- 5.245. Once applied, these sensitivities do not alter the CMA's conclusion that the Differentials were material and sufficiently large to be deemed excessive, and therefore reinforce that conclusion. The cumulative effect of these two sensitivities could potentially increase the cost per pack by:
- up to [X]** in the case of 20mg hydrocortisone tablets; and
 - approximately **[X]** in the case of 10mg hydrocortisone tablets.
- 5.246. These sensitivities therefore assure confidence in the results of the CMA's Cost Plus assessment and its findings that Auden/Actavis's prices were excessive throughout the Unfair Pricing Abuses.¹⁷³³

¹⁷³² A higher WACC will always increase Auden/Actavis's Cost Plus figure and will therefore reduce the scale of any resulting differential between the Cost Plus figure and its prices.

¹⁷³³ Compare *Albion Water II* [2008] CAT 31, paragraph 93.

ii. **First sensitivity analysis: alternative measures for allocation of common costs**

5.247. The first sensitivity analyses the effect of using alternative measures for allocation of common costs. As explained in section 5.C.III.a.ii above, there are several alternative measures but the CMA considered sales volumes based allocation of common costs the most appropriate, based on available data. However, given that cost causation cannot be established based on available data, no allocation methodology will be uniquely correct, and to improve the robustness of its findings the CMA has performed a sensitivity analysis using the equal allocation method.

5.248. Tables 5.36 and 5.37 below set out the impact of using the equal allocation method on 10mg and 20mg hydrocortisone tablets. It is favourable to Accord/Actavis for 20mg hydrocortisone tablets as it increases Actavis's Cost Plus and therefore reduces the scale of any differential between the Cost Plus figure and its prices, but unfavourable for 10mg hydrocortisone tablets.

Table 5.36: Equal allocation method sensitivity analysis for 10mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	January 2017- July18	Whole period
Price / Revenue	£29.53	£49.57	£65.31	£35.26	£37.87
Base Case Cost Plus	£4.45	£3.90	£2.29	£2.17	£3.87
EA Sensitivity Adjustment	[X]	[X]	[X]	[X]	[X]
EA Scenario Cost Plus	[X]	[X]	[X]	[X]	[X]
Differential %	[X]	[X]	[X]	[X]	[X]

Table 5.37: Equal allocation method sensitivity analysis for 20mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	Whole period
Price / Revenue	£29.81	£56.81	£60.77	£38.59
Base Case Cost Plus	£5.20	£4.62	£2.91	£4.81
EA Sensitivity Adjustment	[X]	[X]	[X]	[X]
EA Scenario Cost Plus	[X]	[X]	[X]	[X]
Differential %	[X]	[X]	[X]	[X]

5.249. Because the equal allocation method allocates common costs equally across each of a company's products, it is a favourable approach when compared to a volume based cost allocation when determining Differentials for products

which account for a relatively small proportion of a company's total sales volumes. This is because it will allocate a higher level of common cost to those products than would be the case with a volume-based approach.

- 5.250. This is applicable for 20mg hydrocortisone tablets from 1 January 2014 onwards. However, while equal allocation would increase Cost Plus for 20mg tablets between 1 January 2014 and 31 August 2015 and between 1 September 2015 and 8 January 2017 by [X] and [X] per pack respectively, it would be unfavourable to Auden/Actavis between 1 October 2008 and 31 December 2013, reducing it by [X] per pack.
- 5.251. For 10mg hydrocortisone tablets, whose total sales volumes are significantly higher than those of 20mg hydrocortisone tablets, equal allocation would have been unfavourable to Auden/Actavis in comparison with volume-based allocation throughout the period from October 2008 to July 2018. This is because the equal allocation method would allocate a lower level of common costs to 10mg tablets and, consequently, give rise to a higher Differential when compared to volume-based allocation.¹⁷³⁴

iii. **Second sensitivity analysis: applying a higher WACC**

- 5.252. The second sensitivity modelled by the CMA is the impact of using a higher pre-tax nominal WACC than the **[5%-15%]** used for the purposes of its Cost Plus analysis, which was based on the WACC in the valuation model Allergan used in connection with its acquisition of AM Pharma. While the CMA considers that this provides an appropriate level of ROCE within the context of the CMA's Cost Plus analysis, it has applied a sensitivity of a **[5%-15%]** WACC.

Table 5.38: WACC sensitivity analysis for 10mg hydrocortisone tablets

<u>WACC Sensitivity Analysis – 10mg tablets</u>	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	January 2017- July18	Whole period
Price / Revenue	£29.53	£49.57	£65.31	£35.26	£37.87
Base Case Cost Plus	£4.45	£3.90	£2.29	£2.17	£3.87
WACC Sensitivity Adjustment	[X]	[X]	[X]	[X]	[X]
WACC Scenario Cost Plus	[X]	[X]	[X]	[X]	[X]
Differential %	[X]	[X]	[X]	[X]	[X]

¹⁷³⁴ As explained in paragraph 5.144 the CMA also compared the sales volume method with the EPMU method and found it led to similar level of common costs being allocated to both 10mg and 20mg hydrocortisone tables.

Table 5.39: WACC sensitivity analysis for 20mg hydrocortisone tablets

WACC Sensitivity Analysis – 20mg tablets	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	Whole period
Price / Revenue	£29.81	£56.81	£60.77	£38.59
Base Case Cost Plus	£5.20	£4.61	£2.91	£4.81
WACC Sensitivity Adjustment	[X]	[X]	[X]	[X]
WACC Scenario Cost Plus	[X]	[X]	[X]	[X]
Differential %	[X]	[X]	[X]	[X]

5.253. Auden/Actavis's prices were so high during the Unfair Pricing Abuses that even if the WACC applied was significantly increased (from **[5%-15%]** to **[5%-15%]**) they would still be excessive as a matter of law.

5.254. A WACC of **[5%-15%]** increases the Cost Plus level by around [X] per pack for 10mg hydrocortisone tablets and [X] per pack for 20mg hydrocortisone tablets. Accordingly, if the CMA used this significantly increased rate of return it would not affect its conclusion that Auden/Actavis's prices were excessive.

iv. Cumulative effect of the sensitivity analyses

5.255. The CMA has also considered the cumulative effect of a higher **[5%-15%]** WACC and the impact to Auden/Actavis of using equal allocation for allocation of common costs,¹⁷³⁵ as outlined below in tables 5.40 and 5.41 below.

5.256. For 10mg hydrocortisone tablets, the cumulative effect of the two sensitivity scenarios is to increase Cost Plus by **up to [X]** per pack.

5.257. For 20mg hydrocortisone tablets, the **cumulative** effect of the two sensitivity scenarios is to increase Cost Plus by **up to [X]** per pack.

¹⁷³⁵ As outlined above, there is no favourable impact from using the equal allocation method for 10mg tablets, and the impact is favourable for 20mg tablets only for the period from 1 January 2014 to 8 January 2017.

Table 5.40: Cumulative sensitivity analysis for 10mg hydrocortisone tablets

	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	January 2017- July18	Whole period
Price / Revenue	£29.53	£49.57	£65.31	£35.26	£37.87
Base Case Cost Plus	£4.45	£3.90	£2.29	£2.17	£3.87
Sensitivity Adjustment	[X]	[X]	[X]	[X]	[X]
Sensitivities Scenario Cost Plus	[X]	[X]	[X]	[X]	[X]
Differential %	[X]	[X]	[X]	[X]	[X]

Table 5.41: Cumulative sensitivity analysis for 20mg hydrocortisone tablets

<u>Sensitivities Scenario</u>	October 2008 – December 2013	January 2014 – August 2015	September 2015 – January 2017	Whole period
Price / Revenue	£29.81	£56.81	£60.77	£38.59
Base Case Cost Plus	£5.20	£4.61	£2.91	£4.81
Cumulative Adjustments	[X]	[X]	[X]	[X]
Sensitivities Scenario Cost Plus	[X]	[X]	[X]	[X]
Differential %	[X]	[X]	[X]	[X]

- 5.258. The CMA considers the outcome of its sensitivity analyses to be favourable to Auden/Actavis when assessing whether its prices were excessive, particularly given that the WACC sensitivity analysis excludes any adverse sensitivities.
- 5.259. Although the cumulative effect of these two sensitivities could potentially increase the cost per pack by **up to [X]** in the case of 20mg hydrocortisone tablets (approximately [X] in the case of 10mg hydrocortisone tablets), the Differentials would remain material and therefore excessive as a matter of law throughout the Unfair Pricing Abuses:
- For 10mg hydrocortisone tablets, the Differential would increase from approximately [X] between 1 October 2008 and 31 December 2013 to over [X] by 1 September 2015 before declining to approximately 1 [X] between 9 January 2017 and 31 July 2018.
 - For 20mg hydrocortisone tablets, the Differential would increase from [X] between 1 October 2008 and 31 December 2013 to approximately [X] by 1 September 2015.
- 5.260. Based on the above analysis the CMA considers that using an equal allocation method and/or adopting a rate of return of **[5%-15%]** (and likely

much higher) would not have resulted in a change to its conclusion that Auden/Actavis's prices were excessive.

V. The parties' representations on whether Auden/Actavis's prices were excessive

5.261. In this section, the CMA considers the representations that the parties submitted in response to the provisional finding in the SSO that Auden/Actavis's prices were excessive.

a. The relevance and application of Cost Plus

i. 'Cost Plus is detached from market reality'

5.262. Auden/Actavis and Intas/Accord-UK submitted that the CMA should not assess whether Auden/Actavis's prices were excessive by reference to Cost Plus.¹⁷³⁶ Auden/Actavis submitted that *'a Cost Plus approach based on ROCE [...] is based on a theoretical approach that is not based on real-world competition'*¹⁷³⁷ and *'may provide an inappropriate counterfactual'*.¹⁷³⁸ Intas/Accord-UK submitted that Cost Plus was *'detached from the functioning of the market and cannot reasonably be considered within the CMA's margin of "manoeuvre"'*.¹⁷³⁹ Instead, Intas/Accord-UK submitted that the CMA should have assessed whether Auden/Actavis's prices were excessive using the approach of the Director General of Fair Trading (DGFT) in *Napp*. In that case the DGFT, and the CAT on appeal, considered that a price would be excessive where it is above that which would exist in a competitive market.¹⁷⁴⁰

5.263. The Court of Appeal has held that:

'the first step in the analysis for the excessive limb is likely in most cases to be for the competition authority to consider whether the costs of production or the costs actually incurred in relation to the product in question, including of course a reasonable rate of return, can be ascertained. In some cases that simply cannot be done, and in others, it may provide an inappropriate counterfactual. But, where it can be

¹⁷³⁶ Document 205217, Auden/Actavis's RSSO, paragraph 1.8.1 and Document 205212, Intas/Accord-UK's RSSO, paragraphs 14-16.

¹⁷³⁷ Document 205217, Auden/Actavis's RSSO, paragraph 1.8.1.

¹⁷³⁸ Document 205217, Auden/Actavis's RSSO, paragraphs 4.17.

¹⁷³⁹ Document 205212, Intas/Accord-UK's RSSO, paragraphs 15, 124 and 125.

¹⁷⁴⁰ Document 205212, Intas/Accord-UK's RSSO, paragraphs 114-115. Compare Document 205217, Auden/Actavis's RSSO, paragraphs 3.77 and 4.13. *Napp Pharmaceutical Holdings v DGFT*, [2002] CAT 1, paragraphs 390-392 and 397.

*done, there is no reason, based on the applicable authorities, why the authority should not use that methodology’.*¹⁷⁴¹

- 5.264. As explained in paragraph 5.77 above, in this case Auden/Actavis’s costs actually incurred in relation to hydrocortisone tablets, including a reasonable rate of return, can be ascertained.
- 5.265. Further, in this case Cost Plus provides an appropriate counterfactual. The results of the CMA’s Cost Plus assessment are corroborated by an extensive volume of real-world evidence, including the fact that the current prices of all of Auden/Actavis’s competitors (including its only full label competitor, Waymade) have converged at levels substantially [X] and that Auden/Actavis’s own prices have fallen, in the case of 10mg tablets to [X], and in the case of 20mg tablets to [X].
- 5.266. When applied to this case, Cost Plus is therefore not a theoretical approach detached from the functioning of the market: real-world competition demonstrates that assessing Auden/Actavis’s prices by reference to Cost Plus is generous to Auden/Actavis. There is no need to conduct an assessment of what a hypothetical competitive price would be (a proposition rejected by the Court of Appeal in *Phenytoin*, which did not apply the *Napp* test).¹⁷⁴²
- 5.267. In fact, notwithstanding the parties’ submissions that Cost Plus bears no relation to the reality of pharmaceutical markets, Accord’s Executive Vice President for Europe and EMENA has publicly stated that *‘on average in the UK Accord sells a pack of medicine, typically for over 28 doses, for around GBP 1.19, less than a cup of coffee from a high street chain’*.¹⁷⁴³

ii. ‘Cost Plus is not appropriate for portfolio businesses’

- 5.268. Auden/Actavis submitted that generic pharmaceutical businesses set prices and allocate costs across their portfolio of drugs as a whole. Auden/Actavis therefore submitted that Cost Plus (and components of Cost Plus such as ROCE) is not appropriate for such businesses: multi-product firms are interrelated at an investment, operational and cost level and these

¹⁷⁴¹ *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 252.

¹⁷⁴² *Phenytoin CoA*, paragraphs 249-250 and 254.

¹⁷⁴³ [PharmaBoardroom | Interview: James Burt - Executive Vice President Europe and EMENA, Accord Healthcare](#). See also Accord’s 2018 accounts, which state that *‘the average pack price sold’* was £1.20. It is also the case that the Cost Plus range that the CMA has calculated is consistent with the prices that Auden initially determined it would be profitable to enter at: see section 5.C.IV.a above.

interdependencies mean that the profitability of individual products should not be considered in isolation.¹⁷⁴⁴

- 5.269. This submission fails to take into account the fact that undertakings have a special responsibility in relation to those products in respect of which they have a dominant position (here, hydrocortisone tablets). Indeed, this argument was considered and rejected in *Napp* where the CAT held that:

*‘Napp’s whole argument based on “portfolio pricing”, impermissibly directs attention away from the specific product market which we are required to consider when deciding whether there is an abuse of a dominant position under section 18 of the Act. In our view, it is not appropriate, when deciding whether an undertaking has abused a dominant position by charging excessive prices in a particular market, to take into account the reasonableness or otherwise of its profits in other, unspecified, markets comprised in some wider but undefined “portfolio” unrelated to the market in which dominance exists’.*¹⁷⁴⁵

iii. **‘The CMA should not require Auden/Actavis to price at Cost Plus’**

- 5.270. Auden/Actavis and Intas/Accord-UK submitted that it was unreasonable for the CMA to expect Auden/Actavis to price hydrocortisone tablets at Cost Plus and that the CMA was unjustified in finding that its prices were excessive and unfair simply because they exceeded Cost Plus.¹⁷⁴⁶
- 5.271. This mischaracterises the CMA’s findings. As explained in paragraphs 5.18 to 5.19 above, the CMA has not made a finding that any price above Cost Plus was excessive or unfair. Instead, the CMA has exercised its discretion to determine its administrative priorities in this case and not reached a conclusion regarding at what level above Cost Plus but below **£20 per pack** (which is **285%** above the upper bound of Cost Plus) Auden/Actavis’s prices became excessive and unfair as a matter of law. Given the nature of

¹⁷⁴⁴ Document 205217, Auden/Actavis’s RSSO, paragraph 4.29. See also Document 01454, Auden/Actavis’s RSO1, paragraph 5.17.

¹⁷⁴⁵ *Napp* [2002] CAT 1, paragraph 413. Further, Auden/Actavis’ business model with respect to hydrocortisone tablets was very different from those of some of the businesses it cited as ‘comparable’ in support of its portfolio pricing argument (Document 205217, Auden/Actavis’s RSSO, paragraph 4.29). Whereas those companies carry out research and development as part of originating pharmaceutical products, Auden/Actavis simply acquired the MAs for hydrocortisone tablets from MSD and replaced the originator’s branded product, which already had an established customer base and did not face any competition, with its generic versions. Auden/Actavis did not take the risk of investing in the development of hydrocortisone tablets alongside a number of other products in order to obtain a new MA and compete with an incumbent product. It did not make any incremental investment in the drug and did not face issues associated with manufacturing interdependencies (referred to in academic papers it cited in further support of its argument): it purchased its end product directly from Tiofarma, its CMO. The CMA therefore does not consider that hydrocortisone tablets are sufficiently interrelated with other products to justify considering their performance together; it remains appropriate to assess ROCE on an individual product basis.

¹⁷⁴⁶ Document 205217, Auden/Actavis’s RSSO, paragraph 1.8.1 and paragraph 4.36 and Document 205212, Intas/Accord-UK’s RSSO, paragraphs 6 and 15.

hydrocortisone tablets and the context in which their prices were set during the period covered by this Decision, this has given Auden/Actavis a very significant margin before its prices were clearly excessive and unfair.

5.272. In a follow-up submission, Intas/Accord-UK submitted that *‘in the absence of any indication of what the CMA considers “materially” above Cost Plus, a putative dominant undertaking ... would in practice be constrained to price at, or very close to, Cost Plus’*.¹⁷⁴⁷

5.273. As explained in paragraph 5.20 above, the CMA has not stipulated what a ‘fair’ price for hydrocortisone tablets would be. It is for a dominant undertaking to set its prices at a level that complies with competition law, taking into account the special responsibility it has and its own knowledge of its costs and market dynamics. The CMA has therefore not required Auden/Actavis to price at Cost Plus and the CMA has not imposed directions in this case. In any event, as explained in paragraph 5.78 above, in this case Cost Plus is likely to overstate the economic value of hydrocortisone tablets.

iv. ‘Auden would have been loss-making at Cost Plus’

5.274. Auden/Actavis submitted that *‘had Auden priced in line with the CMA’s Cost Plus framework, Auden’s business would have been loss-making for a number of years’*:

*‘when the CMA’s measure of “reasonable return” is applied to the Auden business as a whole, had Auden priced hydrocortisone tablets at a level that the CMA indicates would not have been excessive, it would have made losses across its entire business in each financial year between 2009 and 2012.’*¹⁷⁴⁸

5.275. It is not clear whether by these statements Auden/Actavis meant that Auden would have been loss-making:

- a. if it had priced all the drugs in its portfolio in line with Cost Plus; or
- b. if it had priced only hydrocortisone tablets in line with Cost Plus.

5.276. In any event, neither submission is relevant or credible.

¹⁷⁴⁷ Document 205579, letter from Intas/Accord-UK to the CMA dated 30 October 2020, paragraph 1.1. Compare Auden/Actavis’s RSSO, paragraph 4.15.

¹⁷⁴⁸ Document 205217, Auden/Actavis’s RSSO, paragraphs 1.9 and 4.34.

- 5.277. First, as explained in paragraphs 5.18 to 5.20 above, the CMA's findings in this case do not require Auden/Actavis to price hydrocortisone tablets, let alone all drugs in its portfolio,¹⁷⁴⁹ in line with Cost Plus.
- 5.278. Secondly, an undertaking cannot be permitted to 'prop up' an otherwise unprofitable business by charging excessive and unfair prices on a product where it holds a dominant position and therefore has a special responsibility not to abuse that position. As explained in paragraph 5.269 above, this argument has been rejected by the CAT.
- 5.279. In any event, the claim that Auden was loss-making on products other than hydrocortisone tablets is not supported by the evidence. Auden incurred operating losses of £22.7 million up to 31 March 2012 on products other than hydrocortisone tablets. However, these losses were avoidable: the prices of these products were set below their direct costs. Further, Auden did not need to depend on profits from hydrocortisone tablets to recoup those losses.¹⁷⁵⁰ Auden subsequently earned operating profits of £52.9 million over the next three years on these other products, at an overall operating profit margin of 18.1%. This demonstrates that those investments were profitable on their own and did not require excessive returns on hydrocortisone tablets in order to be financially viable.

v. 'Cost Plus favours monopoly'

- 5.280. Intas/Accord-UK submitted that pricing at Cost Plus would not act as a signal for competitors to enter and that by assessing Auden/Actavis's prices by reference to Cost Plus the CMA '*favours monopoly*'.¹⁷⁵¹ Intas/Accord-UK also submitted that '*a price which incentivises market entry is not an unfair price*'.¹⁷⁵²
- 5.281. Cost Plus does not '*favour monopoly*'. In this case there were several competing suppliers for each tablet strength charging prices that were below

¹⁷⁴⁹ Excessive and unfair pricing concerns only the conduct of a dominant undertaking. The CMA has not made a finding that Auden/Actavis was dominant in any market other than the relevant market(s) in this case.

¹⁷⁵⁰ For example, during this period, Auden sponsored the Renault Formula One racing team ([New sponsors for Renault - Eurosport](#)), a decision that is not consistent with a loss-making business. Such sponsorship continued in later periods. See Document 00681, Project Apple due diligence report dated 11 December 2014, page 24: '*The Company sponsored the Lotus and Force India Formula One teams in FY13 and FY14. We understand that such sponsorship has stopped and associated contracts terminated (although we have yet to see evidence of this) and unlikely to continue under your ownership, as such we have removed these costs.*'

¹⁷⁵¹ Document 205212, Intas/Accord-UK's RSSO, section 3.2.5, paragraphs 139-141 and 155

¹⁷⁵² Document 205212, Intas/Accord-UK's RSSO, paragraphs 168-171. See also paragraphs 17, 113, 146 and 168.

even the lowest bounds of Cost Plus, demonstrating that it is feasible for suppliers to set prices at this level.¹⁷⁵³

5.282. In any event, the emergence of competition is not an end in itself. In the case of hydrocortisone tablets, entry was unlikely to generate the non-price benefits (such as increased output, quality improvements, efficiency enhancement, introduction of new and better products) that competition can bring in other markets for the following reasons:

- a. By the time that competitive entry happened, the markets for hydrocortisone tablets were already well-established, with little scope to grow demand (through, for example, targeting new patient groups or finding new applications for or different ways to administer hydrocortisone tablets). Since there is a finite demand for hydrocortisone tablets, the low prices that entry may be expected to lead to in the long term would not result in an increase in the volume supplied.
- b. As hydrocortisone tablets are an old and established drug with limited scope for improvement, independent entry by other suppliers of hydrocortisone tablets has not resulted in substantially increased quality or better products. It has simply led to a number of generic versions being available, which would be expected to lower prices and keep prices low (see section 3.B.III above).

5.283. As explained in section 3.B.III above, with generic, commoditised products such as hydrocortisone tablets, the principal benefit of competition is price reductions. This would not be necessary but for Auden/Actavis's significant and sustained price increases. Intas/Accord-UK's submission implies that customers (in this case, the NHS) should be expected to 'sponsor' new entry by paying high prices to an incumbent in order to bring prices back down to where they began but without customers having a means to recover the higher prices they paid during the period when prices were increasing and high. In that scenario, customers would lose out in order to revert to the scenario that prevailed prior to prices increasing.

¹⁷⁵³ As explained in section 5.D.III.a.i below, while some suppliers have exited the market, there remain a number of existing suppliers, none of which has indicated an intention to exit the market. It is also the case that the prevailing prices of competing hydrocortisone tablets were significantly below Auden/Actavis's prices during the Unfair Pricing Abuses prior to any supplier exiting.

b. The components of the CMA's Cost Plus calculation

5.284. As explained in paragraph 5.78 above, the CMA's Cost Plus calculation is generous to Auden/Actavis: at a number of points when required to make assumptions, the CMA has erred in favour of Auden/Actavis.

5.285. Auden/Actavis nonetheless submitted that the CMA's Cost Plus calculations were flawed.

i. 'ROCE is inappropriate for asset-light businesses'

5.286. Auden/Actavis submitted that it is '*well established*' that ROCE is a poor measure of profitability for '*asset-light*' businesses.¹⁷⁵⁴

5.287. Where firms are genuinely asset-light, as oppose to employing assets that are difficult to measure or value, the CMA does not consider ROCE to be inappropriate. However, the CMA recognises that where firms genuinely employ very few assets, ROCE percentages can become volatile (due to a small denominator).

5.288. However, the CMA notes that Auden/Actavis is not particularly asset light due to the significant working capital balances associated with the sale of hydrocortisone tablets. As a result, it is not evident that this is a relevant consideration in this case. However, as explained in paragraphs 5.213 to 5.215, the CMA has considered what ROS margin was implied by its ROCE calculation (as a cross-check) and found this to be at the upper end of the margins put forward by Auden/Actavis (and five times higher than the allowed margin in the PPRS). This indicates that adopting an alternative approach to identifying a reasonable return on capital would not result in a materially different estimate of Cost Plus.

5.289. Further, Auden/Actavis provided no evidence to support the inclusion of assets omitted from the CMA's assessment and provided limited insight into how certain asset valuations could be adjusted.¹⁷⁵⁵

ii. 'Auden/Actavis should be allowed a higher rate of return'

5.290. Auden/Actavis submitted that it should be allowed a higher rate of return than the CMA has included in its Cost Plus calculations because:

¹⁷⁵⁴ Document 205217, Auden/Actavis's RSSO, paragraph 4.29

¹⁷⁵⁵ Document 205217, Auden/Actavis's RSSO, paragraph 4.29. See also Document 01454, Auden/Actavis's RSO1, paragraph 5.24.

- a. Individual products may require a premium above WACC to reflect product specific risks not reflected in the company's WACC.¹⁷⁵⁶
- b. ROCE should incorporate the opportunity cost of investing today rather than tomorrow.¹⁷⁵⁷
- c. Other industry benchmarks provide much higher rates of return, such as the target ROCE under the PPRS of 21%, which could be increased to 31.5%.¹⁷⁵⁸
- d. WACC is not an appropriate benchmark because it should be regarded as the minimum rate of return that an investor would require and so the CMA has underestimated what should be considered a 'reasonable rate of return'.¹⁷⁵⁹

5.291. None of these submissions is relevant in this case:

- a. The only asymmetric risk suggested by Auden/Actavis was launch risk. However, Auden/Actavis's generic hydrocortisone tablets simply replaced the originator drug which already had an established customer base. Auden/Actavis was the sole supplier of hydrocortisone tablets and faced no launch risk.
- b. Allergan decided to acquire AM Pharma after discounting the profits of individual products by a WACC of **[5%-15%]**. Consequently, this WACC figure must have already incorporated the opportunity cost of entering the market(s) 'today' rather than investing 'tomorrow'.
- c. The target ROCE of 21% under the PPRS was much greater than the WACC of most pharmaceutical companies, which according to publicly available information sits within a range of 8% to 12%.¹⁷⁶⁰ This difference is due to two key adjustments made in the PPRS calculation: the values of the intangible assets were excluded from capital employed; and the amortisation expenses with regards to these assets were excluded from the profitability assessment. These adjustments

¹⁷⁵⁶ Document 205217, Auden/Actavis's RSSO, paragraph 4.27. See also Document 01454, Auden/Actavis's RSO1, section 5, paragraph 5.49 and footnote 136.

¹⁷⁵⁷ Document 205217, Auden/Actavis's RSSO, paragraph 4.27. See also Document 01454, Auden/Actavis's RSO1, section 5, paragraph 5.51.

¹⁷⁵⁸ Document 205217, Auden/Actavis's RSSO, paragraph 4.60.

¹⁷⁵⁹ Document 205217, Auden/Actavis's RSSO, paragraph 4.30

¹⁷⁶⁰ The companies the CMA considered in making this assessment and their WACCs were: AstraZeneca 10% (pre-tax); GSK 10% (pre-tax); Bayer 9.0 – 9.3% (pre-tax); Alliance Pharma stated that its WACC was lower than its 10% discount rate; Meda AB 12% in Europe (excluding Nordic countries); Recordi S.p.A 9.65% (pre-tax), excluding Turkey, and Stada Arzneimittel AG 11.2% in Central Europe and 8.9% in Germany. Where it was not explicitly stated, the CMA assumed that the stated WACC is pre-tax as this is the usual figure given. The CMA did not look at all potential comparator companies given the similarity in values which arose from its initial review.

had the effect of reducing capital employed and increasing profit, which artificially increased the ROCE of these businesses. There is no justification for making such adjustments in this assessment and so the CMA does not consider the PPRS figure to be an appropriate benchmark.

- d. As explained in paragraph 5.206 above, using a WACC gives investors a reasonable return, calculated from the actual debt costs and actual average realised equity returns in the market, rather than the minimum required return. As explained in paragraph 5.148 above, the purpose of allowing a reasonable rate of return in this assessment is to ensure that Auden/Actavis is sufficiently compensated for the risk and investment undertaken when entering and participating in the market(s). The use of WACC achieves this aim in this case.

D. Auden/Actavis's prices were unfair

I. Conclusion

- 5.292. The CMA finds that throughout the Unfair Pricing Abuses, Auden/Actavis's prices were unfair by reference to the *United Brands* Test.
- 5.293. The CMA finds, first, that Auden/Actavis's prices were unfair in themselves (see section 5.D.II below).
- 5.294. The Unfair Limb is an alternative rather than a cumulative test.¹⁷⁶¹ The CMA's finding that Auden/Actavis's prices were unfair in themselves is sufficient for a finding of unfairness in law.¹⁷⁶² However, in this case the CMA also finds, secondly, that Auden/Actavis's prices were unfair when compared to competing products (see section 5.D.III below).
- 5.295. Thirdly, the CMA finds that the economic value of Auden/Actavis's hydrocortisone tablets is no greater than that already reflected in the CMA's calculation of Cost Plus and that Auden/Actavis's prices therefore bore no reasonable relation to the economic value of its hydrocortisone tablets throughout the Unfair Pricing Abuses (see section 5.D.IV below).

II. Auden/Actavis's prices were unfair in themselves

- 5.296. The CMA has concluded that Auden/Actavis's prices were unfair in themselves for the following reasons:
- a. the substantial disparities between Auden/Actavis's prices and Cost Plus (section 5.D.II.a below);
 - b. Auden/Actavis's prices during the Unfair Pricing Abuses were not justified by any features of hydrocortisone tablets (section 5.D.II.b below). In particular:
 - i. hydrocortisone tablets have been long off-patent and in the third stage of the drug lifecycle where competition is expected to drive prices of generic drugs down and keep prices low even where they are essential (section 5.D.II.b.i below); and

¹⁷⁶¹ C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255, where the CAT also held that the test was alternative in nature; and *Phenytoin CoA*, paragraph 259.

¹⁷⁶² C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255; *Phenytoin* [2018] CAT 11, paragraph 366; and *Phenytoin CoA*, paragraphs 97(vii), 257 and 259.

- ii. there was no improvement to hydrocortisone tablets, or their production or distribution, and no innovation or investment which might justify Auden/Actavis's prices (section 5.D.II.b.ii below).
- c. the features of the relevant market(s) enabled Auden/Actavis to fulfil its pricing ambitions and meant that those markets were incapable of functioning in a manner likely to produce a reasonable relationship between price and economic value (section 5.D.II.c below);¹⁷⁶³
- d. the scale and significance of Auden/Actavis's price increases, in the context of the lack of any accompanying material increase in production costs, investment or innovation, as well as in comparison to both the prices charged by MSD before Auden acquired MSD's hydrocortisone tablets business and Auden/Actavis's prices over time (section 5.D.II.d below);
- e. the adverse effects that Auden/Actavis's prices had on the end customer and on patient welfare, with NHS spending on hydrocortisone tablets increasing significantly (more than tenfold during the Unfair Pricing Abuses), with no associated benefit and with negative effects on CCGs' ability to provide patient care (section 5.D.II.e below);¹⁷⁶⁴ and
- f. the lack of any independent or objective justification for Auden/Actavis's prices (section 5.D.II.f below).¹⁷⁶⁵

a. The substantial disparities between Auden/Actavis's prices and Cost Plus

- 5.297. Neither Auden/Actavis nor any of its staff, contemporaneously or in interviews, has given a plausible explanation for why the prices of hydrocortisone tablets increased so much.
- 5.298. As section 5.C above makes clear, Auden/Actavis's prices were not justified by its costs.
- 5.299. As explained in section 3.E.V.a.i above, the initial price increases for hydrocortisone tablets were covered in a *Daily Mail* article on 18 July 2010. In response to the *Daily Mail*'s questions, [Auden Senior Employee 1] attributed the price increases to Auden's investment in a new manufacturing

¹⁷⁶³ Compare *Albion Water II* [2008] CAT 31, paragraphs 266 and 268.

¹⁷⁶⁴ Compare *Phenytoin* [2018] CAT 11, paragraph 369.

¹⁷⁶⁵ Compare *Phenytoin* [2018] CAT 11, paragraph 369.

plant and indicated that Auden had needed to increase prices in order to recoup that investment, following which prices would fall:

'For hydrocortisone, there is a very specific raw material required. Basically, the plant that made that was no longer prepared to do that. There had to be a multi-million-pound investment put in to ensure that [production] continued.

This sort of product cannot be made in a general facility. There are dangers of cross contamination. A new manufacturing plant had to be put up.

Either we just let this product go, just let it die. But it is crucial to certain patients, so we can't do that. Now the majority of the investment which has been made has been recouped.

*So now you will steadily see [the price] coming back down. It will creep back down because the company has recouped what it needed to. It was not simple and it was a very expensive process.'*¹⁷⁶⁶

- 5.300. However, [Auden Senior Employee 1] *'refused to give further details of his company's spending that he said had led to the price increase'*.¹⁷⁶⁷
- 5.301. In fact, Auden/Actavis made no material investment in hydrocortisone tablets.^{1768,1769} As explained in section 3.E.V above, following publication of the *Daily Mail* article and a subsequent article, Auden's prices remained stable for a time before beginning to increase once more.
- 5.302. When communicating these subsequent price increases Auden informed some of its customers that they were attributable to increasing costs.¹⁷⁷⁰
- 5.303. However, there is no evidence to suggest that Auden's costs were increasing.¹⁷⁷¹ Further, in interview both [Auden Senior Employee 2]¹⁷⁷² and

¹⁷⁶⁶ [REDACTED].

¹⁷⁶⁷ [REDACTED].

¹⁷⁶⁸ [REDACTED].

¹⁷⁶⁹ To the extent that it was appropriate to account for any increased production costs or investment in hydrocortisone tablets, that would be covered in the CMA's assessment of Cost Plus in section 5.C.III above.

¹⁷⁷⁰ Document 00033, email from [Auden Senior Employee 2] to [REDACTED] dated 25 January 2013; Document 00040, email from [Auden Senior Employee 2] to [REDACTED] dated 29 August 2013 and Document 00185, email from [Auden Senior Employee 2] to [REDACTED] dated 10 March 2014.

¹⁷⁷¹ For example, a contemporaneous internal email from [Auden Senior Employee 2] to [Auden Senior Employee 1], recommending increasing prices for 10mg hydrocortisone tablets, did not refer to Auden's costs: Document 00032, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 18 May 2012.

¹⁷⁷² Document 00719, transcript of interview with [Auden Senior Employee 2] dated 21 September 2016, pages 4-8.

[Auden Senior Employee 1] were unable to point to any increases in costs for hydrocortisone tablets.¹⁷⁷³

- 5.304. Auden's claimed cost increases related to '*API*', '*manufacturing*' and '*production*'.¹⁷⁷⁴ Given that Auden did not manufacture hydrocortisone tablets and instead purchased finished products from its CMO, any such cost increases would be expected to have been reflected in its cost of goods. As explained in section 5.C.III above, Auden's costs remained broadly constant, with its cost of goods actually decreasing slightly during the period in which Auden informed some of its customers that its costs were increasing.
- 5.305. Auden/Actavis also submitted that price increases were required in order for the supply of hydrocortisone tablets to become commercially viable.¹⁷⁷⁵ However, at most, that could justify Auden's initial prices only (which were £4.54 for 10mg tablets and £5.14 for 20mg tablets) given that as the sole supplier of hydrocortisone tablets and without being constrained by the PPRS in the prices it could set, Auden would not be expected to set launch prices that were unprofitable.
- 5.306. Even when a reasonable rate of return is added to costs, Auden/Actavis's prices were not justified. As shown in tables 5.20 and 5.21 above, Auden/Actavis's Cost Plus for hydrocortisone tablets ranged between:
- a. £2.17 and £4.45 per pack of 10mg tablets.
 - b. £2.91 and £5.20 per pack of 20mg tablets.
- 5.307. The extent by which Auden/Actavis's prices exceeded Cost Plus in itself is an indicator that those prices were unfair in themselves (with other indicators set out in sections 5.D.II.b to 5.D.II.e below).¹⁷⁷⁶ The extent of these Differentials was substantial, particularly at the peak of Auden/Actavis's prices.
- 5.308. Auden/Actavis's Differentials above Cost Plus are set out in tables 5.24 and 5.27 and figures 5.25, 5.26, 5.28 and 5.29 above. These Differentials ranged

¹⁷⁷³ Document 00727, transcript of interview with [Auden Senior Employee 1] dated 26 July 2016, pages 31-36. Both [Auden Senior Employee 2] and [Auden Senior Employee 1] referred to general costs across Auden's business. However, such costs are not attributable to hydrocortisone tablets; and [Auden Senior Employee 2]'s contemporaneous emails to Alliance refer to increasing costs of API and production/manufacturing, indicating that Auden faced increasing costs specific to hydrocortisone tablets, which it did not.

¹⁷⁷⁴ Document 00033, email from [Auden Senior Employee 2] to [X] dated 25 January 2013; Document 00040, email from [Auden Senior Employee 2] to [X] dated 29 August 2013 and Document 00185, email from [Auden Senior Employee 2] to [X] dated 10 March 2014.

¹⁷⁷⁵ Document 205217, Auden/Actavis's RSSO, paragraphs 4.43-4.47.

¹⁷⁷⁶ Compare *Phenytoin* [2018] CAT 11, paragraph 369. See also *British Leyland v Commission*, EU:C:1986:421, paragraph 28, in which a significant increase in price without an increase in costs was one element contributing to the court's finding that a price was unfair and abusive; and recitals 178-181 of the European Commission's Commitments decision in Case AT.40394 *Aspen*.

from around 550% to 2,750% for 10mg tablets and from around 450% to 2,000% for 20mg and show that there were substantial disparities between Auden/Actavis's prices and Cost Plus.

5.309. The disparities were also substantial when Auden/Actavis's prices are compared against the prices at which the CMA prioritised investigating the Unfair Pricing Abuses (£20 per pack, see paragraph 5.18 above). Auden/Actavis's prices exceeded £20 per pack by up to 260%. This is despite the prioritised prices being significantly (at least 285%) greater than the CMA's estimates of Cost Plus.¹⁷⁷⁷

5.310. In the absence of any relevant non-cost related factors, these substantial disparities could, in themselves, suffice to establish that Auden/Actavis's prices bore no reasonable relation to the economic value of hydrocortisone tablets.¹⁷⁷⁸ The CMA has found that there are no such non-cost related factors (see section 5.D.IV below).

b. Auden/Actavis's prices were not justified by any features of hydrocortisone tablets

5.311. There were also no features inherent in Auden/Actavis's hydrocortisone tablets that justified Auden/Actavis's prices.¹⁷⁷⁹ In fact, when considered in their full context, those prices should have been low.

i. Hydrocortisone tablets were long off-patent and in the third stage of the drug lifecycle

5.312. As explained in section 3.B.VII above, hydrocortisone tablets are essential but old and well-established drugs that were first sold in the 1950s, and were long off-patent by the time Auden acquired the licences from MSD in 2008. Hydrocortisone tablets had therefore long been in the third stage of the drug lifecycle.

5.313. As explained in section 3.B.III above, once generic entry can occur, the third stage of the drug lifecycle begins. At this stage, the expectation is that the cost of innovation that led to a drug's creation has been recouped via the patent protection and any innovation rewarded. The rewards required to provide incentives for ongoing production are much lower than those

¹⁷⁷⁷ Cost Plus for 10mg tablets is between £2.17 and £4.45 (£3.87 throughout the 10mg Unfair Pricing Abuse) for 10mg tablets and between £2.91 and £5.20 (£4.81 throughout the 20mg Unfair Pricing Abuse) for 20mg tablets.

¹⁷⁷⁸ *Albion Water II* [2008] CAT 31, paragraph 225. See also paragraphs 264-265. See also *Attheraces CoA*, paragraph 204: a price which 'significantly exceeds' the economic value of the product supplied 'will be *prima facie* excessive and unfair'.

¹⁷⁷⁹ See *Phenytoin* [2018] CAT 11, paragraph 369: 'such factors as: ... any independent or objective justification ... could all be factors which it was relevant for it [the CMA] to weigh when considering the application of the 'unfair in itself' test'.

required to generate incentives to innovate. Since patent protection for hydrocortisone tablets had long expired, it can be assumed that any investment in the products had already been recovered.¹⁷⁸⁰

- 5.314. When a drug enters the third stage of the drug lifecycle, provided market features or anti-competitive collusion do not shield a drug from effective competition, competition between generic suppliers is expected to result in significant price falls (see section 3.B.III above).¹⁷⁸¹ Competition between generic suppliers is then expected to ensure that generic prices remain low even for essential drugs.
- 5.315. If several suppliers enter the market during the third stage of the drug lifecycle, generic products usually become 'commoditised', meaning that suppliers of generic medicines are not able to use brand value or product quality to differentiate themselves (see section 3.B.III above).¹⁷⁸² This is the case even for essential drugs. The primary focus of competition for suppliers of generic medicines is then the price offered to wholesalers and pharmacies. This competition causes the average drug price to fall gradually towards the cost level.
- 5.316. Typically, provided market features did not shield a drug from effective competition, if the price of a drug was significantly above the competitive price during the third stage of the drug lifecycle then it would be expected that the high price would act as a signal and incentivise new entrants to the market. The market price should then correct as the introduction of more competitors supplying a homogenous generic medicine will inevitably lead to more intense price competition and the movement of market volumes to lower priced generic versions of the product.¹⁷⁸³

ii. There was no innovation, investment or improvement to justify Auden/Actavis's prices

- 5.317. Hydrocortisone tablets were not the subject of any innovation by Auden/Actavis that might justify being rewarded or costs needing to be recovered.¹⁷⁸⁴ In fact, Auden/Actavis's tablets were identical to those

¹⁷⁸⁰ In this case, it is also the case that the costs of any innovation that led to the creation of hydrocortisone tablets were borne by MSD (as the originator) rather than Auden/Actavis given that it acquired the products from MSD rather than developing them itself.

¹⁷⁸¹ See also European Commission, *Pharmaceutical Sector Inquiry Final Report*, 8 July 2009, sections 1.2 and 1.3; British Generic Manufacturers Association, *About generics*; and Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 1.13.

¹⁷⁸² See also Oxera, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 3.21.

¹⁷⁸³ Oxera report, *The supply of generic medicines in the UK*, 26 June 2019, paragraph 4.33.

¹⁷⁸⁴ To the extent that it was appropriate to account for any research and development costs, that would be covered in the CMA's assessment of Cost Plus in section 5.C.III above.

previously sold by MSD and there was no change to their formulation.¹⁷⁸⁵ Auden/Actavis's prices therefore did not reflect any additional benefits having been created for patients. Nor was there any material investment by Auden/Actavis.¹⁷⁸⁶

iii. Conclusion on the features of hydrocortisone tablets

- 5.318. None of the features considered in sections 5.D.II.b.i and 5.D.II.b.ii above in any way suggests that the prices of hydrocortisone tablets should have been high or increasing.
- 5.319. In fact, these features show that the prices of hydrocortisone tablets should have been relatively low and stable.
- 5.320. However, Auden/Actavis increased its prices significantly and over a prolonged period during the Unfair Pricing Abuses. At their peak (around £72 for both 10mg and 20mg tablets), Auden/Actavis's prices were around 1,500% (for 10mg tablets) and around 1,300% (for 20mg tablets) higher than the prices at which Auden first sold hydrocortisone tablets (£4.54 for 10mg tablets and £5.14 for 20mg tablets) (see section 3.E.V.a.i above). Even when generic competition eventually began (through independent entry in 2015), Auden/Actavis maintained substantial price premiums over its competitors' prices during the Unfair Pricing Abuses (see section 3.E.V.b.iv above).

c. Auden/Actavis's prices reflected its substantial market power

- 5.321. Belatedly, competition has brought prices down. Both the prices currently charged by Actavis's competitors (see section 5.D.III.a below) and Actavis's current prices (see section 5.D.II.c.ii below) have fallen to levels [X] (except for Actavis's current 10mg tablet price, which is [X]).
- 5.322. The assumption that competition between suppliers will keep generic drug prices low in the third phase of the drug lifecycle (with generic drugs prices being unregulated on that assumption)¹⁷⁸⁷ has therefore ultimately proved correct in relation to hydrocortisone tablets.
- 5.323. However, during the Unfair Pricing Abuses the features of the relevant market(s) in this case enabled Auden/Actavis to both increase its prices over

¹⁷⁸⁵ In fact, as explained in paragraph 3.341 above, when Auden first introduced its generic hydrocortisone tablets in April 2008, patients quickly pointed out that its tablets could not easily be halved to achieve the correct dose, leading Auden immediately to reintroduce the oval tablets that MSD had sold.

¹⁷⁸⁶ To the extent that it was appropriate to account for any increased production costs or investment in hydrocortisone tablets, that would be covered in the CMA's assessment of Cost Plus in section 5.C.III above.

¹⁷⁸⁷ See section 3.B.III above.

a prolonged period and sustain those prices.¹⁷⁸⁸ Those features, explained in detail below, were:

- a. Auden/Actavis was the monopoly supplier for a prolonged period, from 2008 to 2015. During that period, when faced with the threat of competition, Auden/Actavis entered into anticompetitive agreements with its potential competitors to preserve its market power and its ability to both sustain and continue to increase its prices.
- b. When independent entry finally occurred, Auden/Actavis's market power was preserved by the barrier to expansion created by the orphan designation, enabling Auden/Actavis to price at a significant premium compared to its competitors.
- c. Even following independent entry, the way that the Drug Tariff price was calculated meant that Auden/Actavis faced a reduced constraint on its prices.
- d. Customers were also not able to act to constrain Auden/Actavis's pricing conduct.

5.324. Individually and collectively those features ensured that Auden/Actavis was *'shielded from effective competitive pressure'* and this, in turn, enabled it *'to fulfil its pricing ambitions'*.¹⁷⁸⁹ As a result, during the Unfair Pricing Abuses the relevant market(s) were not *'capable of functioning in a manner that is likely to produce a reasonable relationship of price to economic value'*.¹⁷⁹⁰

5.325. These market features meant that the prices Auden/Actavis imposed during the Unfair Pricing Abuses reflected its substantial market power.

i. Auden/Actavis was the monopoly supplier from 2008 to 2015

5.326. Auden/Actavis was the monopoly supplier of 10mg and 20mg hydrocortisone tablets during the majority of the Unfair Pricing Abuses: from October 2008 to July 2015 (for 20mg tablets) and October 2015 (for 10mg tablets). Auden de-branded hydrocortisone tablets in April 2008 (see section 3.F.I.a above), freeing itself of the constraints of the PPRS (see section 3.B.V.a above) and

¹⁷⁸⁸ The CAT has held that: *'factors that establish a dominant position, notably barriers to entry, may well be relevant to determining whether a price is so high as to amount to an abuse'*. *Albion Water II* [2008] CAT 31, paragraph 213. See also *Phenytoin* [2018] CAT 11, paragraph 241. It is inherent in a finding of a dominant position that an undertaking can price sustainably above what might be considered to be the normal competitive price. Market power can itself be thought of as *'the ability profitably to sustain prices above competitive levels'* (*Assessment of market power guidelines* (OFT415), paragraph 3.1). Accordingly, the CMA has also relied on its analysis of Auden/Actavis's dominant position in section 4.B.II above to support its conclusion that Auden/Actavis's prices were unfair in themselves.

¹⁷⁸⁹ *Albion Water II*, [2008] CAT 31, paragraphs 213 and 266.

¹⁷⁹⁰ *Albion Water II* [2008] CAT 31, paragraph 268.

enabling it, as the sole supplier, to increase its prices significantly and sustain those prices.

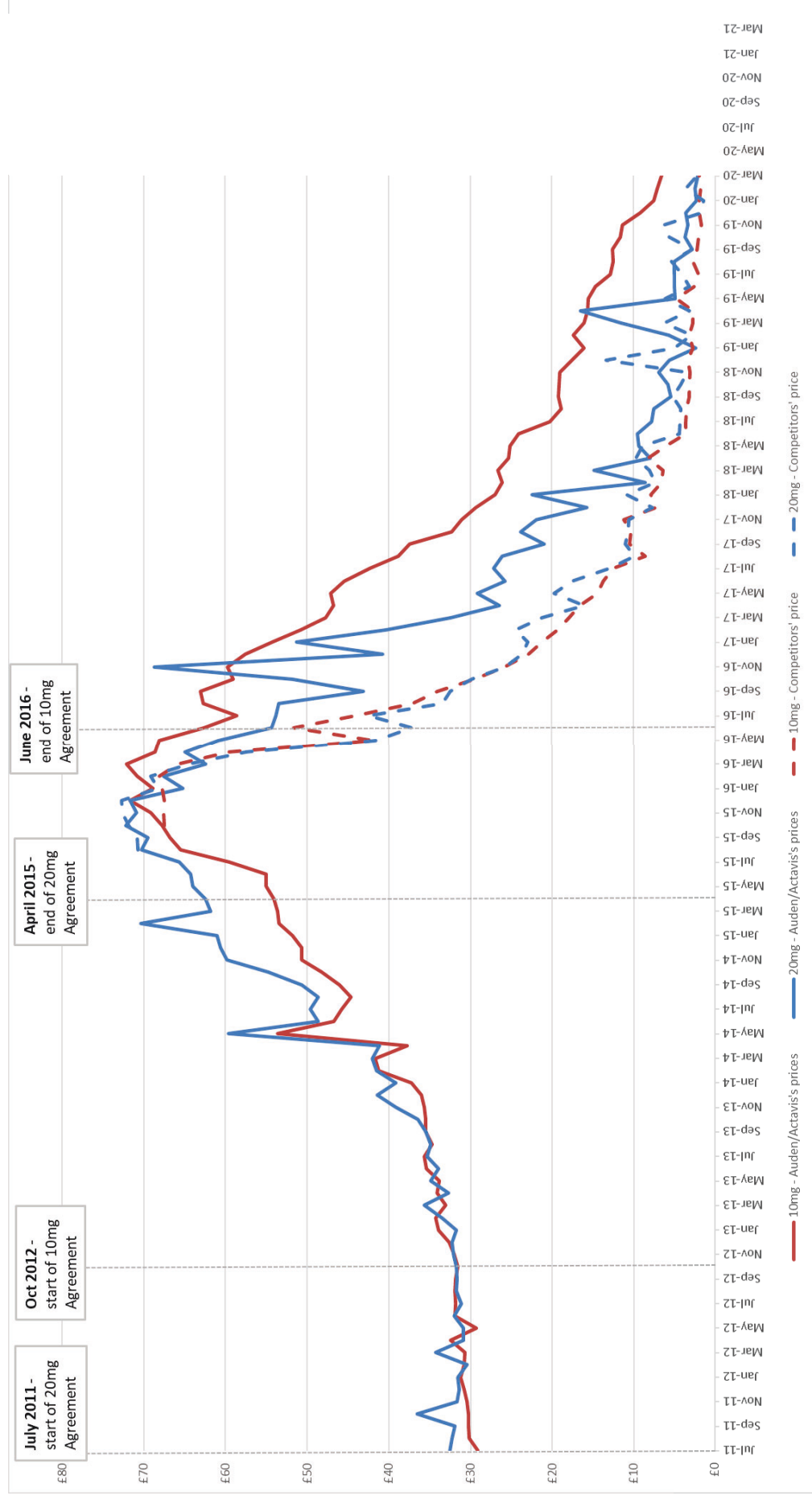
- 5.327. As the monopoly supplier, and in the absence of any effective competitive constraint, Auden/Actavis was able to increase its prices to very high levels and sustain those increases. Auden/Actavis's price increases in the period that it was the monopoly supplier of hydrocortisone tablets amounted to:
- a. For 20mg tablets, an increase of 1,178%, from £5.14 a pack in April 2008 to £65.67 a pack in July 2015 (when independent entry first occurred).
 - b. For 10mg tablets, an increase of 1,395%, from £4.54 a pack in April 2008 to £67.74 a pack in October 2015 (when independent entry first occurred).
- 5.328. During this period, when Auden began to face the threat of competition from potential entry by Waymade (in respect of 10mg and 20mg tablets) and AMCo (in respect of 10mg tablets), which would have begun a process putting downward pressure on its high prices, Auden responded by buying off that threat by making payments to Waymade and AMCo in exchange for them agreeing not to enter the market with their own hydrocortisone tablets. The CMA has concluded that in entering into those agreements Auden/Actavis aimed to maintain its position as the monopoly supplier of 10mg and 20mg hydrocortisone tablets (see section 6.D.II below). The Agreements aimed to delay competitive entry to enable Auden/Actavis to continue to impose its prices without effective constraint, so that it could not only sustain but also continue to increase its prices.
- 5.329. From its initial entry in April 2008 until the points that it entered into anticompetitive agreements with its potential competitors:
- a. Auden increased its price for 20mg hydrocortisone tablets by 533%, from £5.14 a pack in April 2008 to £32.56 a pack in July 2011, when the 20mg Agreement began.
 - b. Auden increased its price for 10mg hydrocortisone tablets by 595%, from £4.54 a pack in April 2008 to £31.55 a pack in October 2012, when the 10mg Agreement began.
- 5.330. During the terms of the Agreements:
- a. Auden increased its price for 20mg hydrocortisone tablets by 92%, from £32.56 in July 2011 to £62.45 in April 2015, when the 20mg Agreement

ended. Auden/Actavis's price peaked at £72.19 a pack in October 2015.

- b. Auden/Actavis increased its price for 10mg hydrocortisone tablets by 99%, from £31.55 to £62.63 in June 2016, when the 10mg Agreement ended. Auden/Actavis's price peaked at £72.14 a pack in March 2016.

5.331. As a result of the Agreements, Auden/Actavis maintained its monopoly position for longer than it would otherwise have done and was able to continue reaping trading benefits which it would not have reaped if there had been normal and sufficiently effective competition. This is demonstrated in figure 5.42 below.

Figure 5.42: Auden/Actavis's prices during the Agreements compared with the average prices of competing hydrocortisone tablets once entry occurred



Source: CMA analysis based on data submitted by relevant parties.

5.332. Figure 5.42 shows that Auden/Actavis's prices continued to increase during the Agreements. As explained in section 6.D.II below, the Agreements enabled Auden/Actavis to continue increasing prices and delay the process of price falls that ultimately followed independent entry.

ii. The orphan designation

5.333. When independent entry belatedly occurred, Auden/Actavis was protected from effective competition by the barrier to expansion created by the orphan designation.

5.334. As explained in section 3.D.III.c above, as a result of the regulatory windfall derived from the fact that it happened to hold hydrocortisone tablets MAs when Plenadren was granted its MA in November 2011, Auden became until November 2021:

- a. the only supplier who held or could hold a full label 10mg MA; and
- b. one of only two suppliers (with Waymade) who held or could hold a full label 20mg MA.

5.335. 10mg hydrocortisone tablets account for 96% of all hydrocortisone tablets dispensed (see section 3.C.II above).¹⁷⁹¹

5.336. As explained in section 4.C.II.c.iii above, the barrier to expansion created by the orphan designation resulted in a substantial portion of the market(s) remaining captive to Actavis following independent entry. That protection afforded to Actavis meant that it was able to continue to behave, to an appreciable extent, independently of its competitors, its customers and ultimately consumers during the latter period of the Unfair Pricing Abuses, with Actavis pricing at substantial premiums compared to its competitors' prices.

iii. The Drug Tariff

5.337. As explained in section 3.B.IV above, the Drug Tariff aims to reflect competition in the market by setting reimbursement prices by reference to selling prices across the market. This in turn aims to lower prices and keep prices low as the reimbursement price acts as a ceiling on the prices suppliers are able to charge customers. Until 30 June 2019 (when Scheme M expired) the Drug Tariff price of 10mg hydrocortisone tablets was calculated from data submissions by Scheme M members.

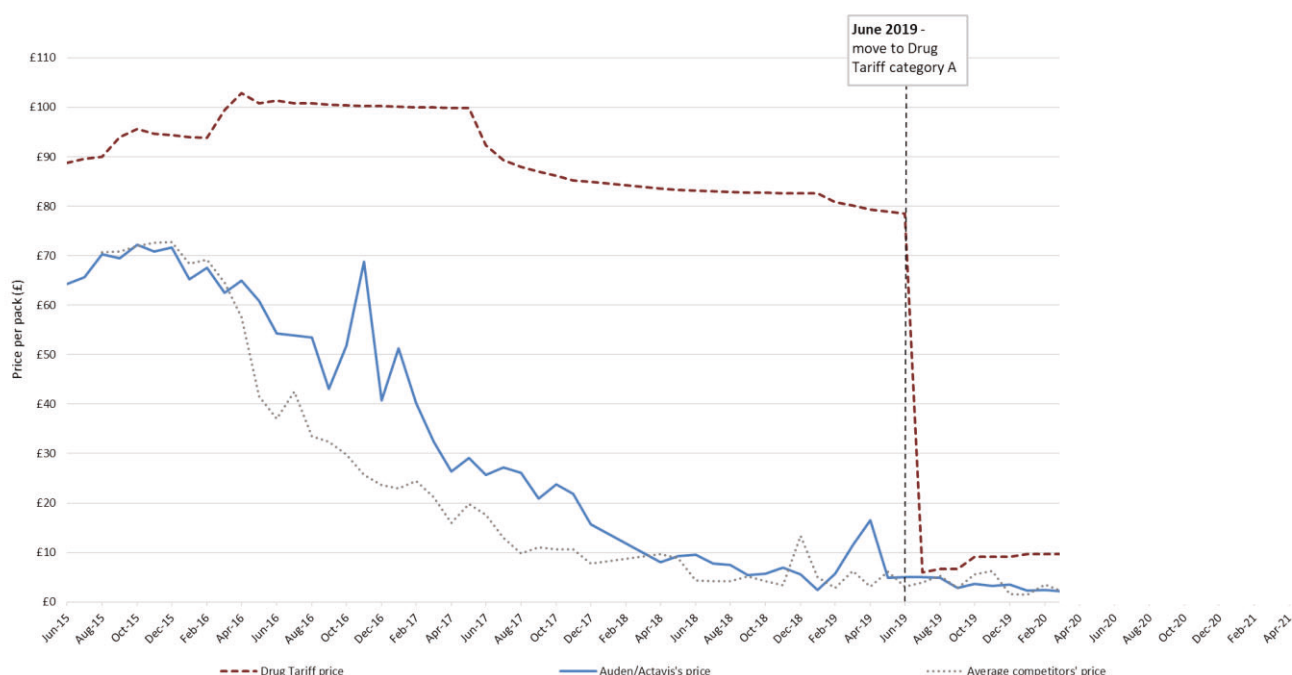
¹⁷⁹¹ NHS BSA data.

- 5.338. Although Accord-UK was a Scheme M member, which meant that its 10mg price was included in the Category M Drug Tariff price calculations, the majority of its competitors were not Scheme M members. This meant that the Drug Tariff price for 10mg tablets remained an incomplete reflection of competition in the market, as explained in section 3.E.I.b above. Of the seven competing suppliers of 10mg hydrocortisone tablets, only three in addition to Accord-UK (AMCo from May 2016, Teva from February 2017 and Genesis Pharmaceuticals from November 2017) were Scheme M members.¹⁷⁹²
- 5.339. Following the entry of competing suppliers, Actavis therefore benefited from the limitations to the way the Drug Tariff price for 10mg hydrocortisone tablets was calculated (see section 4.C.II.c.ii above), which reduced the (indirect) constraint it would otherwise have faced from the inclusion of its competitors' prices in the Drug Tariff price.
- 5.340. Intas/Accord-UK acknowledged this in a letter to the DHSC dated 7 December 2017. Intas/Accord-UK wrote to the DHSC suggesting that it request information on supply prices from non-Scheme M members on a voluntary basis to use in formulating the Drug Tariff price for 10mg hydrocortisone tablets, which '*would quickly lower the latter and reinforce the competitive process*' (see section 4.C.II.c.ii above).¹⁷⁹³
- 5.341. The position for 20mg hydrocortisone tablets was even more extreme. The Drug Tariff price for 20mg tablets imposed no constraint whatsoever on Auden/Actavis during the 20mg Unfair Pricing Abuse. As explained in section 3.E.I.b above, 20mg tablets were in Category A during the 20mg Unfair Pricing Abuse. The Drug Tariff price for 20mg hydrocortisone tablets did not reflect any competition because Category A prices were determined based on suppliers' list prices, not actual selling prices, with competition reflected in changes to selling prices rather than to changes in list prices. This was the case until June 2019 when 20mg tablets were moved to Category M.
- 5.342. This can be seen from the fact that the Drug Tariff price for 20mg tablets remained broadly constant throughout the 20mg Unfair Pricing Abuse (and, in fact, increased following independent entry) despite suppliers' prices falling and only fell in a significant way when 20mg tablets were moved to Category M in June 2019 (see figure 5.43 below).

¹⁷⁹² The other suppliers of 10mg hydrocortisone tablets (Alissa, Bristol Laboratories, Resolutions Chemicals and Renata) were not Scheme M members.

¹⁷⁹³ Document 02194, Intas letter to the DHSC dated 7 December 2017.

Figure 5.43: 20mg hydrocortisone tablet prices and Drug Tariff price



Source: CMA analysis based on data submitted by relevant parties and NHS BSA data.

iv. No countervailing buyer power

5.343. As explained in section 4.C.II.d above, Auden/Actavis faced no effective constraint from its customers during the Unfair Pricing Abuses, whether from the DHSC/NHS as end customer, or from its intermediate customers (wholesalers and pharmacies). This is clear, fundamentally, from its pricing behaviour. This meant that Auden/Actavis did not face effective competition during the Unfair Pricing Abuses, with its customers having to pay the prices Auden/Actavis imposed and not being able to constrain Auden/Actavis's conduct. As a result, Auden/Actavis was able to act in the relevant market(s) *'without regard to the ultimate interests of [the end customer]'*,¹⁷⁹⁴ in this case, the NHS.

d. The scale and significance of Auden/Actavis's price increases

5.344. The evolution of pricing over time further demonstrates that Auden/Actavis's prices were unfair in themselves.¹⁷⁹⁵ The scale of Auden/Actavis's price increases over time was significant, as shown in section 3.E.V.a.i above,

¹⁷⁹⁴ *Albion Water II* [2008] CAT 31, paragraph 269.

¹⁷⁹⁵ The CAT has stated that *'a large price rise, sustained over a considerable period, may be indicative of an abuse of a dominant position'*, although it cautioned that *'it should not be confused with the test for unfair pricing itself'*: *Phenytoin* [2018] CAT 11, paragraph 439. See also paragraph 369: *'such factors as: the increase in price ... could all be factors which it was relevant for it [the CMA] to weigh when considering the application of the 'unfair in itself' test'*.

without any accompanying material increase in production costs, investment or innovation.

- 5.345. The scale and significance of Auden/Actavis's price increases is demonstrated by a comparison of Auden/Actavis's prices during the Unfair Pricing Abuses with:
- the prices that hydrocortisone tablets were sold at when they were still supplied by MSD; and
 - Auden/Actavis's own prices over a longer period of time, comparing the prices at which it entered the market in April 2008 with its current prices after a prolonged period of competition.
- 5.346. Both of those comparisons, summarised in table 5.44 below, further support the CMA's conclusion that Auden/Actavis's prices were unfair in themselves.

Table 5.44: Auden/Actavis's prices compared with MSD's prices, Auden's entry prices and Actavis's current prices

Tablet strength	Auden/Actavis's prices during the Unfair Pricing Abuses	MSD's prices	Auden's entry prices	Actavis's current prices*
10mg	£20 - £72.14	£0.70	£4.54	[£1-£4]
20mg	£20 - £72.19	£1.07	£5.14	[£1-£4]

* Weighted average over the period February to April 2021.

i. MSD's prices

- 5.347. The branded hydrocortisone tablets that MSD previously supplied and Auden/Actavis's generic hydrocortisone tablets are identical. The only physical difference between them is the packaging (see section 3.F.I above).¹⁷⁹⁶ As hydrocortisone tablets were first commercialised in 1955, supplying them as a generic drug rather than under a brand name would not incur additional costs. Accordingly, MSD's prices represent '*real world*' prices, to which Auden/Actavis's prices can be compared.¹⁷⁹⁷
- 5.348. MSD's prices were very significantly below Auden/Actavis's prices during the Unfair Pricing Abuses. Between 2006 and 2008, MSD's average prices (based on reimbursement prices) were:

¹⁷⁹⁶ In fact, as explained in paragraph 3.341 above, when Auden first introduced its generic hydrocortisone tablets in April 2008, patients quickly pointed out that its tablets could not easily be halved to achieve the correct dose, leading Auden immediately to reintroduce the oval tablets that MSD had sold.

¹⁷⁹⁷ Compare *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 121: '*the counterfactuals of greatest practical value are often those drawn from real life*'.

- a. £0.70 per pack of 10mg hydrocortisone tablets; and
- b. £1.07 per pack of 20mg hydrocortisone tablets.¹⁷⁹⁸

5.349. In comparison, Auden/Actavis's prices during the Unfair Pricing Abuses ranged between:

- a. £20 and £72.14 per pack of 10mg hydrocortisone tablets; and
- b. £20 and £72.19 per pack of 20mg hydrocortisone tablets (see section 3.E.V above).

5.350. The scale and significance of the differences between Auden/Actavis's prices and MSD's prices set out in table 5.44 above further show that Auden/Actavis's prices were unfair in themselves.¹⁷⁹⁹

ii. Auden/Actavis's prices over time

5.351. The CMA's conclusion that Auden/Actavis's prices during the Unfair Pricing Abuses were unfair in themselves is further supported by a comparison of those prices with:

- a. Auden's entry prices, which Auden initially determined appropriate for it to profitably sell hydrocortisone tablets in the UK,¹⁸⁰⁰ as explained in paragraphs 5.231 to 5.232 above; and
- b. Actavis's current prices, following a prolonged period of competition from and between a number of competing suppliers of hydrocortisone tablets.

¹⁷⁹⁸ Document 00561, MSD's response to questions 1,3 and 4 of the CMA's section 26 notice dated 22 June 2016; see section 3.E.V above. Further, when Auden acquired the MAs for hydrocortisone tablets it confirmed that '*Trade price was below £0.90 per pack of 30 tablets*'; see Document 00164, email from [Auden Senior Employee 4] to MAP BioPharma dated 12 February 2014. The CMA does not have data to determine what MSD's average selling price was prior to Auden acquiring MSD's hydrocortisone MAs. Instead, the CMA has used NHS Reimbursement Prices. As NHS Reimbursement Prices set the maximum price (given that any price above the NHS Reimbursement Price would result in a pharmacy making a loss), using those prices to determine MSD's prices overestimates the average selling price and is likely to overestimate the level of MSD's prices.

¹⁷⁹⁹ Auden/Actavis submitted that MSD's prices were '*an unfair benchmark to use as a comparator because market dynamics are not considered, and MSD prices did not represent an effective competitive market in 2008*' (Document 205217, Auden/Actavis's RSSO, paragraph 4.44). Similarly, Intas/Accord-UK submitted that MSD's prices were '*not a legitimate comparator as regards the Intas Period*' (Document 205212, Intas/Accord-UK's RSSO, paragraphs 22 and 172-183). However, the CMA did not use MSD's prices as the basis for a finding that Auden/Actavis's prices were unfair when compared to competing products. A comparison between Auden/Actavis's prices during the Unfair Pricing Abuses and MSD's prices is used to show the scale and significance of Auden/Actavis's price increases, providing an additional indication of the fact that Auden/Actavis's prices were unfair in themselves.

¹⁸⁰⁰ Auden/Actavis submitted that it launched its generic versions of hydrocortisone tablets in order for supply to become commercially viable: Document 205217, Auden/Actavis's RSSO, paragraphs 4.43-4.47. As the sole supplier of hydrocortisone tablets and without being constrained by the PPRS in the prices it could set, Auden would not be expected to set launch prices that were unprofitable.

- 5.352. The prices at which Auden entered in April 2008 were:
- £4.54 per pack of 10mg hydrocortisone tablets; and
 - £5.14 per pack of 20mg hydrocortisone tablets.
- 5.353. Over the period February to April 2021, Actavis's average prices were:
- [£1-£4] for 10mg hydrocortisone tablets, which even now represents a premium when compared to the average price of competing 10mg hydrocortisone tablets over the same period (£1.34), reflecting the benefit that Actavis still receives from the barrier created by the orphan designation.
 - [£1-£4] for 20mg hydrocortisone tablets.
- 5.354. In comparison, Auden/Actavis's prices during the Unfair Pricing Abuses ranged between:
- £20 and £72.14 per pack of 10mg hydrocortisone tablets; and
 - £20 and £72.19 per pack of 20mg hydrocortisone tablets (see section 3.E.V above).¹⁸⁰¹
- 5.355. The scale and significance of the differences between Auden/Actavis's prices during the Unfair Pricing Abuses and both Auden's entry prices and Actavis's current prices set out in table 5.44 above further show that Auden/Actavis's prices were unfair in themselves.
- e. Auden/Actavis's prices had adverse effects on the end customer and on patient welfare**
- 5.356. The adverse effects that Auden/Actavis's prices had on the end customer and on patient welfare further demonstrate that Auden/Actavis's prices were unfair in themselves.
- 5.357. As set out in section 5.B.III.a above, *'the primary interest to be protected under the Chapter II prohibition is that of the consumer'*.¹⁸⁰² It is, therefore, important to look beyond the immediate customer and take the interests of end customers, as well as consumers, into account when assessing whether

¹⁸⁰¹ Although Auden's prices fell below £20 in a few individual months during the Unfair Pricing Abuses (its 10mg price in a single month, August 2010, and its 20mg price in November 2008 and January, April and July 2009), these were single-month fluctuations in the context of sustained price increases over the period from 2008 to 2015. See figure 5.6 above.

¹⁸⁰² *Albion Water II* [2008] CAT 31, paragraph 218. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 215.

a price is unfair.¹⁸⁰³ That is the case regardless of whether the price in question is assessed by reference to the unfair in itself or unfair when compared to competing products test.

- 5.358. The end customer in this case is the NHS (in the form of its CCGs and corresponding purchasers in Northern Ireland, Scotland and Wales), which pays for hydrocortisone tablets.
- 5.359. The NHS budget is finite and legitimate demands for healthcare will always exceed its capacity. Accordingly, financial resources need to be prioritised. For example, in the period 2010 to 2015 the NHS Efficiency Policy tasked the NHS with making £20 billion of efficiency savings in order to make more funds available to treat patients.¹⁸⁰⁴ Budgetary constraints and efficiency savings continue to pose a significant challenge to the NHS and its constituent parts with an unmitigated funding gap of £30 billion needing to be covered in the period 2015 to 2020/21.¹⁸⁰⁵
- 5.360. Auden/Actavis's prices have resulted in the NHS paying significantly more for hydrocortisone tablets when compared to the prices that the NHS was paying prior to Auden de-branding hydrocortisone tablets and to the current price levels as a result of a prolonged period of competition.
- 5.361. As explained in section 3.E.V.d above, in 2007, the last full year that hydrocortisone tablets were supplied by MSD before being de-branded by Auden, the NHS's annual expenditure on 10mg and 20mg hydrocortisone tablets was approximately £500,000. By contrast, under Auden/Actavis the NHS's annual expenditure on 10mg and 20mg hydrocortisone tablets increased from £7.8 million in 2008 to £74.1 million in 2015, and to a peak of £83.8 million in 2016, despite independent entry by suppliers of competing hydrocortisone tablets.¹⁸⁰⁶ Annual NHS spending began falling thereafter, with an annual spend of £62 million in 2017, approaching £40 million in 2018 and down to just under £10m in 2020.

¹⁸⁰³ *Albion Water II* [2008] CAT 31, paragraph 271. See also *Phenytoin* [2018] CAT 11, paragraph 369: '*such factors as: ... the impact on the buyer ... could all be factors which it was relevant for it [the CMA] to weigh when considering the application of the 'unfair in itself' test*'.

¹⁸⁰⁴ See www.gov.uk/government/publications/2010-to-2015-government-policy-nhs-efficiency/2010-to-2015-government-policy-nhs-efficiency.

¹⁸⁰⁵ NHS Five Year Forward View, October 2014 (www.england.nhs.uk/wp-content/uploads/2014/10/5yfv-web.pdf).

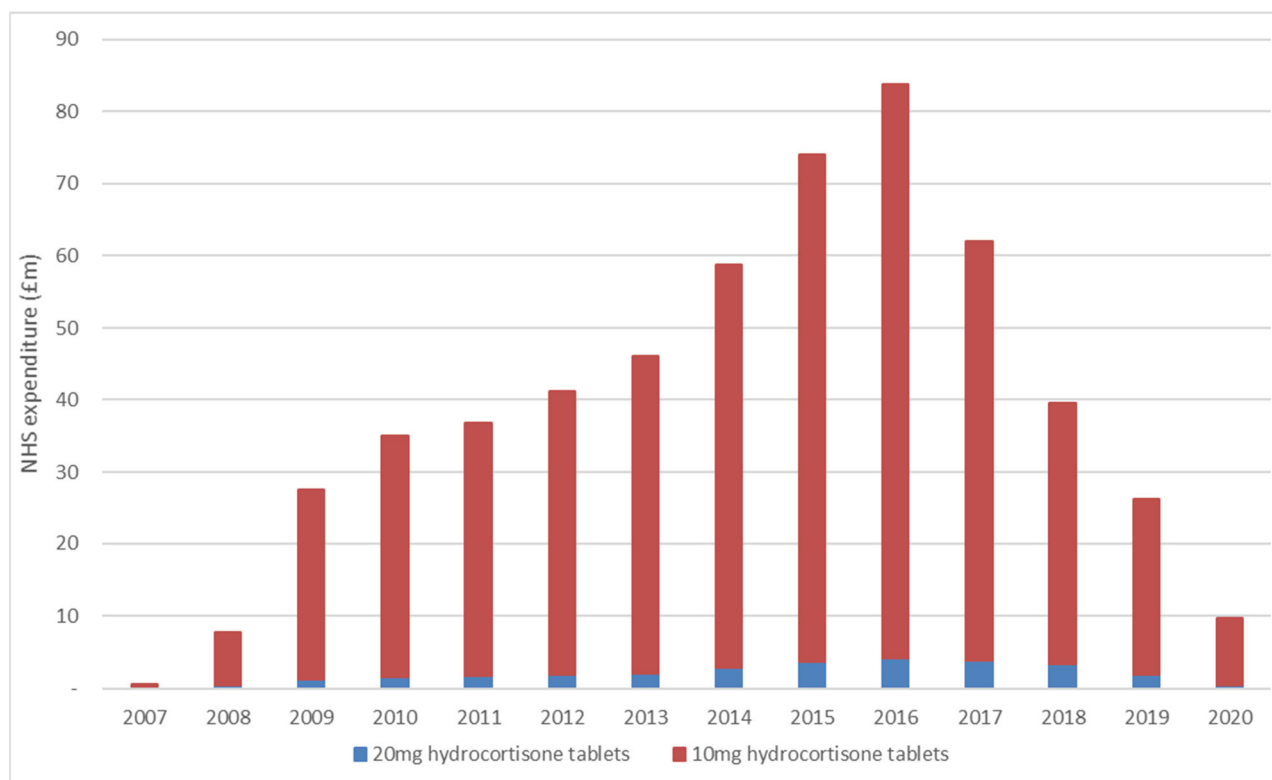
¹⁸⁰⁶ The NHS's annual spending on hydrocortisone tablets has been calculated using the quantity of hydrocortisone tablets (including 'Hydrocortone' tablets) dispensed and the NHS Reimbursement Price data contained within the PCA data for England, Wales, Scotland and Northern Ireland. The 2008 figure includes the period January to March 2008, prior to Auden starting to sell hydrocortisone tablets (from April 2008).

Table 5.45: NHS annual expenditure on hydrocortisone tablets

(£m)	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
10mg	0.5	7.4	26.2	33.4	35.1	39.3	44.0	55.8	70.3	79.6	58.2	36.3	24.5	9.3
20mg	0.04	0.4	1.3	1.6	1.7	1.9	2.1	2.9	3.7	4.2	3.9	3.3	1.8	0.4
Total	0.5	7.8	27.5	35.1	36.8	41.1	46.1	58.7	74.1	83.8	62.1	39.6	26.3	9.6

Source: NHS BSA data based on PCA data

Figure 5.46: NHS annual expenditure on hydrocortisone tablets (£m)



Source: NHS BSA data based on PCA data

- 5.362. As a result of Auden/Actavis's prices, CCGs had to commit extra money from their constrained budgets to continue to fund the supply of hydrocortisone tablets to patients. This has inevitably reduced the money available to CCGs for other healthcare services (see paragraph 3.72 above).
- 5.363. This is illustrated by evidence from three CCGs on the detrimental impact that the price increases for hydrocortisone tablets had on their budgets and ability to deliver services:
- Coastal West Sussex CCG confirmed that during the years 2012 to 2017, its total spending on hydrocortisone tablets increased from around £400,000 to around £800,000; that the higher cost of hydrocortisone tablets did not reflect any additional benefit, efficiency or improvement to patient welfare which was not available prior to the

price increases; and that, in fact, this led to a decrease in healthcare available to the local population, through the reduction in financial resources available within a finite budget and a deficit financial position.¹⁸⁰⁷

- b. Gloucestershire CCG also confirmed that the price increases reflected no additional benefit. The price increases had a direct impact on its ability to fund other items from its prescribing budget, and any other discretionary items such as improvement initiatives.¹⁸⁰⁸
- c. South Devon & Torbay CCG's annual spending on hydrocortisone tablets increased from about £86,000 in 2012/2013 to about £332,000 in 2016/2017. Its view was also that there was no additional benefit reflected in the price increases.¹⁸⁰⁹

5.364. The pressures on these individual CCGs as a result of Auden/Actavis's conduct, and the difficult choices they faced as a result, are illustrative of the effect of Auden/Actavis's high and increasing prices on the NHS as a whole.

f. Lack of any independent or objective justification for Auden/Actavis's prices

5.365. Auden/Actavis has not provided any independent or objective justification for its prices (see section 5.D.II.a above).¹⁸¹⁰ In particular, Auden/Actavis's prices were not justified by any investments that it made in hydrocortisone tablets¹⁸¹¹ or any additional benefit to the NHS.¹⁸¹²

III. Auden/Actavis's prices were unfair when compared to competing products

5.366. The Unfair Limb is an alternative rather than a cumulative test.¹⁸¹³ Accordingly, it is sufficient to demonstrate that one of the unfairness

¹⁸⁰⁷ Document 01604, Coastal West Sussex CCG's response to the CMA's section 26 notice dated 16 May 2017, response to questions 4 and 5.

¹⁸⁰⁸ Document 01612, Gloucestershire CCG's response to the CMA's section 26 notice dated 16 May 2017, response to questions 4 and 6.

¹⁸⁰⁹ Document 01638A, South Devon & Torbay CCG's response to the CMA's section 26 notice dated 16 May 2017, response to questions 4 and 6.

¹⁸¹⁰ See *Phenytoin* [2018] CAT 11, paragraph 369: '*such factors as: ... any independent or objective justification ... could all be factors which it was relevant for it [the CMA] to weigh when considering the application of the 'unfair in itself' test*'.

¹⁸¹¹ To the extent that Auden/Actavis did invest in hydrocortisone tablets (which it did not), that would be reflected in the CMA's analysis of Cost Plus.

¹⁸¹² See sections 5.D.II.e above (on the cost to the NHS) and 5.D.IV below (on the lack of any additional benefit to the NHS).

¹⁸¹³ *C-159/08 P Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255; *Phenytoin CoA*, paragraph 259.

alternatives ('*unfair in itself*' or '*unfair when compared to competing products*') is satisfied to establish an infringement.¹⁸¹⁴

- 5.367. In section 5.D.II above, the CMA has found that Auden/Actavis's prices were unfair in themselves. That finding is a sufficient basis for a finding of unfairness in law.¹⁸¹⁵ However, in the specific circumstances of this case, the CMA has also concluded that Auden/Actavis's prices were unfair when compared to competing products, namely the current prices of competing hydrocortisone tablets.
- 5.368. In this case, there are competing products within the same relevant market(s) as Auden/Actavis's hydrocortisone tablets. However, that is not in itself sufficient to justify an assessment of whether Auden/Actavis's prices were unfair when compared to those products.
- 5.369. For the purposes of determining whether a price is unfair when compared to competing products, a comparator does not need to be identical¹⁸¹⁶ or in the same relevant market,¹⁸¹⁷ but it does need to be sufficiently similar to the product concerned to allow for a '*meaningful*' comparison on objective, verifiable and appropriate criteria.¹⁸¹⁸ This means that a comparison of the prices can be made on a consistent basis and the figures that are compared are really comparable.¹⁸¹⁹
- 5.370. Further, '[t]he basic test for abuse' is '*whether the price is "unfair"*'. In broad terms '*a price will be unfair when the dominant undertaking has reaped trading benefits which it could not have obtained in conditions of "normal and sufficiently effective competition"*'.¹⁸²⁰ Prices that are not set in conditions of effective competition are therefore unlikely to be meaningful comparators. A comparator cannot be considered meaningful simply on the basis that the

¹⁸¹⁴ *Phenytoin* [2018] CAT 11, paragraph 366. See also *Phenytoin CoA* paragraphs 97(vii) and 257. However, irrespective of which alternative is chosen, '*the competition authority will always need, at least as part of its duty of good administration, to give some consideration to prima facie valid comparators advanced evidentially by the undertakings.*' *Phenytoin CoA*, paragraph 259 and 260. The CMA has evaluated the arguments and evidence put forward by the parties in this case (see in particular, sections 5.D.III.b and 5.D.V below). Noting the alternative nature of the unfair tests ('*in itself*' and '*when compared to competing products*') is not an '*attempt to shift the burden onto Auden/Accord-UK*' (Document 205217, Auden/Actavis's RSSO, paragraph 1.8.2). In any event, the CMA has considered and concluded on both of the unfairness alternatives in this Decision.

¹⁸¹⁵ C-159/08 P *Isabella Scippacercola and Ioannis Terezakis v Commission*, EU:C:2009:188, paragraph 47; *Albion Water II* [2008] CAT 31, paragraph 255; *Phenytoin* [2018] CAT 11, paragraph 366; and *Phenytoin CoA*, paragraphs 97(vii), 257 and 259.

¹⁸¹⁶ *Albion Water II* [2008] CAT 31, paragraph 252.

¹⁸¹⁷ *Phenytoin* [2018] CAT 11, paragraph 373.

¹⁸¹⁸ See for example *Albion Water II* [2008] CAT 31, paragraph 252; *Phenytoin* [2018] CAT 11, paragraphs 373, 392 and 444; and *Latvian Copyright*, EU:C:2017:689, paragraphs 41 and 51.

¹⁸¹⁹ See for example *Albion Water II* [2008] CAT 31, paragraphs 252 and 253; *Scandlines*, paragraphs 169 and 175; and *Latvian Copyright*, EU:C:2017:689, paragraphs 38, 44-45 and 51.

¹⁸²⁰ *Phenytoin CoA*, paragraph 97(i); *United Brands*, EU:C:1978:22, paragraph 249. See also *Phenytoin CoA*, paragraph 249.

customer is paying the price imposed.¹⁸²¹ Comparisons should not be drawn with products the price of which may have been inflated by the exercise of substantial market power.¹⁸²²

- 5.371. In this case, the CMA has concluded that all **competing hydrocortisone tablets** are sufficiently similar to Auden/Actavis's hydrocortisone tablets to allow for a meaningful comparison between their prices and Auden/Actavis's prices for the determination of whether Auden/Actavis's prices were unfair when compared to competing products.
- 5.372. 'Competing hydrocortisone tablets' includes all hydrocortisone tablets, both skinny and full label, supplied by Auden/Actavis's competitors. This comprises all skinny label 10mg tablets,¹⁸²³ all skinny label 20mg tablets,¹⁸²⁴ and Waymade's full label 20mg tablets.¹⁸²⁵
- 5.373. The CMA has used the **current prices** of competing hydrocortisone tablets (weighted averages) as its comparator because these prices are no longer inflated by the exercise of Auden/Actavis's substantial market power during the Unfair Pricing Abuses and are set in conditions of effective competition between Auden/Actavis's competitors.
- 5.374. When referring to 'current prices' the CMA is referring to the weighted average prices over the period from February to April 2021.¹⁸²⁶
- 5.375. The CMA has considered whether there are further products which are sufficiently similar to Auden/Actavis's hydrocortisone tablets to allow for a meaningful comparison between their prices and Auden/Actavis's prices and has concluded there are no such products (see section 5.D.III.b below).

a. The current prices of competing hydrocortisone tablets

- 5.376. The current prices of competing hydrocortisone tablets provide a meaningful comparator against which to assess whether Auden/Actavis's prices during the Unfair Pricing Abuses were unfair. As explained in sections 5.A and 5.C.IV.a above, it is also the case that the current prices of competing hydrocortisone tablets are broadly in line with and corroborated by:

¹⁸²¹ See for example *Albion Water I* [2006] CAT 23, paragraphs 754 to 756.

¹⁸²² See *Albion Water I* [2006] CAT 23, paragraph 757 and *Albion Water II* [2008] CAT 31, paragraph 257.

¹⁸²³ Sold by AMCo (Aesica), Alissa, Bristol Laboratories, Genesis, Renata, Resolution Chemicals and Teva.

¹⁸²⁴ Sold by AMCo (Aesica and Focus), Bristol Laboratories, Genesis, Renata, Resolution Chemicals and Teva.

¹⁸²⁵ In the analysis that follows, Waymade's prices are shown separately from the prices of skinny label suppliers to demonstrate that its full label 20mg MA did not result in a premium over skinny label tablets.

¹⁸²⁶ April 2021 is the most recent sales data on the CMA's file. For Waymade's full label 20mg tablets, the period is May to July 2020 because [REDACTED], see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

- a. the CMA's estimates of Cost Plus, which are between £2.17 and £4.45 for 10mg tablets and between £2.91 and £5.20 for 20mg tablets;
- b. Auden's initial prices, which were £4.54 for 10mg tablets and £5.14 for 20mg tablets; and
- c. the prices that Allergan projected would result from competitive entry, which were approximately £5.20 for 10mg tablets and approximately £6.10 for 20mg tablets.

i. Competing hydrocortisone tablets are sufficiently similar to provide for a meaningful comparison

- 5.377. First, competing hydrocortisone tablets are sufficiently similar products to Auden/Actavis's hydrocortisone tablets for a comparison to be meaningful.
- 5.378. There is no difference between Auden/Actavis's full label 20mg tablets and Waymade's full label 20mg tablets. The products are bioequivalent and are fully indicated for all treatments (including adult adrenal insufficiency).
- 5.379. As explained in section 3.D.III.c above, there is also no meaningful difference between skinny and full label hydrocortisone tablets. The only difference between full and skinny label tablets relates to the date on which the relevant MA was granted. As explained in section 3.D.III.c above, this was purely a matter of timing and regulatory circumstance that resulted in Auden/Actavis's tablets (and Waymade's 20mg tablets) being fully indicated and benefiting from the orphan designation granted to Plenadren but all other suppliers' tablets being skinny label.
- 5.380. However, as explained in section 3.D.I above, full and skinny label tablets are bioequivalent, fully interchangeable and used to treat the same conditions, as is reflected by market behaviour and expert opinion.
- 5.381. In terms of market behaviour, in 2017 skinny label hydrocortisone tablets accounted for 52% of all sales volumes of 10mg and 20mg hydrocortisone tablets combined, with skinny label tablets accounting for 52% of all sales volumes of 10mg tablets and 34% of all sales volumes of 20mg tablets (see section 3.E.V.b.v above). These sales have come at the expense of full label tablets. Prior to skinny label tablet entry in October 2015, full label tablets accounted for 100% of the sales of hydrocortisone tablets and there is no evidence to suggest that the introduction of skinny label tablets created new demand or met previously unmet demand.

- 5.382. The sales volumes achieved by skinny label hydrocortisone tablets demonstrate that they are readily dispensed to patients with adult adrenal insufficiency – despite not being indicated for that condition. For example, the Royal Society of Pharmacists estimated that approximately 90-95% of prescriptions for hydrocortisone tablets each year (95% for 10mg, 90% for 20mg) are for adult adrenal insufficiency (the treatment area for which only full label tablets are indicated).¹⁸²⁷ By way of comparison, skinny label tablets accounted for 52% of the market by volume in 2017 and currently account for 60% by volume.
- 5.383. The practice of dispensing skinny label hydrocortisone tablets for adult adrenal insufficiency has also not raised any concerns with various pharmaceutical regulators.
- 5.384. In a letter dated 20 May 2014, [Chief Pharmaceutical Officer for NHS England] [X] informed [Auden Senior Employee 1] that there were '*no material differences*' between skinny and full label tablets and that there were no '*risks to patient safety*' from off label supply. Consequently, [Chief Pharmaceutical Officer for NHS England] explained that he saw no reason to correspond with senior pharmacists to discourage off label supply for adult adrenal insufficiency (as Auden had requested).¹⁸²⁸ This view was shared by the MHRA, which advised [Chief Pharmaceutical Officer for NHS England] and assisted him in responding to Auden's correspondence.¹⁸²⁹
- 5.385. The fact that skinny and full label hydrocortisone tablets are to all intents and purposes the same product is further demonstrated by the NHS pricing system.
- 5.386. Both skinny and full label tablets were treated collectively as one product for the purposes of the Drug Tariff scheme used to calculate the reimbursement price for the dispensing of all hydrocortisone tablets. The reimbursement scheme created one reimbursement price which was payable to pharmacies. The reimbursement price did not distinguish between full and skinny label tablets and simply took account of the selling prices of those suppliers whose prices feed into the Drug Tariff. This was the case for both 10mg and 20mg hydrocortisone tablets, with the reimbursement price for each of those

¹⁸²⁷ See section 3.E.III.c.ii above.

¹⁸²⁸ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden Senior Employee 1], [Auden Senior Employee 4] and [Auden's External Consultant], dated 20 May 2014.

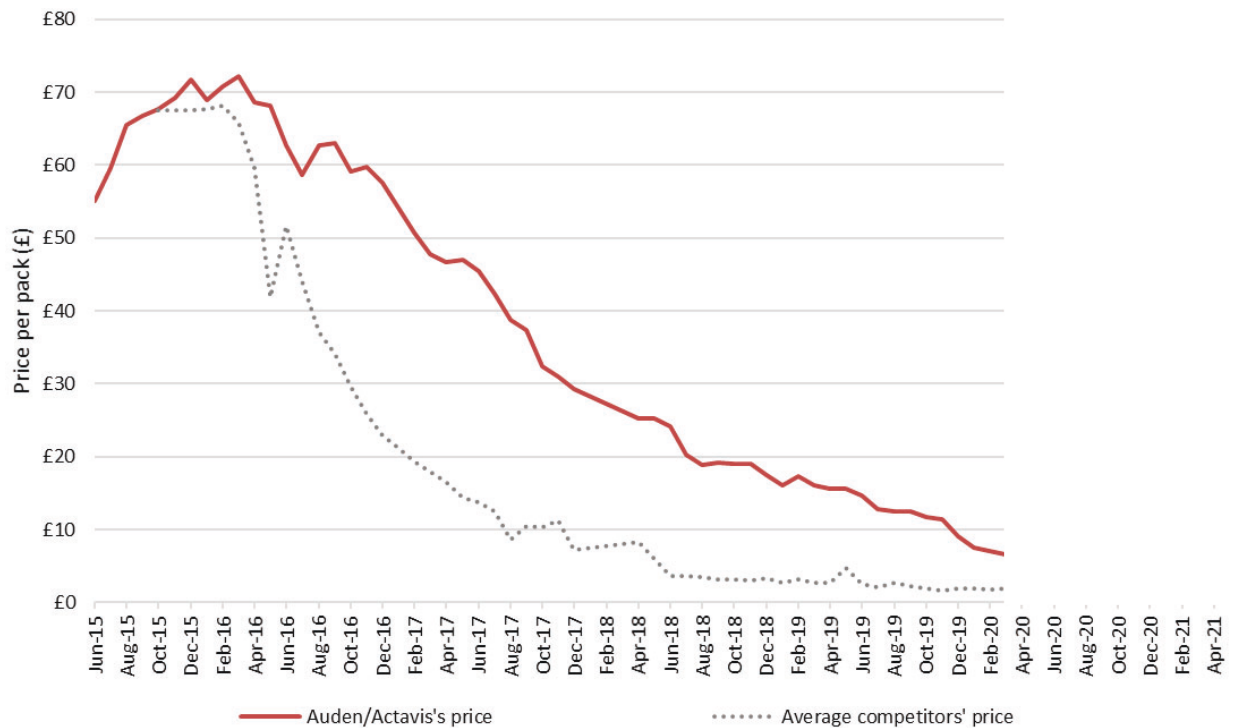
¹⁸²⁹ Document 206640, note of call between the CMA and the MHRA on 31 March 2021, paragraph 2.1 and Document 206557, note of call between the CMA and NHS England and NHS Improvement on 22 March 2021, paragraph 2.1.

products not differentiating between full and skinny label versions of the product.

- 5.387. For all these reasons, the CMA has concluded that skinny label hydrocortisone tablets are sufficiently similar products to Auden/Actavis's hydrocortisone tablets for a comparison to be meaningful.
- 5.388. On entry, the prices of competing hydrocortisone tablets were distorted and inflated as a result of the extremely high prices that had been imposed by Auden/Actavis over the preceding seven years.
- 5.389. However, over time, competition has resulted in prices being competed down and stabilising at low levels.¹⁸³⁰
- a. For 10mg tablets, Actavis's competitors' prices converged around mid-2018 and have begun to flatten. However, Actavis's price [✂] as its price has continued to fall.
 - b. For 20mg tablets, both Actavis's price and its competitors' prices converged around early 2018 and [✂].
- 5.390. This is demonstrated in the figures below.

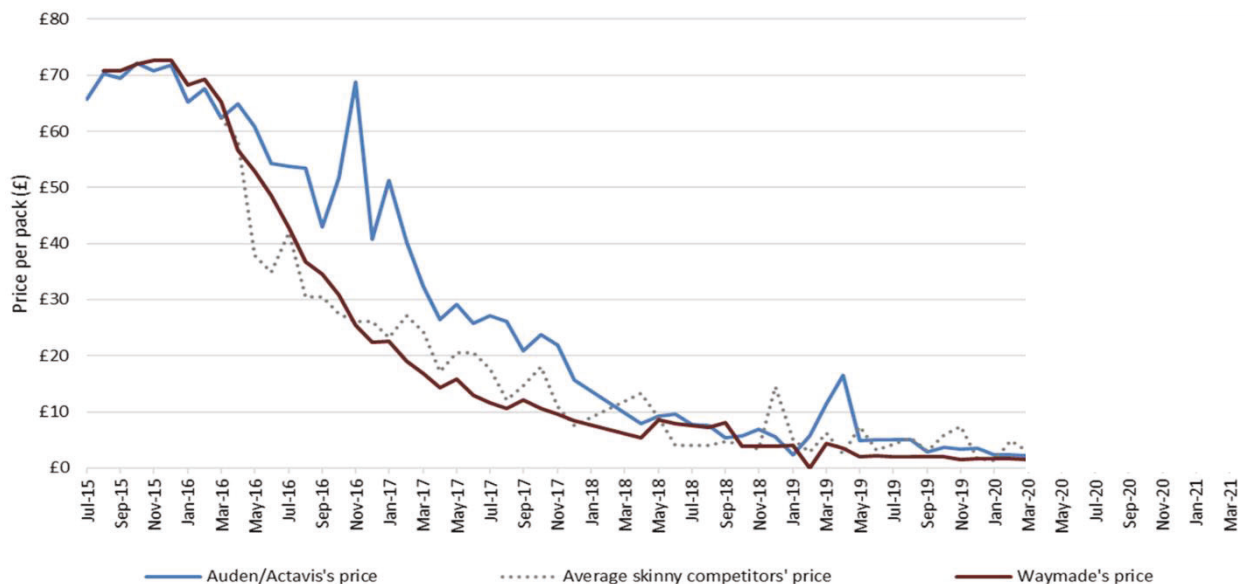
¹⁸³⁰ Compare *Phenytoin* [2018] CAT 11, paragraph 390.

Figure 5.47: Prices of 10mg hydrocortisone tablets over time



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

Figure 5.48: Prices of 20mg hydrocortisone tablets over time



Source: CMA analysis based on data submitted by relevant parties and the Drug Tariff price for England.

- 5.391. Accordingly, the current prices of competing hydrocortisone tablets allow for a meaningful comparison with Auden/Actavis's prices during the Unfair Pricing Abuses and can therefore be used to determine whether Auden/Actavis's prices were unfair when compared to competing products.

- 5.392. The comparison that is made is between the prices the suppliers of competing hydrocortisone tablets currently charge and the prices Auden/Actavis's imposed during the Unfair Pricing Abuses.¹⁸³¹
- 5.393. In calculating the current prices of competing products, the CMA has used average prices from February to April 2021 for skinny label tablets and from May to July 2020 for Waymade's full label tablets,¹⁸³² weighted by sales. That results in the following prices:¹⁸³³
- a. For 10mg skinny label tablets: **£1.34 per pack**.¹⁸³⁴
 - b. For 20mg skinny label tablets, **£1.85 per pack**.¹⁸³⁵
 - c. For Waymade's 20mg full label tablets, **[£]** per pack.¹⁸³⁶
- 5.394. These weighted averages are similar to the average prices at the end of the averaged period.¹⁸³⁷ The current prices of competing hydrocortisone tablets are all also substantially below Cost Plus.¹⁸³⁸
- ii. Auden/Actavis's prices during the Unfair Pricing Abuses were unfair when compared to the current prices of competing hydrocortisone tablets**
- 5.395. Tables 5.49, 5.50 and 5.51 below set out the differences in price per pack in pounds and percentage terms, when Auden/Actavis's prices during the Unfair Pricing Abuses are compared to the current prices of competing

¹⁸³¹ The CMA has considered Actavis's current prices (averaged over the same period as competing prices). However, that was done in the context of whether Auden/Actavis's prices during the Unfair Pricing Abuses were unfair in themselves (see section 5.D.II.c.ii above). Whether Auden/Actavis's full label tablets have greater economic value than skinny label tablets is considered in section 5.D.IV below.

¹⁸³² [£], see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

¹⁸³³ This average is calculated in two steps. First, monthly averages are calculated using average prices across all competitors for each month, weighted by their relative sales in that month. Second, to create the three-month average these are then weighted again by total sales (of all competitors combined) in each of the three months.

¹⁸³⁴ The average price of 10mg skinny label tablets at the end of the averaged period (ie in April 2021) was £1.55.

¹⁸³⁵ The average price of 20mg skinny label tablets at the end of the averaged period (ie in April 2021) was £1.89.

¹⁸³⁶ Waymade's price at the end of the averaged period (ie in July 2020) was [£].

¹⁸³⁷ Using weighted averages over a period reduces the effects of monthly fluctuations in sales volumes and prices.

¹⁸³⁸ Auden/Actavis submitted that current average competing prices cannot be used as a comparator because they were loss-making, as shown by the number of suppliers exiting or abandoning entry, and because those price levels were unlikely to have incentivised suppliers to have invested in developing hydrocortisone tablets (Document 205217, Auden/Actavis's RSSO, paragraphs 4.48 to 4.52; Document 206667, Auden/Actavis's RLOF, paragraph 3.47 to 3.51; and Document 207027, letter from Auden/Actavis dated 7 July 2021, paragraphs 3.1 to 3.2). As explained in paragraph 5.376 above, the current average prices of competing hydrocortisone tablets are broadly in line with and corroborated by a number of other measures in this case. While some suppliers have exited, there remain a number of existing suppliers, none of which has indicated an intention to exit the market. It is also the case that the prevailing prices of competing hydrocortisone tablets were significantly below Auden/Actavis's prices during the Unfair Pricing Abuses prior to any supplier exiting. Even if a slightly higher competing price was used, Auden/Actavis's prices would still be unfair when compared to competing products, such was the level of Auden/Actavis's excesses.

hydrocortisone tablets. These tables also set out the difference in revenues.¹⁸³⁹

Table 5.49: Comparison of Auden/Actavis's prices during the Unfair Pricing Abuses with the current prices of 10mg skinny label hydrocortisone tablets

	October 2008- December 2013	January 2014- August 2015	September 2015- January 2017	January 2017- July 2018	Whole period
Hydrocortisone 10mg - price £	£29.53	£49.57	£65.31	£35.26	£37.87
Current average skinny label price £	£1.34	£1.34	£1.34	£1.34	£1.34
Difference - £	£28.19	£48.23	£63.97	£33.92	£36.53
Difference %	2,104%	3,599%	4,774%	2,531%	2,726%
Revenue difference (£m)	£129.4	£71.0	£54.0	£27.7	£282.1

Table 5.50: Comparison of Auden/Actavis's prices during the Unfair Pricing Abuses with the current prices of 20mg skinny label hydrocortisone tablets

	October 2008- December 2013	January 2014-August 2015	September 2015- January 2017	Whole period
Hydrocortisone 20mg - price £	£29.81	£56.81	£60.77	£38.59
Current average skinny label price £	£1.85	£1.85	£1.85	£1.85
Difference - £	£27.96	£54.96	£58.92	£36.74
Difference %	1,511%	2,971%	3,185%	1,986%
Revenue difference (£m)	£7.5	£4.0	£2.7	£14.2

Table 5.51: Comparison of Auden/Actavis's prices during the Unfair Pricing Abuses with the current price of Waymade's 20mg full label hydrocortisone tablets

	October 2008- December 2013	January 2014-August 2015	September 2015- January 2017	Whole period
Hydrocortisone 20mg - price £	£29.81	£56.81	£60.77	£38.59
Waymade's current 20mg full label price £	[X]	[X]	[X]	[X]
Difference - £	[X]	[X]	[X]	[X]
Difference %	[X]	[X]	[X]	[X]
Revenue difference (£m)	[X]	[X]	[X]	[X]

5.396. These differences demonstrate that Auden/Actavis's prices during the Unfair Pricing Abuses were unfair when compared to competing products. The scale of the differences is significant. Auden/Actavis's prices exceeded the current prices of 10mg and 20mg skinny label hydrocortisone tablets on average by around 2,700% for 10mg hydrocortisone tablets and 2,000% for 20mg hydrocortisone tablets throughout the whole of the 10mg and 20mg

¹⁸³⁹ Calculated by multiplying the price differences per pack by the number of packs of hydrocortisone tablets sold.

Unfair Pricing Abuses, and exceeded the current price of Waymade's 20mg full label hydrocortisone tablets on average by over [REDACTED].

5.397. As explained in sections 3.E.V and 5.C.II above, Auden/Actavis's prices during the Unfair Pricing Abuses ranged between:

- a. £20 and £72.14 a pack for 10mg tablets.
- b. £20 and £72.19 a pack for 20mg tablets.¹⁸⁴⁰

5.398. At their lowest, Auden/Actavis's prices during the Unfair Pricing Abuses exceeded the current prices of skinny label hydrocortisone tablets by:

- a. £18.66 a pack for 10mg tablets, equivalent to 1,300%.
- b. £18.15 a pack for 20mg tablets, equivalent to 900%.

5.399. At their peak, Auden/Actavis's prices exceeded the current prices of skinny label hydrocortisone tablets by:

- a. £70.80 a pack for 10mg tablets, equivalent to 5,200%.
- b. £70.34 a pack for 20mg tablets, equivalent to 3,700%.

5.400. Further, Auden/Actavis's prices during the Unfair Pricing Abuses exceeded the current price of Waymade's 20mg full label tablets by [REDACTED] a pack, equivalent to [REDACTED], at their lowest, and by [REDACTED] a pack, equivalent to [REDACTED], at their peak.

b. No other products allow for a meaningful comparison with Auden/Actavis's prices

5.401. In this section, the CMA has assessed whether any further products may provide a meaningful comparator against which to assess whether Auden/Actavis's prices were unfair.

5.402. The CMA has assessed the following two hydrocortisone-based products, which have both been raised by parties to this investigation as potential comparators:¹⁸⁴¹

¹⁸⁴⁰ Although Auden's prices fell below £20 in a few individual months during the Unfair Pricing Abuses (its 10mg price in a single month, August 2010, and its 20mg price in November 2008 and January, April and July 2009), these were single-month fluctuations in the context of sustained price increases over the period from 2008 to 2015. See figure 5.6 above.

¹⁸⁴¹ Document 205217, Auden/Actavis's RSSO, paragraphs 1.10.1, 3.19-3.32 and 4.64-4.66, and Document 205212, Intas/Accord-UK's RSSO, paragraph 21 and 184-188, Document 206667, Auden/Actavis's RLOF, paragraphs 3.17 to 3.21; and Document 206676, Intas/Accord-UK's RLOF, paragraph 9 and pages 8 and 9.

- a. Plenadren; and
- b. soluble hydrocortisone tablets.¹⁸⁴²

5.403. The CMA has concluded that neither product provides a suitable comparator against which to assess whether Auden/Actavis's prices were unfair. This is because:

- a. First, neither product is sufficiently similar to Auden/Actavis's hydrocortisone tablets to allow for a meaningful comparison between its prices and Auden/Actavis's prices in order to determine whether the latter were unfair:
 - i. Both Plenadren and soluble hydrocortisone tablets are innovative products and their suppliers have incurred development costs in bringing the products to market which they may still be seeking to recoup.¹⁸⁴³ By contrast, Auden/Actavis's hydrocortisone tablets are a very old product for which the development costs were long since recouped before Auden acquired the licences.
 - ii. Unlike full and skinny label hydrocortisone tablets – which are the first-line treatment for adrenal insufficiency (and consequently are used for around 95% of all adult patients),¹⁸⁴⁴ both Plenadren and soluble hydrocortisone tablets have niche uses and consequently comparatively very low volumes. Collectively they account for around 1% of all hydrocortisone tablet sales in the UK (regardless

¹⁸⁴² Auden/Actavis also stated that Auden had priced by reference to injectable hydrocortisone (Hydrocortistab) (Document 205217, Auden/Actavis's RSSO, paragraphs 3.32 and 11.14; and Document 206667, Auden/Actavis's RLOF, paragraphs 3.17 and 3.18). However, it provided no evidence for this statement and the CMA is aware of no contemporaneous evidence to support it (the only reference of which the CMA is aware was by [Auden Senior Employee 1] in a witness statement submitted during this investigation (see Document 00725, witness statement of [Auden Senior Employee 1], paragraphs 1.7 to 1.8)). Auden/Actavis has therefore not discharged the evidential burden on it to adduce evidence that Hydrocortistab is a *prima facie* valid comparator, such that the CMA's duty fairly to consider that evidence is engaged (*Phenytoin CoA*, paragraphs 114 and 116). For the avoidance of any doubt, Hydrocortistab would not provide a meaningful comparator against which to assess whether Auden/Actavis's prices were unfair. It is a different product (an injection) with a different active ingredient (hydrocortisone acetate), which is not used to treat long-term adrenal insufficiency but primarily for certain arthritic conditions or, exceptionally, where oral medication is not appropriate (such as where a patient is going through adrenal crisis) or tolerated (such as in cases of severe illness, pre- and post-major procedures, or where the patient is nil by mouth) (see summary of product characteristics for Hydrocortistab Injection 25mg/ml: www.medicines.org.uk/EMC/medicine/10796/SPC/Hydrocortistab+Injection+25+mg+ml/). There is no evidence that its price is set in conditions of [effective] competition: it is a single-supplier product and, like Plenadren, is in Category C of the Drug Tariff, the category used when there is no competition for supply of the product. There is no evidence to suggest that there is any competitive interaction between hydrocortisone tablets and Hydrocortistab.

¹⁸⁴³ Soluble hydrocortisone tablets were first introduced to the market in March 2019. While Plenadren has been on the market since September 2012, the orphan designation granted to recognise and allow recovery of the investment in creating Plenadren does not expire until November 2021.

¹⁸⁴⁴ Document 00603, response to question 2, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

of whether the form is immediate-release, modified-release or soluble).¹⁸⁴⁵

- b. Secondly, the market conditions in which the prices of each of these potential comparators is set are fundamentally different from those of hydrocortisone tablets. Unsurprisingly given their negligible sales volumes, both Plenadren and soluble tablets have sole suppliers. Their prices cannot be considered meaningful comparators for the prices of hydrocortisone tablets simply because customers are paying them.¹⁸⁴⁶ There is no evidence of those prices being set in conditions of effective competition.¹⁸⁴⁷
- c. Thirdly, the weakness of both of these potential comparators is emphasised by the strength of the comparison to the current prices of competing hydrocortisone tablets (which were set out in section 5.D.III.a above). Competing hydrocortisone tablets:
 - i. are the same (bioequivalent) product as Auden/Actavis's full label hydrocortisone tablets, with Waymade also selling a full label tablet;
 - ii. are readily interchangeable with Auden/Actavis's tablets;
 - iii. sell in similar volumes to Auden/Actavis's tablets;
 - iv. are priced in conditions of effective competition between competing suppliers; and
 - v. are in the same Drug Tariff category as Auden/Actavis's tablets.

i. Plenadren

5.404. Plenadren is a delayed release hydrocortisone tablet which is used to treat adult adrenal insufficiency. It is expensively priced (between approximately [£200-£250] for a pack of 50 5mg tablets and between approximately [£300-£450] for a pack of 50 20mg tablets). Superficially the fact that it is a similar product to hydrocortisone tablets (which are immediate release) and the fact it is used in the same treatment area as hydrocortisone tablets may suggest Plenadren is a suitable comparator against which to assess whether Auden/Actavis's prices were unfair.

¹⁸⁴⁵ CMA calculations based on NHS BSA data and Document 206280, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁸⁴⁶ See for example *Albion Water I* [2006] CAT 23, paragraphs 754 to 756.

¹⁸⁴⁷ Compare *Phenytoin CoA*, paragraph 155.

- 5.405. However, on closer examination the similarities are, in fact, limited and a series of market features means that Plenadren is not a meaningful comparator.
- 5.406. First, there are **significant qualitative differences** between Plenadren and hydrocortisone tablets.
- 5.407. Auden/Actavis's hydrocortisone tablets are a **very old product**. They were first sold in the 1950s, are long off-patent and have not been the subject of any recent innovation or investment (see section 3.B.VII above).
- 5.408. By contrast, Plenadren is a relatively **new and innovative product**. It was granted an MA in November 2011 and launched in September 2012¹⁸⁴⁸ – at which point Auden/Actavis's hydrocortisone tablets had already been on the market for over four years (and had been on the market for many years before that when previously sold by MSD).
- 5.409. Plenadren was specifically developed for a niche use: adult sufferers of adrenal insufficiency who *'do not do well on'* immediate-release hydrocortisone tablets.¹⁸⁴⁹ As explained in section 3.D.III above, Plenadren was granted an orphan designation for adrenal insufficiency in May 2006 and this further differentiates it from Auden/Actavis's hydrocortisone tablets.
- 5.410. In order to receive the orphan designation, Plenadren needed to demonstrate that it would *'be of significant benefit'* to patients affected by adrenal insufficiency (ie when compared to products already available – most particularly Auden/Actavis's hydrocortisone tablets).¹⁸⁵⁰
- 5.411. The threshold for demonstrating a *'significant benefit'* to patients is a high one and required that Plenadren show a *'clinically relevant advantage or a major contribution to patient care'*¹⁸⁵¹ which is *'established by means of comparison with existing authorised medicinal products [...], not just by assessing the intrinsic qualities of the product in question'*.¹⁸⁵²
- 5.412. Accordingly, Plenadren is an innovative drug which has shown that it provides a *'significant benefit'* and a *'clinically relevant advantage'* over and

¹⁸⁴⁸ Document 200320, response to question 4, Shire's response to the CMA's section 26 notice dated 20 June 2016.

¹⁸⁴⁹ Document 200320, response to question 6, Shire's response to the CMA's section 26 notice date 20 June 2016.

¹⁸⁵⁰ Regulation 141/2000, Article 3(1)(b).

¹⁸⁵¹ Regulation 847/2000, Article 3(2).

¹⁸⁵² Commission notice on the application of Articles 3, 5 and 7 of Regulation (EC) No 141/2000 on orphan medicinal products (2016/C 424/03), citing T-74/08 *Nov Pharm AG v European Commission*, EU:T:2010:376, paragraph 46.

above those provided by Auden/Actavis's immediate-release hydrocortisone tablets (see section 3.D.III above).

- 5.413. Moreover, despite the fact that both immediate release hydrocortisone tablets and Plenadren are within the same treatment area (adrenal insufficiency), Plenadren is barely prescribed in the UK. CCGs do not recommend the use of Plenadren for adrenal insufficiency (as explained in section 3.C.III above).^{1853,1854} It is also not available for use in Scotland or Wales.¹⁸⁵⁵
- 5.414. Consequently, Plenadren's sales volumes have always been very low when compared to hydrocortisone tablets. As explained in section 3.C.III above, Plenadren was used by less than 1% of all adult patients with adrenal insufficiency between its launch (in September 2012) and 2020 and dispensing has remained at a low level since its launch in the UK in 2012.¹⁸⁵⁶
- 5.415. Further, Shire (the owner of Plenadren) no longer proactively markets or promotes the sale of Plenadren in the UK and only makes reactive sales.¹⁸⁵⁷
- 5.416. Accordingly, given its low sales volumes, the fact most CCGs do not list or recommend the product and Shire's apparent lack of desire to increase its sales, little can be read into the price levels that Shire has attached to the product.
- 5.417. In addition to these material differences between the products, Plenadren's suitability as a potential comparator for determining the fairness of Auden/Actavis's prices is further and substantially undermined by the fact that there is no evidence that its price is set in conditions of effective competition.¹⁸⁵⁸

¹⁸⁵³ Shire explained to the CMA that '*Plenadren faces severe market access restrictions, primarily due to not (yet) being included in primary and secondary care formularies*' (see Document 200320, Shire's response to question 6 of the CMA's section 26 notice dated 20 June 2016). More recently, Shire explained that it '*approached the Leeds Area Prescribing Committee in October 2017 as a pilot project*' but that committee '*declined to proceed with the proposal, due to it not being attractive enough for them*' and that it '*has made no further efforts to obtain formulary status and as a result it [Plenadren] is not to our knowledge included in any formularies*' (Document 206381, Shire's response to questions 1 and 2 of the CMA's section 26 notice dated 9 March 2021).

¹⁸⁵⁴ Document 02046.B, note of call between the CMA and [Professor of Endocrinology] dated 17 November 2017, response to questions 4.a and 4.b, page 4.

¹⁸⁵⁵ Document 01604, response to question 8, Coastal West Sussex CCG's response to the CMA's section 26 notice dated 16 May 2017. See also Scottish medicines 2016 [press release](#) and [advice](#) and [All Wales Medicines Strategy Group Statement of Advice](#).

¹⁸⁵⁶ See also Document 00603, response to question 2, Society for Endocrinology's response to the CMA's section 26 notice dated 20 June 2016.

¹⁸⁵⁷ Document 206381, Shire's response to question 1 of the CMA's section 26 notice dated 9 March 2021.

¹⁸⁵⁸ Intas/Accord-UK submitted that there was no requirement that a comparator must be set in conditions of effective competition to be meaningful, and that the price of Plenadren was set under the PPRS and/or statutory scheme and is therefore a meaningful comparator (Document 205579, letter from Intas/Accord-UK to the CMA dated 20 October 2020, paragraph 2). However, as explained in paragraph 5.58 above, comparisons to other

- 5.418. Unsurprisingly given the very low sales volumes, Plenadren is the only form of delayed release hydrocortisone tablet available in the UK. It sits within Category C of the UK Drug Tariff system – a category which is only used where there is no competition for the supply of the drug in question (see section 3.E.I.b above).
- 5.419. Therefore, the market context for Plenadren is that it is an innovative, low volume product which is no longer proactively marketed by its owner – with only reactive sales being made at what are very high prices without being exposed to competition. There is nothing in this context which suggests that Plenadren would be an objectively meaningful comparator against which to assess whether Auden/Actavis's prices were unfair – there are several factors which mean the comparison would not be on a consistent basis.
- 5.420. Additionally, the evidence shows that there is little evidence of Plenadren exerting a competitive constraint on hydrocortisone tablets as there was no discernible switching away from hydrocortisone tablets despite significant prices (see section 4.B.II.c above).

ii. Soluble hydrocortisone tablets

- 5.421. Soluble hydrocortisone tablets are another form of hydrocortisone-based treatment. They differ from hydrocortisone tablets because of their means of administration. Hydrocortisone tablets (such as those sold by Auden/Actavis) are solid and need to be swallowed. By contrast soluble tablets are dissolved in water before being taken by a patient.¹⁸⁵⁹
- 5.422. As is the case with Plenadren, soluble tablets are a relatively new product. Development was commenced in 2012, with an MA being granted in 2018¹⁸⁶⁰ and the product itself being launched in the UK in March 2019.¹⁸⁶¹ Accordingly, similarly to Plenadren, development costs would have recently been incurred in developing the product and may still be being recouped – which was not the case with Auden/Actavis's hydrocortisone tablets.

products which may not be cost-justified are unlikely to be meaningful (*Albion Water I* [2006] CAT 23, paragraph 757 and *Albion Water II* [2008] CAT 31, paragraph 257). That the price of Plenadren was set under the regulatory scheme in place for branded drugs does not mean it is a meaningful comparator for the price of generic hydrocortisone tablets. In any event, the CMA's reasons for rejecting Plenadren as a comparator include more than the fact that it is a single-supplier product.

¹⁸⁵⁹ Document 206315B, response to question 4.a, Colonis Pharma' response to the CMA's section 26 notice dated 9 March 2021.

¹⁸⁶⁰ Document 206315B, response to question 2.a, Colonis Pharma' response to the CMA's section 26 notice dated 9 March 2021.

¹⁸⁶¹ Document 206315B, response to question 4.c Colonis Pharma' response to the CMA's section 26 notice dated 9 March 2021 and Document 206279, response to question 1.b, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

- 5.423. Again, like Plenadren, soluble tablets are a low volume product with a niche use: for patients who have a preference or need for a liquid form of hydrocortisone. This includes patients suffering from dysphagia (difficulty swallowing) or very young children.¹⁸⁶² Soluble tablets' sales volumes are very low: averaging under 200 packs of 10mg tablets per month since launch (accounting for less than 0.5% of total sales of hydrocortisone tablets). To date, 20mg soluble tablets have not been launched in the UK.¹⁸⁶³
- 5.424. Soluble and hard tablets are not readily interchangeable. The use of soluble tablets is limited at clinician level – with a prescription needing to specify that a patient requires the soluble form.¹⁸⁶⁴
- 5.425. Unsurprisingly given the very low sales volumes, there is only one supplier of soluble hydrocortisone tablets in the UK.
- 5.426. Accordingly, the market context suggests that there are significant differences between soluble tablets and hydrocortisone tablets such that soluble tablets are not a meaningful comparator for assessing whether Auden/Actavis's prices were unfair. Indeed, as with Plenadren, the context strongly suggests that the price of soluble tablets is not set in conditions of effective competition.
- 5.427. An analysis of pricing patterns also shows that there is no significant competitive interaction between soluble hydrocortisone tablets and the hard form of tablet sold by Auden/Actavis.
- 5.428. At the time of the launch of soluble tablets in March 2019, Actavis's 10mg price was £16.06 and its 20mg price was £11.49. Soluble hydrocortisone tablets launched in the same month at a price of £31.09 for 10mg tablets.¹⁸⁶⁵
- 5.429. Whereas Actavis's prices continued to decline from March 2019 onwards down to [REDACTED] (for 10mg tablets) and [REDACTED] (for 20mg tablets) in February 2021 (and have since fallen further to [REDACTED] (for 10mg tablets) and [REDACTED] (for 20mg tablets) in April 2021), the price of 10mg soluble hydrocortisone tablets remained stable at around [REDACTED] (its price in February 2021 was [REDACTED]).¹⁸⁶⁶

¹⁸⁶² Document 206279, response to question 1, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁸⁶³ Document 206279, response to question 1.b, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁸⁶⁴ This fact meant that soluble tablets required specific promotion; see Document 206279, response to question 4.b, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁸⁶⁵ To date, 20mg soluble tablets have not been launched in the UK due to the low level of expected demand for that tablet strength; see Document 206279, response to question 2.b, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

¹⁸⁶⁶ Document 206280, Zentiva's response to the CMA's section 26 notice dated 10 March 2021.

However, despite a very significant price gap the volumes of both the hard and the soluble 10mg tablets have remained broadly the same.

IV. Economic value

- 5.430. Economic value is ‘*an economic concept which describes what it is that users and customers value and will reasonably pay for*’.¹⁸⁶⁷ The economic value of a product may exceed Cost Plus as a result of non-cost related factors,¹⁸⁶⁸ but in the absence of any relevant non-cost related factors, Cost Plus for a particular product or service can represent its economic value.¹⁸⁶⁹ Economic value is not ‘*a discrete advantage or justification for a high price*’: if it is properly factored into ‘Plus’ or fairness, or is reflected in other evidence which can stand as a proxy for economic value, there is no incremental obligation to take economic value into account again.¹⁸⁷⁰
- 5.431. Competition authorities are not required to adopt any particular approach to determining economic value,¹⁸⁷¹ and have a considerable margin of appreciation when doing so.¹⁸⁷²
- 5.432. The CMA finds that there are no non-cost related factors associated with either 10mg or 20mg hydrocortisone tablets that increase their economic value beyond that already reflected in Cost Plus. The economic value of hydrocortisone tablets is therefore already factored into Cost Plus.
- 5.433. In drawing this conclusion, the CMA has relied upon the following factors which have been relied upon in section 5.D above in demonstrating Auden/Actavis's prices were unfair:
- First, the age of hydrocortisone tablets as a medicine and their position in the drug lifecycle, which indicate that they should have no further value than Cost Plus (see section 5.D.II.b.i above).
 - Secondly, the current prices of competing hydrocortisone tablets, which are now substantially below the lowest bounds of Cost Plus (see section 5.D.III.a above).
 - Thirdly, the erosion of Auden/Actavis's prices, which are now at levels [X], with Actavis's 20mg tablet price [X] and its 10mg tablet [X] and have continued to fall (see section 5.D.II.c.ii above).

¹⁸⁶⁷ *Phenytoin CoA*, paragraph 171.

¹⁸⁶⁸ See *Albion Water II* [2008] CAT 31, paragraph 222; and *Scandlines*, paragraph 226. See also *Attheraces Court of Appeal* [2007] EWCA Civ 38, paragraph 218.

¹⁸⁶⁹ *Albion Water II* [2008] CAT 31, paragraphs 225 and 249. See also *Deutsche Post*, paragraph 162.

¹⁸⁷⁰ *Phenytoin CoA*, paragraph 172.

¹⁸⁷¹ *Phenytoin CoA*, paragraph 253

¹⁸⁷² *Albion Water I* [2006] CAT 23, paragraph 310 and *Albion Water II* [2008] CAT 31, paragraphs 216 and 263. See also *Phenytoin* [2018] CAT 11, paragraphs 407 and 425.

a. The age of hydrocortisone tablets and their position in the drug lifecycle

- 5.434. The age of hydrocortisone tablets and their position within the drug lifecycle means they would not be expected to offer any '*particular enhanced value from the customer's perspective*'¹⁸⁷³ beyond Cost Plus.
- 5.435. As explained in section 3.B.VII above, hydrocortisone tablets are an old drug and were first sold in the 1950s. They were long-off patent at the time of the Unfair Pricing Abuses and have not been the subject of any recent innovation. They are in the third phase of the drug lifecycle, when generic competition occurs and is expected to reduce the price of drugs and keep them relatively low. This is not to say that hydrocortisone drugs are not an important or useful treatment – they are. However, even essential drugs which generate significant (even life-saving) patient benefits should become relatively inexpensive in the third stage of the drug lifecycle, provided that competition is effective (see section 3.B.III above). Indeed, this is now clearly reflected in the prices of competing hydrocortisone tablets, where prices have fallen significantly and are now below the lower bound of Cost Plus despite the fact nothing has changed in relation to the usefulness of the treatment. Actavis's current prices have also shown a similar pattern, particularly for its 20mg hydrocortisone tablet price, which is [X]. Actavis's current 10mg hydrocortisone tablet price is also [X] as Actavis's price continues to fall.

b. The current prices of competing hydrocortisone tablets

- 5.436. That the model of competition driving down the prices of even essential drugs in the third stage of the lifecycle applies to hydrocortisone tablets is demonstrated by the current prices of competing hydrocortisone tablets. Those prices further demonstrate that the economic value of hydrocortisone tablets is no greater than Cost Plus.
- 5.437. The CMA used the current prices of competing hydrocortisone tablets because they have been reached following a prolonged competitive process. As such, they do not simply provide a '*proxy*' for the economic value of hydrocortisone tablets. They provide real-world evidence of what consumers are prepared to pay for hydrocortisone tablets in conditions where their prices are no longer distorted by Auden/Actavis's exercise of substantial market power during the Unfair Pricing Abuses.¹⁸⁷⁴

¹⁸⁷³ *Albion Water II* [2008] CAT 31, paragraph 222.

¹⁸⁷⁴ Compare *Phenytoin CoA*, paragraphs 155 and 172.

- 5.438. From April 2008 to July 2015 (for 20mg tablets) and October 2015 (for 10mg tablets) Auden/Actavis was a monopolist in the supply of hydrocortisone tablets in the UK. It imposed its prices unilaterally. Prices during this time rose from £5.14 to £65.67 (20mg) and from £4.54 to £67.74 (10mg).
- 5.439. The absence of competition means that the prices paid during this period for hydrocortisone tablets do not serve as an appropriate measure of their economic value, since this would mean economic value would be defined as anything that Auden/Actavis '*could get away with*', and would equate proper value with an unfair price.¹⁸⁷⁵
- 5.440. Indeed, during this monopoly period Auden/Actavis bolstered its pricing power (and its ability to '*get away with*' very high prices) by preventing competitive entry by entering into market exclusion agreements (see section 6.D.II below).
- 5.441. Auden/Actavis could not delay competition indefinitely. Once independent entry occurred, however, the prices of competing hydrocortisone tablets took time to be competed down – such was the level of distortion created by Auden/Actavis's very high prices over the previous seven years.
- 5.442. However, the current prices of competing hydrocortisone tablets have been competed down and broadly flattened at low levels. As explained in section 5.D.III.a above:
- a. The current prices of competing skinny label hydrocortisone tablets are **£1.34** for 10mg and **£1.85** for 20mg.¹⁸⁷⁶
 - b. The current price of Waymade's full label 20mg hydrocortisone tablets is **[REDACTED]**.¹⁸⁷⁷
- 5.443. These prices are substantially below even the lowest bounds of Cost Plus. Cost Plus for hydrocortisone tablets is:
- a. For 10mg tablets, between **£2.17** and **£4.45** per pack.
 - b. For 20mg tablets, between **£2.91** and **£5.20** per pack.

¹⁸⁷⁵ *Phenytoin CoA*, paragraph 154.

¹⁸⁷⁶ As explained above, these are weighted averages over the period February to April 2021.

¹⁸⁷⁷ Average from May to July 2020. **[REDACTED]**, see Document 206689, Waymade's response to question 4 of the CMA's section 26 notice dated 9 June 2021.

- 5.444. These prices are also very substantially below the price at which the CMA has prioritised its enforcement activity in this case (£20 per pack, see paragraph 5.18 above).
- 5.445. This evidence demonstrates that the CMA's calculation of Cost Plus is an appropriate – indeed, a generous – measure of the economic value of hydrocortisone tablets.^{1878,1879} It also demonstrates that Auden/Actavis's prices during the Unfair Pricing Abuses bore no reasonable relation to the economic value of hydrocortisone tablets.
- 5.446. The evidence that the current prices of competing hydrocortisone tablets provide includes '*proxy evidence of the economic value of patient benefit*'¹⁸⁸⁰ that attaches to hydrocortisone tablets. The current prices of competing hydrocortisone tablets demonstrate that no additional economic value should be allocated for patient benefit beyond what is already reflected in Cost Plus. If there was some additional value due to patient benefit, such value would be expected to be reflected in the prices of all tablets regardless of which supplier sold them.
- 5.447. The evidence that the current prices of competing hydrocortisone tablets provide also demonstrates that the economic value of hydrocortisone tablets is no different whether they are supplied under a full label or skinny label licence. This is demonstrated by the development of prices for 20mg hydrocortisone tablets (where there is a second full label supplier (Waymade)).¹⁸⁸¹
- 5.448. If there was additional economic value to be attributed to a full label licence, it would be expected that Waymade would have been able to maintain a premium for its full label 20mg tablets. All other suppliers have skinny label MAs. However, figure 5.52 below shows that was not the case: Waymade's price for 20mg tablets closely followed the average price of skinny label

¹⁸⁷⁸ See *Phenytoin CoA*, paragraph 172. As explained in paragraph 5.78, the CMA's calculation of Cost Plus is in itself generous to Auden/Actavis, as the CMA has made assumptions in Auden/Actavis's favour at a number of points in the calculation.

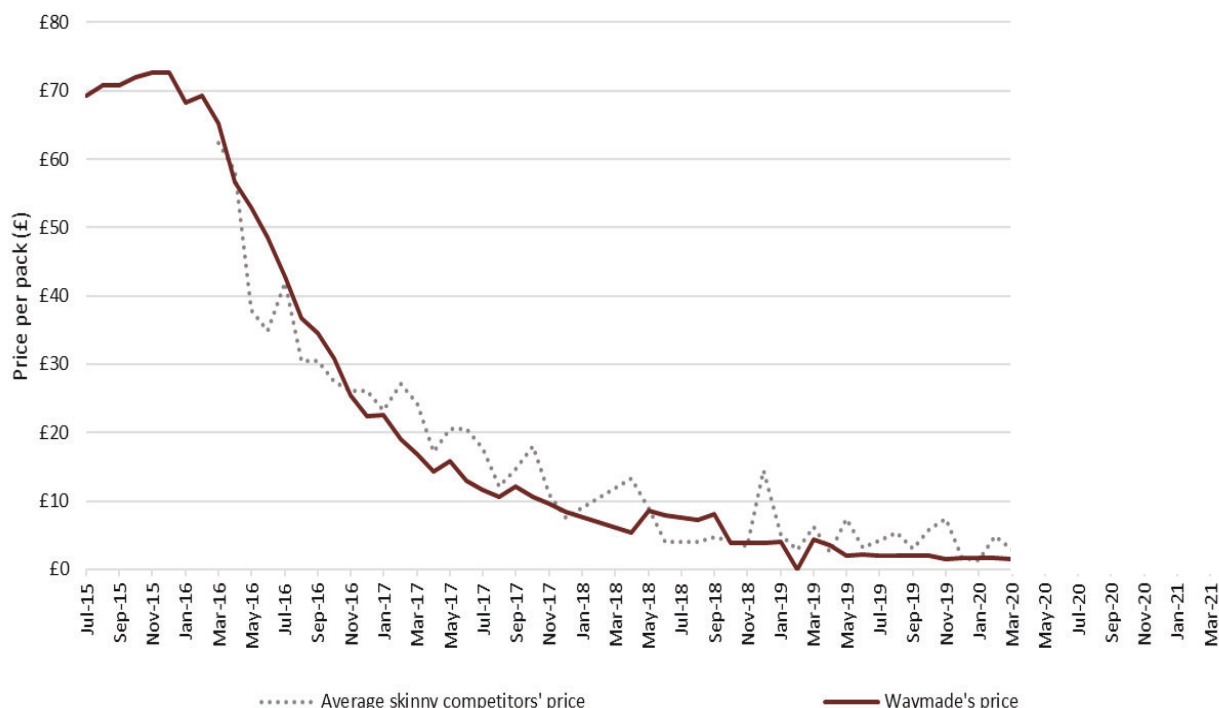
¹⁸⁷⁹ Economic value may, in principle, differ as between different products and suppliers where cost-related factors are different. Such differences would, however, be reflected in the assessment of Cost Plus (under the Excessive Limb of the *United Brands* Test) and be consistent with a conclusion that the economic value of the product is no greater than that reflected in Cost Plus. In this case, the current prices of competing hydrocortisone tablets demonstrate that there are no non-cost related factors that would justify increasing the economic value of Auden/Actavis' hydrocortisone tablets above that of other suppliers'.

¹⁸⁸⁰ *Phenytoin CoA*, paragraph 172.

¹⁸⁸¹ There should not be any difference in accounting for any non-cost related factors as between 10mg and 20mg hydrocortisone tablets given that the only difference is the strength of the tablet, and not any differences in the tablets themselves or any benefits they provide.

20mg tablets and Waymade's full label 20mg tablets commanded no premium when compared to skinny label 20mg tablets.¹⁸⁸²

Figure 5.52: Waymade's price for 20mg hydrocortisone tablets compared with skinny label 20mg tablet prices



5.449. By contrast, Actavis maintained a (gradually eroding) premium over all competing products during the Unfair Pricing Abuses (see figures 5.47 and 5.48 above). Since its competitors on 20mg included Waymade, another supplier with a full label licence, that premium cannot have reflected any inherent value in the fact that Actavis's licence was full label.

5.450. There is therefore no '*particular enhanced value from the customer's perspective*'¹⁸⁸³ inherent in the fact that a supplier holds a full label MA.¹⁸⁸⁴ As explained in section 3.D.I above, skinny and full label tablets are bioequivalent. There is no qualitative difference between them. The only distinguishing feature between them is that skinny label tablets are not indicated for adult adrenal insufficiency. This is simply the result of the date on which the MA was granted to the supplier, with those granted before

¹⁸⁸² See also section 3.E.V.b.iv above.

¹⁸⁸³ *Albion Water II* [2008] CAT 31, paragraph 222.

¹⁸⁸⁴ Moreover, as explained in section 3.D.III.c above, the fact that Actavis and Waymade hold full label MAs is purely a result of coincidence: they benefited from a regulatory windfall in that they happened to hold MAs at the time Plenadren was granted its MA in November 2011. The orphan designation granted to Plenadren reflects Plenadren's (assumed) therapeutic advantage over hydrocortisone tablets; it does not reflect any greater enhanced value from the customer's perspective in full label over skinny label hydrocortisone tablets.

November 2011 benefitting from the orphan designation granted to Plenadren and therefore being licensed for all indications.

- 5.451. For these reasons, notwithstanding the more limited list of indications, skinny label tablets have readily been substituted in place of Auden/Actavis's tablets (including for patients suffering from adult adrenal insufficiency) by a significant part of the market (see sections 3.E.IV.c and 4.B.II.c.ii above).

c. The erosion of Auden/Actavis's prices

- 5.452. The erosion of Auden/Actavis's prices for its 10mg and 20mg hydrocortisone tablets further demonstrates that the economic value of those tablets should be no higher than Cost Plus.
- 5.453. As explained in section 4.C.II.c.ii above, after competition arrived, Auden/Actavis retained the ability to maintain a premium for its hydrocortisone tablets when compared to its competitors during the Unfair Pricing Abuses. This was principally because of two market features which meant that the competitive constraints it experienced were reduced.
- 5.454. First, Actavis benefited from an assured customer base arising from the regulatory windfall of the orphan designation (see section 4.C.II.c.iii above). As explained in sections 3.E.IV.c above, several major pharmacies reached the view that they could not switch to skinny label tablets and therefore had no choice but to continue to purchase Auden/Actavis's tablets despite them being significantly more expensive.
- 5.455. Secondly, the limitations to the Drug Tariff mechanism. As explained in section 4.C.II.c.ii above, the fact that most skinny label tablet suppliers were not Scheme M members meant that their price and sales data did not contribute to the calculation of the Drug Tariff price for 10mg tablets, limiting the indirect constraint on Actavis's pricing.
- 5.456. However, over time Auden/Actavis's prices came down – particularly since Scheme M expired on 30 June 2019 and the DHSC began collecting data from all suppliers in the market in its calculations of the Drug Tariff Price, after which Actavis felt a stronger (indirect) constraint from skinny label entry and price competition. As explained in section 5.D.II.d.ii above, Actavis' current prices are:
- a. For 10mg tablets: **[£1-£4]**. These prices continue to decline.

b. For 20mg tablets: **[£1-£4]**.¹⁸⁸⁵

5.457. Actavis's current prices themselves have therefore [✂] in the case of 20mg tablets.

5.458. If there was additional economic value inherent in Auden/Actavis' hydrocortisone tablets, it would have been expected that it would maintain its prices. Any additional economic value beyond that already reflected in Cost Plus should be observable through Auden/Actavis maintaining price differences for its 10mg and 20mg hydrocortisone tablets despite the introduction of price competition resulting from independent entry, which has not been the case based on Actavis's current prices.

5.459. Further, if there was any additional economic value in Auden/Actavis's hydrocortisone tablets, it would also be expected to maintain a price difference across both tablet strengths. That is not the case: Actavis's premium reduced more quickly for 20mg tablets than for 10mg tablets and its price converged with its competitors' prices around early 2018 (see paragraph 5.389 above).

5.460. The fact that Actavis did not maintain its premium – and that its prices have stabilised (for 20mg hydrocortisone tablets) or continue to decline (for 10mg hydrocortisone tablets) – reflects the fact that Auden/Actavis's prices during the Unfair Pricing Abuses were significantly above the economic value of hydrocortisone tablets. Those prices reflected Auden/Actavis's market power and not any inherent value in its hydrocortisone tablets.

V. The parties' representations on whether Auden/Actavis's prices were unfair

5.461. In this section, the CMA considers the representations that the parties submitted in response to the allegation in the SSO that Auden/Actavis's prices were unfair.

a. 'The CMA should have included Actavis's 2019 prices in the current prices of competing products'

5.462. Auden/Actavis and Intas/Accord-UK submitted that the CMA should have included Actavis's prices charged in 2019 (the latest data available at the time of the SSO) in the current prices of competing products and compared Auden/Actavis's prices during the Unfair Pricing Abuses with prices across the entire market after entry. They submitted that excluding Actavis's prices has a material impact on the price level of the comparator which ignores the

¹⁸⁸⁵ As for competing skinny label tablets, these are averages over the period February to April 2021.

recognised benefits in the industry of full label tablets and fails to properly reflect the additional economic value arising from having a full label tablet.¹⁸⁸⁶

- 5.463.** As explained in section 5.D.III.a.i above, the CMA finds that the current prices of all **competing** 10mg and 20mg hydrocortisone tablets (ie both full and skinny label tablets sold by suppliers other than Auden/Actavis) provide for a meaningful comparison with Auden/Actavis's prices. This is because competing hydrocortisone tablets are sufficiently similar products to Auden/Actavis's hydrocortisone tablets for a comparison to be meaningful and those prices are no longer distorted by Auden/Actavis's exercise of substantial market power during the Unfair Pricing Abuses. The CMA has had regard to Actavis's current prices as part of its finding that prices during the Unfair Pricing Abuses were unfair in themselves (see section 5.D.II.d.ii above).
- 5.464. As explained in paragraphs 4.228 and 5.18 to 5.19 above, as the CMA has deprioritised investigating Actavis's prices after the end of the Unfair Pricing Abuses, it has made no finding as to whether Actavis retained a dominant position or continued to price abusively after those dates.¹⁸⁸⁷ However, Actavis continued to maintain a price premium over its competitors' 10mg prices during 2019, with the competitive process still running its course. Actavis's prices continued to be inflated by its exercise of market power during the nine years of the Unfair Pricing Abuses and its retention of an assured base of customers after independent entry (see figure 5.47 above) and it continued to face an insufficient constraint (as it acknowledged in relation to Scheme M in its letter to the DHSC).¹⁸⁸⁸
- 5.465. This is demonstrated by the fact that, as explained in section 3.E.V.b.ii, following a prolonged period of competition from competing hydrocortisone tablets and the termination of Scheme M in June 2019 Actavis's current prices as of April 2021 are:
- a. **[£1-£4]** for 10mg tablets; and
 - b. **[£1-£4]** for 20mg tablets.

¹⁸⁸⁶ Document 205217, Auden/Actavis's RSSO, paragraphs 1.10.2, 4.48.5 to 4.48.7; and Document 205212, Intas/Accord-UK's RSSO, paragraph 155.

¹⁸⁸⁷ This was explained in a letter to Intas/Accord-UK dated 20 November 2020 (Document 206685).

¹⁸⁸⁸ Document 02194, Intas letter to the DHSC dated 7 December 2017.

b. 'The CMA equates patient benefit with dependency'

- 5.466. Auden/Actavis submitted that when assessing the economic value of hydrocortisone tablets the CMA ignored the therapeutic benefit of hydrocortisone tablets and assumed such value was negated by the fact that patients are dependent on hydrocortisone tablets.¹⁸⁸⁹
- 5.467. The CMA has not ignored the therapeutic benefit of hydrocortisone tablets when assessing their economic value. Hydrocortisone tablets are an essential treatment for adrenal insufficiency. However, they are a very old drug having first been sold in the 1950s, have not been the subject of any recent innovation and are in the third stage of the drug lifecycle. At this stage, generic competition is expected to reduce the price of even essential drugs and keep prices low.
- 5.468. In the circumstances of this case, the CMA has used the current prices of competing hydrocortisone tablets in its assessment of the economic value of hydrocortisone tablets because this process of competition has taken place. Their prices provide '*proxy evidence of the economic value of patient benefit*'¹⁸⁹⁰ that attaches to hydrocortisone tablets. If there was some additional value due to patient benefit, such value would be expected to be reflected in the prices of all tablets regardless of which supplier sold them, since all hydrocortisone tablets are bioequivalent.
- 5.469. The CMA has found that the economic value of hydrocortisone tablets is no greater than its calculation of Cost Plus (see section 5.D.IV above). That includes any value in patient benefit. However, as explained in paragraph 5.443 above, the current prices of competing hydrocortisone tablets are in fact substantially below Cost Plus. This means that the CMA's assessment of the economic value of hydrocortisone tablets is in fact generous to Auden/Actavis: the evidence provided by the current prices of competing hydrocortisone tablets indicates that such value as may lie in the product's benefit to patients does not increase their economic value even to the level of Cost Plus. The Cost Plus calculation allows for further value of, on average, £2.30 per pack or 190% for 10mg tablets when compared to the price of competing hydrocortisone tablets and £2.30 or 240% for 20mg tablets.
- 5.470. Finally, in any event, notwithstanding that the CMA's calculation of Cost Plus itself is a generous measure, as explained in paragraphs 5.18 to 5.19 above, the CMA has not made a finding that any price above Cost Plus was

¹⁸⁸⁹ Document 205217, Auden/Actavis's RSSO, paragraph 4.78.

¹⁸⁹⁰ *Phenytoin CoA*, paragraph 172.

excessive or unfair. Instead, as explained in paragraph 5.18 above, the CMA has exercised its discretion to determine its administrative priorities and not reached a conclusion regarding at what level above Cost Plus but below **£20 per pack** Auden/Actavis's prices became excessive or unfair as a matter of law. This means that the **lowest** price at which the CMA has made a finding that Auden/Actavis's prices were excessive and unfair exceeds the upper bound of Cost Plus by more than **280%** and Auden/Actavis's current prices by at least [~~3~~].

c. 'Auden/Actavis's hydrocortisone tablets have greater economic value than others'

5.471. Intas/Accord-UK and Auden/Actavis submitted that customers '*have been prepared to purchase from Accord-UK at prices above the CMA's estimate of Cost Plus, thereby establishing that the economic value of Accord-UK's Hydrocortisone Tablets is above Cost Plus.*'¹⁸⁹¹

5.472. Intas/Accord-UK submitted that its hydrocortisone tablets had greater economic value than those supplied by its competitors. It submitted that the following factors justified a higher price for its hydrocortisone tablets:

- a. Accord-UK's full label licence, which customers exercising '*free choice*' place value upon.¹⁸⁹²
- b. Accord-UK's hydrocortisone tablets are scored so that patients can accurately halve or quarter them to achieve the correct dose.¹⁸⁹³
- c. Accord-UK is able to offer greater security of supply than its competitors.¹⁸⁹⁴
- d. Accord-UK is able to offer a superior delivery service to its competitors.¹⁸⁹⁵
- e. Accord-UK can offer a wider range of products compared to many of its competitors.¹⁸⁹⁶

¹⁸⁹¹ Document 205212, Intas/Accord-UK's RSSO, paragraphs 19, 156; Document 205217, Auden/Actavis' RSSO, paragraph 1.11.1, 4.75., 4.83; Document 206676, Intas/Accord-UK's RLOF, page 9.

¹⁸⁹² Document 205212, Intas/Accord-UK's RSSO, paragraphs 10, 12, 19, 69, 71, 156, 158 and 166. See also paragraph 137(iv) and Document 206676, Intas/Accord-UK's RLOF, paragraph 8; Document 206667, Auden/Actavis's RLOF, paragraph 3.4.

¹⁸⁹³ Document 205212, Intas/Accord-UK's RSSO, paragraphs 165.

¹⁸⁹⁴ Document 205212, Intas/Accord-UK's RSSO, paragraphs 161-162.

¹⁸⁹⁵ Including more drop-off points, twice daily delivery; servicing smaller customers by supplying its product range through national wholesalers; and supplying both Boots and Lloyds Pharmacy with an own-label offering.

¹⁸⁹⁶ Document 205212, Intas/Accord-UK's RSSO, paragraphs 164-166.

- f. Accord-UK has a reputation for being reliable and efficient.¹⁸⁹⁷
- 5.473. The CMA finds that there is no evidence that these factors (or others) justify a higher economic value for Auden/Actavis's hydrocortisone tablets than Cost Plus. Other suppliers are similarly placed to provide some of the claimed benefits and their products do not command a premium (for example, Teva is an undertaking of similar scale to Intas/Accord-UK with a similarly strong reputation). In fact, the evidence of Auden/Actavis's prices following entry, and its current prices, demonstrates that its hydrocortisone tablets have no greater economic value than others' hydrocortisone tablets.
- 5.474. As explained in section 3.E.V above, following entry Auden/Actavis's prices declined from a very high starting point. The current prices charged by Auden/Actavis are:
- a. **[£1-£4]** for 10mg; and
 - b. **[£1-£4]** for 20mg.¹⁸⁹⁸
- 5.475. Auden/Actavis's current 20mg price is [X] while its 10mg price is [X] and has continued to decrease.
- 5.476. The CMA finds that the economic value of Auden/Actavis's hydrocortisone tablets was always no greater than Cost Plus but market power enabled its prices to be pushed to very high levels and premiums over competitors which have belatedly been reduced since competitive entry in 2015. If there were greater economic value in Auden/Actavis's hydrocortisone tablets than in its competitors', its prices would not have fallen to these levels and would not continue falling. If the economic value of Auden/Actavis's hydrocortisone tablets justified an inherent premium over its competitors' products, that premium would not have eroded in the way it has (or disappeared completely in the case of 20mg tablets).
- 5.477. In any event, as explained in sections 3.E.IV.c.i above, the CMA does not accept that customers made a '*free choice*' to continue purchasing Auden/Actavis's full label hydrocortisone tablets in the period following entry or that customers' continued purchasing of Actavis's hydrocortisone tablets reflected any ready willingness to pay a premium for those tablets.¹⁸⁹⁹ Skinny and full label tablets are bioequivalent (see section 3.D.I above), a fact that was known by wholesalers and pharmacies alike. However, as explained in section 3.E.IV.c.i above, a number of pharmacies reached the view that they

¹⁸⁹⁷ Document 205212, Intas/Accord-UK's RSSO, paragraphs 164-166.

¹⁸⁹⁸ As for competing skinny label tablets, these are averages over the period January to October 2020.

¹⁸⁹⁹ *Albion Water II* [2008] CAT 31, paragraph 226.

could not switch to skinny label tablets and therefore had no choice but to purchase Auden/Actavis's full label tablets, rendering those customers captive to Auden/Actavis and giving it an assured customer base during the Unfair Pricing Abuses.¹⁹⁰⁰ Those customers that switched to using skinny label tablets treated hydrocortisone tablets consistently with their status as a commodity product and acted on the basis of price differences, even marginal differences.¹⁹⁰¹

5.478. In neither case does customers' behaviour indicate that they perceived Auden/Actavis's hydrocortisone tablets to have a greater economic value than others' hydrocortisone tablets.

5.479. In any event, the CMA's decision not to prioritise investigating whether Auden/Actavis's prices were abusive below £20 per pack (see paragraph 5.18 above) means that, even if there were some additional economic value inherent in Auden/Actavis's hydrocortisone tablets over and above those of other suppliers, this would make no difference to the CMA's findings that its prices during the Unfair Pricing Abuses were excessive and unfair.

d. 'The CMA cannot have regard to information outside certain time periods'

5.480. Intas/Accord-UK submitted that the CMA should assess whether Actavis's prices were excessive and unfair during '*the Intas period*' (the period from 9 January 2017, when Accord-UK was acquired by Intas, onwards) discretely, without having regard to factors relevant to prior time periods. Intas/Accord-UK submitted that '*the threshold for intervention by the CMA is not met in respect of the Intas Period*',¹⁹⁰² in particular because Accord-UK's prices during that period were not '*stable or "significant and persistent"*' but declining.¹⁹⁰³ Intas/Accord-UK also criticised the CMA for using '*future information, which would not be known at the time the pricing decisions have to be taken*'.¹⁹⁰⁴

5.481. The CMA has found that the prices charged by the undertaking Auden/Actavis were excessive and unfair during the periods of the Unfair

¹⁹⁰⁰ The CMA therefore rejects Intas/Accord-UK's submission that '*the requirement that Accord-UK's prices must be "imposed" is not met by the fact that customers "chose" or "prefer" or even have a "strong preference" for Accord-UK's product*' (Intas/Accord-UK's RSSO, paragraph 72. See also paragraphs 12 and 107-111 and Document 206676, Intas/Accord-UK's RLOF, page 9).

¹⁹⁰¹ Document 206582, note of call with Sigma dated 4 March 2021, paragraphs 2.5, 2.6 and 3.4; Document 206612, note of call with Mawdsleys dated 3 March 2021, paragraph 2.1, 2.4; Document 206580, note of call with DE Pharma dated 17 March 2021, paragraphs 2.4 and 2.11; and Document 206579, note of call with DE Pharma dated 23 February 2021, paragraph 2.1, 2.2, 2.3, 2.9 and 2.10.]

¹⁹⁰² Document 205212, Intas/Accord-UK's RSSO, paragraphs 112-121, 103, 105, 13, [21].

¹⁹⁰³ Document 205212, Intas/Accord-UK's RSSO, paragraph 116.

¹⁹⁰⁴ Document 205212, Intas/Accord-UK's RSSO, paragraph 132.

Pricing Abuses. In so doing it has taken into account all the evidence available to it, including from those periods and outside them. As in relation to dominance (see paragraph 4.224 above), the fact that the legal entity that sold hydrocortisone tablets (from September 2015 onwards, Accord-UK) was acquired by a new parent company (Intas/Accord) in January 2017 is irrelevant to the assessment of whether its prices were excessive and unfair.¹⁹⁰⁵

- 5.482. When Accord-UK was acquired by Intas/Accord its 10mg price was £54.21. This is over 2,000% above Cost Plus, and £34.21 above prices that the CMA has prioritised in this case (£20 per pack), reflecting the significant and persistent price increases Accord-UK, and AM Pharma before it, had imposed during the previous nine years.
- 5.483. Moreover, at the point Intas/Accord acquired Accord-UK it was aware that the CMA had serious concerns about those price levels. Intas/Accord was made aware of the CMA's investigation, including that this involved a potential abuse of dominance by way of charging excessive and unfair prices for hydrocortisone tablets, prior to acquiring Accord-UK.¹⁹⁰⁶ By the time of Intas/Accord's acquisition of Accord-UK, the pricing of this drug had been under investigation by the CMA for almost a year; [X] of Accord-UK had attended State of Play meetings on behalf of Accord-UK at which the CMA outlined its concerns on two separate occasions;¹⁹⁰⁷ and a Statement of Objections outlining the CMA's provisional conclusions that Accord-UK held a dominant position and was abusing that position by pricing the drug excessively and unfairly had been issued.
- 5.484. Despite this knowledge and its position of special responsibility as a dominant undertaking, Intas/Accord did not act to reduce Accord-UK's prices; instead, those prices continued to decline similar to how they had done in the months prior to the acquisition.¹⁹⁰⁸ As explained in sections 4.D.II.c and 5.A above, the CMA finds that notwithstanding this decline, Actavis continued to hold a dominant position and to abuse that position by imposing excessive and unfair prices until the end of the 10mg Unfair Pricing Abuse.

¹⁹⁰⁵ The CMA has reflected any consequent changes in Actavis's common cost base as a result of the acquisition, as explained in section 5.C.II.a.ii above.

¹⁹⁰⁶ Document 03006, transcript of oral hearing with Intas/Accord-UK on 15 December 2017, page 57 lines 14-20.

¹⁹⁰⁷ Document 00746, note of state of play meeting on 12 May 2016; Document 00747, note of state of play meeting on 7 September 2016 (at this meeting the CMA provided a detailed slide presentation with its provisional views on the case – see Document 00748).

¹⁹⁰⁸ In any event, Intas/Accord-UK's submission that any price must be '*significant and persistent*' to be excessive and unfair is not supported in *United Brands* or *Phenytol CoA*. See Document 205212, Intas/Accord-UK's RSSO, paragraph 116.

5.485. In any event, it is well-established that evidence outside the period in which impugned conduct occurred may be used to inform the assessment of whether an infringement occurred during that period.¹⁹⁰⁹

e. **‘Auden should be given credit for keeping a lifesaving medicine available’**

5.486. Auden/Actavis submitted that:

‘In order for the supply of Hydrocortisone Tablets in the UK to become commercially viable, Auden had no choice but to de-brand Hydrocortisone Tablets and increase the prices charged.’¹⁹¹⁰

5.487. Auden/Actavis further submitted that:

‘the CMA fails to take into account that Auden/Accord-UK maintained the product such that it was available for patients and does not analyse at all the potential benefits generated by the price rises. A key omission of the CMA’s analysis ... is any reference to the fact that prior to the transfer of the MA and prior price rises, MSD was likely to “delete” the product from the market. Had the sole supplier of hydrocortisone tablets withdrawn the product, there would have been no supplier in the UK with the ability to supply, resulting in, on the basis of the CMA’s analysis, materially worse adverse effects on the end customer and patients.’¹⁹¹¹

5.488. These submissions are not credible. That a medicine is clinically essential for patients is not a justification for excessive and unfair prices.

5.489. First, even if the premise that MSD’s prices prior to de-branding were unprofitable were accepted, this cannot mean that Auden *‘had no choice but to de-brand Hydrocortisone Tablets and increase the prices charged’* beyond a level that would make them profitable.

5.490. As explained in paragraphs 5.11 and 5.231 to 5.232 above, when Auden de-branded hydrocortisone tablets and launched its generic versions in April 2008 it set its prices at £4.54 for 10mg and £5.14 for 20mg. It would not be expected to have chosen launch prices that were unprofitable, particularly

¹⁹⁰⁹ For example, see (by analogy) *Streetmap v Google* [2016] EWHC 253 (Ch), paragraph 90: *‘it is for [a claimant or, here, the competition authority] to establish that the conduct was reasonably likely to harm competition. In determining that question, the court will take into account, as a very relevant consideration, evidence as to what the actual effect of the conduct has been.’*

¹⁹¹⁰ Document 205217, Auden/Actavis’s RSSO, paragraph 4.43.

¹⁹¹¹ Document 205217, Auden/Actavis’s RSSO, paragraph 4.38.4.

given that it was the sole supplier of a product without a regulated price, and there is no evidence that it did.

- 5.491. As explained in paragraph 5.18 above, the CMA has not found that those launch prices were excessive and unfair – only that Auden’s prices at £20 per pack and above were. It cannot credibly be stated that Auden had no choice but to increase its prices over many years to around £72 per pack. Indeed, Auden was able to increase its prices to that level because of its position as a dominant undertaking – a position that entailed a special responsibility not to abuse its market power.
- 5.492. Second, Auden/Actavis’s reference to *‘the potential benefits generated by the price rises’* is difficult to understand. As explained throughout this Decision, Auden/Actavis made no further innovation in relation to hydrocortisone tablets and offered no further benefits for patients than were offered when the drug was first sold in 1955. Auden simply purchased a product where it knew it had market power and increased prices. Those price increases benefited no one but Auden/Actavis. Indeed, far from working for the benefit of the NHS, Auden took steps (in the form of market exclusion agreements) to shore up its dominant position by delaying competitive entry.
- 5.493. As explained in section 5.D.II.e above, Auden’s price increases had negative consequences for the NHS, with annual spend on hydrocortisone tablets increasing from £7.8 million in 2008 to a peak of £83.9 million in 2016; and for individual CCGs, which were required as a result to commit extra money from their constrained budgets to continue to fund the supply of hydrocortisone tablets to patients, with inevitable knock-on effects on their ability to provide care overall.¹⁹¹²
- 5.494. Third, Auden/Actavis’s statement that prior to its acquisition of the MAs, *‘MSD was likely to “delete” the product from the market’* in the sense of simply discontinuing supply is mere speculation. MSD told the CMA that the valuation of £190,000 for the *Hydrocortone* trade mark *‘would have been arrived at on the basis that the company was going to delete the product in*

¹⁹¹² Auden/Actavis submitted that *‘The CMA appears to argue that the DH “accepted” the prices being charged for hydrocortisone tablets, the logical extension of this being that they considered the prices were in line with the economic value of Hydrocortisone Tablets’* (Document 205217, Auden/Actavis’s RSSO, paragraph 4.81). The basis for this submission is not clear. For the avoidance of doubt, the CMA has never argued that the DHSC ‘accepted’ the prices of hydrocortisone tablets or considered that they were in line with the product’s economic value.

any event and therefore the sum would typically pay for MSD's internal costs of disposal'.¹⁹¹³ However, MSD further stated:

*'MSD's business model is based on the sale of patented, ethical pharmaceuticals. Historically, the profitability of products after loss of exclusivity of patent protection falls substantially which makes the on-going manufacture, marketing and sale of those products, generally, unattractive. However, typically, products at loss of exclusivity may have been used by patients and prescribed by healthcare professionals over many years and in many cases there is an on-going need for continued supply of product into the marketplace for those patients. Any deletion or cessation of supply is treated sensitively with consideration of options to maintain continuity of supply including divestment.'*¹⁹¹⁴

- 5.495. It is therefore not necessarily the case that in the absence of a sale to Auden, MSD intended simply to discontinue supplying hydrocortisone tablets. MSD noted that although it no longer had information on the cost of manufacturing the product, it assumed that this remained below the selling price even when that price was around £1 per pack.¹⁹¹⁵

E. Exclusions

- 5.496. Section 19 of the Act provides that the Chapter II prohibition does not apply to any of the cases in which it is excluded by or as a result of Schedules 1 to 3 of the Act.
- 5.497. None of the exclusions from the Chapter II prohibition provided for by section 19 or under Schedules 1 to 3 of the Act applies in respect of the Unfair Pricing Abuses.

¹⁹¹³ Document 00561, MSD's response to the CMA's section 26 notice dated 6 July 2016, response to question 5.

¹⁹¹⁴ Document 00561, MSD's response to the CMA's section 26 notice dated 6 July 2016, response to question 6.

¹⁹¹⁵ Document 00561, MSD's response to the CMA's section 26 notice dated 6 July 2016, response to question 7.

6. THE AGREEMENTS

A. Summary

I. The 20mg Agreement

- 6.1. Waymade was a potential competitor to Auden: it had real concrete possibilities of entering the market with its own 20mg hydrocortisone tablets. In particular:
- a. Between 2008 and early 2011 Waymade developed its own 20mg hydrocortisone tablets.
 - b. By 28 March 2011 Waymade had cleared all regulatory requirements.
 - c. Waymade received commercial stock ready for sale on 9 May 2011.
 - d. There were no insurmountable barriers to Waymade's independent entry with its own 20mg hydrocortisone tablets.
- 6.2. However, in July 2011 Waymade entered into an agreement with Auden.
- 6.3. Between 11 July 2011 and 30 April 2015 Auden and Waymade shared a common understanding that:
- a. Auden would supply Waymade with 20mg hydrocortisone tablets on terms that amounted to monthly payments (or 'value transfers') to Waymade; and
 - b. In exchange for these payments, Waymade would not enter the market independently with its own 20mg hydrocortisone tablets.
- 6.4. The common understanding in paragraph 6.3.a and 6.3.b above will be referred to as the **20mg Agreement**.
- 6.5. Auden paid Waymade in monthly cash payments (initially £24,000 per month, increasing over time) and through the transfer of margin on a specified volume of 20mg hydrocortisone tablets supplied to Waymade each month at a discounted price. Auden initially offered to supply Waymade at market rate (£34.50 per pack) before discounting the supply price by **87%** to £4.50 once it became aware of Waymade's 20mg MA.
- 6.6. In total, these payments amounted to **at least £1.8 million** between 11 July 2011 and 30 April 2015.

- 6.7. No party or individual has given a credible explanation for these payments, other than that they were to buy off Waymade's entry. The CMA finds that in exchange Waymade agreed that it would not enter the market independently with its own 20mg hydrocortisone tablets. Accordingly, the 20mg Agreement had the object of preventing, restricting or distorting competition in the supply of 20mg hydrocortisone tablets.

II. The 10mg Agreement

- 6.8. Between 2008 and 2012 Waymade worked to obtain an MA for 10mg hydrocortisone tablets and to develop its own 10mg hydrocortisone tablets.
- 6.9. Between July 2011 and September 2012 Auden supplied Waymade with 10mg hydrocortisone tablets at market rate: between £31.50 and £34.50 per pack.
- 6.10. Waymade obtained a 10mg MA on 27 September 2012. By this date it was a potential competitor to Auden: it had real concrete possibilities of entering the market with its own 10mg hydrocortisone tablets. In particular:
- a. Waymade had developed an approved method for commercial production of 10mg tablets in 2010.
 - b. Waymade now held a 10mg MA, which presented a competitive threat to Auden.
 - c. There were no insurmountable barriers to Waymade's independent entry with its own 10mg hydrocortisone tablets.
- 6.11. In October 2012 – at the latest by 23 October 2012 – Auden and Waymade entered into a further agreement, relating to 10mg hydrocortisone tablets, on essentially the same common understanding as the 20mg Agreement (and through some of the same individuals, especially [Auden Senior Employee 1] and [Amdipharm Senior Employee]). Auden paid Waymade through the monthly transfer of margin on a specified volume of 10mg hydrocortisone tablets, which it supplied to Waymade at £1 per pack: a **97%** discount to its price to Waymade prior to October 2012 and to its price to all other customers.
- 6.12. No party or individual has given a credible explanation for this discount, other than that it was to buy off Waymade's entry. The CMA finds that in exchange Waymade agreed that it would not enter the market independently with its own 10mg hydrocortisone tablets.

- 6.13. On 31 October 2012, the sale of the Amdipharm group completed. Waymade's 10mg MA, 10mg product development and relevant staff, including [Amdipharm Senior Employee], became part of the AMCo undertaking under Cinven's ownership. AMCo became a potential competitor to Auden: it had real concrete possibilities of entering the market with its own 10mg hydrocortisone tablets.
- 6.14. From 31 October 2012 until 24 June 2016, the agreement continued, with AMCo replacing Waymade as Auden's counterparty. [Amdipharm Senior Employee] continued to administer the agreement for AMCo, negotiating with Auden a threefold increase in monthly volumes at the £1 supply price with effect from January 2013 onwards under the supervision of [AMCo Senior Employee 1], who subsequently took over negotiating further increases with Auden in 2014.
- 6.15. AMCo continued to receive substantial monthly payments from Auden (later Actavis): initially through a transfer of margin on 2,000 packs per month at £1 per pack; later 6,000 at £1 per pack and finally 12,000 at £1.78 per pack. The supply price to AMCo remained a 97% discount to Auden/Actavis's price to all other customers throughout this period.
- 6.16. No party or individual has given a credible explanation for this discount, other than that it was to buy off AMCo's entry. The CMA finds that in exchange AMCo agreed not to enter the market independently with its own 10mg hydrocortisone tablets.
- 6.17. The CMA therefore concludes that between 23 October 2012 and 24 June 2016, Auden/Actavis¹⁹¹⁶ shared a common understanding first with Waymade, and then with AMCo, that:
- Auden/Actavis would supply first Waymade, and then AMCo, with 10mg hydrocortisone tablets on terms that amounted to monthly payments (or 'value transfers') to them; and
 - In exchange for these payments, each of Waymade and AMCo would not enter the market independently with its own 10mg hydrocortisone tablets.

¹⁹¹⁶ As explained in section 1 (*Introduction and summary*) above, since AM Pharma sold hydrocortisone tablets until 31 August 2015, and Accord-UK (then known as Actavis UK Limited) took over its business from 1 September 2015, the CMA will refer to 'Auden' when discussing the undertaking until 31 August 2015, and to 'Actavis' when discussing the undertaking after that date. The CMA will refer to 'Auden/Actavis' when discussing the undertaking throughout the period covered by this Decision.

- 6.18. The common understanding in paragraph 6.17.a and 6.17.b above will be referred to as the **10mg Agreement**.
- 6.19. As explained above:
- a. Between 23 and 30 October 2012, Waymade was counterparty to the 10mg Agreement.
 - b. Between 31 October 2012 and 24 June 2016, AMCo was counterparty to the 10mg Agreement.
- 6.20. The 10mg Agreement had the object of preventing, restricting or distorting competition in the supply of 10mg hydrocortisone tablets.
- 6.21. The CMA refers to the 20mg Agreement and the 10mg Agreement together as the **Agreements**.

B. The burden and standard of proof

I. Legal framework

- 6.22. The burden of proving an infringement of the Chapter I prohibition falls on the CMA. The standard of proof is the balance of probabilities.
- 6.23. It is for the CMA to prove infringements *'by adducing ... precise and coherent evidence demonstrating convincingly the existence of the facts constituting those infringements ... That evidence may consist of direct evidence, taking the form, for example, of a written document ... or, failing that, indirect evidence, for example in the form of conduct'*.¹⁹¹⁷
- 6.24. But *'it is not necessary for every item of evidence ... to satisfy those criteria [ie precision and coherence] in relation to every aspect of the infringement. It is sufficient if the body of evidence relied on ..., viewed as a whole, meets that requirement'*.¹⁹¹⁸
- 6.25. What evidence is likely to be sufficiently convincing to prove the infringement will depend on the circumstances and the facts.¹⁹¹⁹ In *JJB Sports*, for example, the CAT held that *'even a single item of evidence, or wholly*

¹⁹¹⁷ T-168/01 *GlaxoSmithKline Services Unlimited v Commission*, EU:T:2006:265, paragraphs 82 to 83.

¹⁹¹⁸ C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, paragraph 47. See also *Durkan Holdings Limited and Others v Office of Fair Trading* [2011] CAT 6, paragraph 95; C-613/13 P *Keramag Keramische Werke*, EU:C:2017:49, paragraphs 52-55; T-56/99 *Marlines v Commission*, paragraph 28; *ICI v Commission*, paragraph 68; T44/02 P *Dresdner Bank v Commission*, EU:T:2006:271, paragraph 63; T-67/00 *JFE Engineering v Commission*, EU:T:2004:221, paragraph 180; T-56/99 *Marlines v Commission*, paragraph 28. See also *ICI v Commission*, paragraph 68; T44/02 P *Dresdner Bank v Commission*, EU:T:2006:271, paragraph 63; and T-67/00 *JFE Engineering v Commission*, EU:T:2004:221, paragraph 180.

¹⁹¹⁹ *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraph 205.

circumstantial evidence, depending on the particular context and the particular circumstances, may be sufficient to meet the required standard'.¹⁹²⁰ However, in other contexts this may not suffice. In *North Midland Construction v OFT*, for instance, the CAT found that the OFT had not established an infringement on the balance of probabilities on the basis of a single item of contemporaneous evidence, capable of multiple interpretations, and subject to an unequivocal denial by the party which the OFT did not challenge in court. It held that *'The combination of that unchallenged evidence... and our unresolved concerns... leave us in a position where we are not satisfied on the balance of probabilities'*.¹⁹²¹

6.26. The nature of the infringement may affect the quality of the evidence. The CAT emphasised in *Claymore Dairies* that: *'Chapter I cases will often concern cartels that are in some way hidden or secret; there may be little or no documentary evidence; what evidence there may be may be quite fragmentary; the evidence may be wholly circumstantial or it may depend entirely on an informant'*. As such, the CAT explained, *'indirect evidence and circumstantial evidence generally, may have a powerful role to play in the factual matrix of a case'*.¹⁹²² The European Court of Justice has similarly noted that *'participation in agreements that are prohibited ... is more often than not clandestine and is not governed by any formal rules'*.¹⁹²³

6.27. An authority is therefore not required to produce express evidence of collusion. In *Hitachi v Commission*, a case involving market sharing, the European General Court stated that:

'as anti-competitive agreements are known to be prohibited, the Commission cannot be required to produce documents expressly attesting to contacts between the traders concerned. The fragmentary and sporadic items of evidence which may be available to the Commission should, in any event, be capable of being supplemented by inferences which allow the relevant circumstances to be reconstituted'.¹⁹²⁴

6.28. The General Court went on to state:

¹⁹²⁰ *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraph 206.

¹⁹²¹ *North Midland Construction v OFT* [2011] CAT 14, paragraphs 28 to 33.

¹⁹²² *Claymore Dairies Ltd v OFT* [2003] CAT 18, paragraphs 3 and 9. See also *Durkan Holdings Limited and Others v Office of Fair Trading* [2011] CAT 6, paragraph 96. Compare C-634/13 P *Total Marketing Services v Commission*, EU:C:2015:614, paragraph 26; and C-403/04 *Sumitomo Metal Industries v Commission*, paragraph 46.

¹⁹²³ C-68/12 *Protimonopolny urad Slovenskej republiky v Slovenska sporitel'na*, EU:C:2013:71, paragraph 26.

¹⁹²⁴ T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 61. See also T-44/02 P *Dresdner Bank v Commission*, EU:T:2006:271, paragraph 64.

*'The existence of a mutual agreement necessarily implies the existence of a meeting of minds, even if there is no evidence which makes it possible to determine with precision the exact point in time that meeting of minds was manifested or which formalised its expression.'*¹⁹²⁵

6.29. In *Sumitomo Metal Industries v Commission*, the General Court held:

*'in practice, the Commission is often obliged to prove the existence of an infringement under conditions which are hardly conducive to that task, in that several years may have elapsed since the time of the events constituting the infringement and a number of the undertakings covered by the investigation have not actively cooperated therein. Whilst it is necessarily incumbent upon the Commission to establish that an illegal market-sharing agreement was concluded ..., it would be excessive also to require it to produce evidence of the specific mechanism by which that object was attained ... Indeed, it would be too easy for an undertaking guilty of an infringement to escape any penalty if it was entitled to base its argument on the vagueness of the information produced regarding the operation of an illegal agreement in circumstances in which the existence and anti-competitive purpose of the agreement had nevertheless been sufficiently established.'*¹⁹²⁶

6.30. The Court of Justice held that: *'That appraisal of the evidence is consistent with well-established case law'*.¹⁹²⁷

II. Application in this case

6.31. The CMA bases its conclusions on the Agreements on the body of available evidence, taken together and assessed as a whole.

6.32. The body of evidence on which the CMA has relied includes contemporaneous documentary evidence and corroborating *ex post* interview evidence.

6.33. The CMA has generally placed greater weight on contemporaneous documents, as this evidence is most likely to give an accurate picture of the arrangements between the parties at the relevant times. The CMA finds that the contemporaneous documents, read in context, establish the existence of the Agreements.

¹⁹²⁵ T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 269.

¹⁹²⁶ T-67/00 *JEF, Nippon Steel and Sumitomo Metal Industries v Commission*, EU:T:2004:221, paragraph 203, quoted with approval in C-403/04 *Sumitomo Metal Industries v Commission*, EU:C:2007:52, paragraph 50.

¹⁹²⁷ C-403/04 *Sumitomo Metal Industries v Commission*, EU:C:2007:52, paragraph 51.

- 6.34. Moreover, in the circumstances of this case, the CMA finds that interview evidence corroborates the contemporaneous documents.
- 6.35. The body of evidence, taken together as a whole, therefore leads to the conclusion that Auden/Actavis, Waymade and AMCo entered into the Agreements.

III. The parties' representations on the burden and standard of proof

- 6.36. The burden and standard of proof in competition cases is well-established. However, the parties made extensive representations on how the burden and standard of proof should apply to the evidence for the Agreements.

a. The standard of proof

- 6.37. Waymade and Cinven submitted that the CMA could not reach an infringement finding on the balance of probabilities but was required to establish the existence of an infringement beyond reasonable doubt, citing the CAT's references to the need for '*strong and compelling evidence*', '*the presumption of innocence*', and '*reasonable doubt*' in *Napp Pharmaceutical Holdings v DGFT*.¹⁹²⁸
- 6.38. The CMA is not required to prove an infringement beyond reasonable doubt.
- 6.39. In *Napp*, the CAT stated that:

'formally speaking, the standard of proof in proceedings under the Act involving penalties is the civil standard of proof, but that standard is to be applied bearing in mind that infringements of the Act are serious matters attracting severe financial penalties. It is for the Director to satisfy us in each case, on the basis of strong and compelling evidence, taking account of the seriousness of what is alleged, that the infringement is duly proved, the undertaking being entitled to the presumption of innocence, and to any reasonable doubt there may be'.¹⁹²⁹

- 6.40. However, '*taking account of the seriousness of what is alleged*' and reflecting that '*infringements of the Act are serious matters attracting severe financial penalties*' does not vary the standard of proof.¹⁹³⁰ The ordinary civil

¹⁹²⁸ Document 204903, Waymade's RSSO, paragraph 2.24. Document 204967, Cinven's RSSO, paragraphs 1.9 and 2.2.

¹⁹²⁹ *Napp Pharmaceutical Holdings v DGFT* [2002] CAT 1, paragraph 109.

¹⁹³⁰ In *BPB v Commission*, the European General Court rejected the argument that the European Commission could be subject to a higher standard of proof based on the seriousness of the alleged infringement: '*the Court must reject the applicant's assertion that the Commission must adduce proof 'beyond reasonable doubt' of the*

standard still applies. This was confirmed by the CAT in *Willis v OFT*.¹⁹³¹ The seriousness of an allegation does not necessarily make it less likely that it is true: context is everything.¹⁹³²

- 6.41. The phrases ‘*strong and compelling evidence*’ and ‘*reasonable doubt*’ also do not imply a heightened standard of proof. In *JJB Sports v OFT* the CAT explained that its judgment in *Napp*:

*‘should not be interpreted as introducing the criminal standard through the back door ... It also follows that the reference by the Tribunal to “strong and compelling” evidence at [109] of Napp should not be interpreted as meaning that something akin to the criminal standard is applicable to these proceedings. The standard remains the civil standard. The evidence must however be sufficient to convince the Tribunal in the circumstances of the particular case, and to overcome the presumption of innocence to which the undertaking concerned is entitled.’*¹⁹³³

- 6.42. Nor does the presumption of innocence affect the standard of proof. The presumption of innocence does not mean that if there is any reasonable doubt, the undertaking is presumed innocent: it means that ‘*Any doubt in the mind of the Tribunal as to whether a point is established on the balance of probabilities must operate to the advantage of the undertaking alleged to have infringed the competition rules*’.¹⁹³⁴

b. The evidence relied upon by the CMA

i. Contemporaneous evidence

- 6.43. Cinven submitted that the CMA had sought to ‘*rebut the natural meaning of contemporaneous documentary evidence*’.¹⁹³⁵

existence of the infringement in cases where it imposes heavy fines’. T-53/03 *BPB v Commission* [2008] ECR II-1333, EU:T:2008:254, paragraph 64, citing cases C-49/92 P *Commission v Anic Participazioni* and C-204/00 *Aalborg Portland*, EU:C:2004:6.

¹⁹³¹ *AH Willis and Sons Limited v OFT* [2011] CAT 13, paragraphs 45-47, citing *Re H (Minors)* [1996] AC 563 at paragraph 586; *Re D (Northern Ireland)* [2008] 1 WLR 1499 at paragraph 28; and *Re B* [2009] 1 AC 11 at paragraph 13.

¹⁹³² *Durkan Holdings Limited and Others v Office of Fair Trading* [2011] CAT 6, paragraph 94, citing opinion of Lady Hale in *In Re B* [2008] 3 WLR 1. Compare *Quarmby Construction v OFT* [2011] CAT 11, paragraphs 73-86.

¹⁹³³ *JJB Sports plc v Office of Fair Trading* [2004] CAT 17, paragraphs 197-204. The CAT also stated that: ‘*In non-criminal proceedings facts are required to be proved on the balance of probability, that is to say that the court must be satisfied on the evidence, that the occurrence of the event is more likely than not. However, the principle is that the more serious the allegation, the stronger should be the evidence before the court concludes that the allegation is established on the balance of probabilities. Hence the civil standard provides for flexibility as to the cogency of the evidence required to satisfy the court of the facts*’ (paragraph 188). Any ‘flexibility’ deriving from the seriousness of the allegation therefore relates to ‘the cogency of the evidence’ and not the standard of proof (see also paragraph 199).

¹⁹³⁴ *Tesco Stores v Office of Fair Trading* [2012] CAT 31, paragraph 88 (emphasis added).

¹⁹³⁵ Document 204967, Cinven’s RSSO, paragraphs 2.35, 2.40 and 7.24.

6.44. As the CAT has recognised, when construing contemporaneous documents:

*'The starting point will be that the author meant what they said and said what they meant. A document is not made in a vacuum, however, and should not be construed as if it had been; we have therefore read documents against the factual background known to the parties at the time.'*¹⁹³⁶

6.45. The CMA has assessed the contemporaneous documents in context, giving each document *'what appears to be its natural meaning'*¹⁹³⁷ against the factual background, as known to the parties at the time.

ii. The written supply deals

6.46. Waymade, Cinven and Auden/Actavis submitted that since the supply deals were documented in emails (in the case of 20mg) and written supply contracts (in the case of 10mg), the CMA could not legally look beyond those written terms to find Waymade and AMCo's agreement not to enter independently.¹⁹³⁸

6.47. This is not an accurate statement of the law. As explained above, the CMA is entitled to, and does, rely on the body of evidence, viewed as a whole, to establish the terms of the Agreements. To take the written supply deals as the exhaustive terms of the agreements between the parties would be to assume that Auden/Actavis agreed to supply its potential competitors Waymade and AMCo on terms that meant it was paying each of them many thousands of pounds a month in exchange for nothing.

iii. Interview evidence

6.48. Cinven submitted that the CMA had placed inappropriate weight on *ex post* interview evidence and had used interview evidence to *'displace the assessment of the contemporaneous documents and information.'*¹⁹³⁹

6.49. The CMA does not accept Cinven's representations, which in any event are inaccurate. The primary source of evidence that the CMA has relied upon in this case is contemporaneous documents. It has sought to highlight where interview evidence is corroborative of the contents of those documents. In particular, the interviews with the key individuals involved in negotiating and

¹⁹³⁶ *Tesco v OFT* [2012] CAT 31, paragraph 126.

¹⁹³⁷ *Tesco v OFT* [2012] CAT 31, paragraph 125.

¹⁹³⁸ Document 204903, Waymade's RSSO, paragraphs 2.5, 7.11 and 7.19. Document 204967, Cinven's RSSO, paragraph 2.29. Document 205217, Auden/Actavis's RSSO, paragraph 5.10. Compare Merck's arguments, rejected by the European Court of Justice, in C-614/16 P *Merck v Commission*, paragraphs 73 and 89-90.

¹⁹³⁹ Document 204967, Cinven's RSSO, paragraph 2.43.

implementing the Agreements (all of which were conducted under section 26A of the Act) had common characteristics. While denying that Waymade or AMCo had agreed not to enter the market independently with their own hydrocortisone tablets:

- a. When asked what legitimate counter-performance Waymade and AMCo were providing in exchange for the payments from Auden/Actavis no interviewee was able to provide a credible explanation.
- b. All the key interviewees, for each party involved, agreed that the supply deals were entered into in order to preserve Auden/Actavis's 'CMO volumes' (the volumes it ordered from its own CMO, Tiofarma) – a rationale that is equivalent to acknowledging that in exchange for the supply deals, Waymade and AMCo would not enter independently with their own hydrocortisone tablets, preserving Auden/Actavis's monopoly position (see further paragraphs 6.915 to 6.920 below).

6.50. Waymade submitted that the witness evidence gathered by the CMA was '*highly problematic*' and '*heavily prejudiced by the process adopted by the CMA; which has been unfair to the extent that it taints the content of the witness evidence*'.¹⁹⁴⁰

6.51. The CMA does not accept Waymade's characterisation of the CMA's interviews.

6.52. The purpose of the CMA's interviews was to seek a full and proper disclosure of facts relevant to the investigations. The CMA conducted its interviews in good faith and uninfluenced by any prejudice. That interviewers did not simply accept without question or challenge any statement or explanation an individual offered is not evidence of an unfair process.¹⁹⁴¹ Where possible, when interviewees made statements that were not credible or were contradicted by evidence or the accounts of other interviewees or the face value reading of contemporaneous documents, interviewers pointed this out and challenged interviewees to explain this.

6.53. Interviewees were interviewed in the presence of their legal advisers (unless they elected not to be) who were free to intervene if they felt questions were

¹⁹⁴⁰ Document 204903, Waymade's RSSO, paragraph 2.55(e)-(f). See also paragraphs 10.2 and 10.7-10.41.

¹⁹⁴¹ Compare *Arab Monetary Fund v Hashim* (1993) 6 Admin LR 348 at paragraph 356: an expression of scepticism is not in itself suggestive of bias.

objectionable. No party raised a complaint about the interview process with the Procedural Officer.¹⁹⁴²

iv. The parties' conduct and the relevance of plausible alternative explanations

- 6.54. AMCo submitted that the CMA had found its agreement not to enter independently solely by inference from its conduct in continuing to deal with Auden/Actavis. That AMCo took supply from Auden/Actavis on favourable terms, it submitted, did not establish that it agreed to any plan Auden/Actavis might have had to keep it off the market.¹⁹⁴³ Each of AMCo, Cinven and Auden/Actavis argued that they need only provide a plausible alternative explanation for the CMA's case to fail.¹⁹⁴⁴
- 6.55. These are not accurate descriptions of the CMA's findings or of the law as applied to them.
- 6.56. The CMA's findings on the Agreements are not established solely on an allegation that there can be no other plausible explanation for the parties' conduct. The CMA's findings are based on contemporaneous documentary evidence and corroborative interview evidence, which are sufficient to demonstrate that the Agreements as defined by the CMA were entered into by the parties and infringed the Chapter I prohibition.¹⁹⁴⁵
- 6.57. Moreover, that evidence shows that AMCo played an active role in negotiating and continuing the 10mg Agreement: it did not passively '*take the deal*' from Auden/Actavis (as AMCo submitted)¹⁹⁴⁶ but successfully used the threat that it would enter to increase payments to buy off that threat. AMCo's conduct (for example, suspending its Aesica product development immediately after securing the Second Written Agreement: see paragraphs 6.725 to 6.736 below) provides additional evidence that it understood the terms of the deal. The CMA is entitled to rely on that conduct in the global assessment of the evidence available to it and to draw conclusions from the fact that this conduct is fully consistent with the rest of that evidence.
- 6.58. Where an authority's case is based on positive evidence, it is incumbent on the parties to engage with that evidence and demonstrate why it does not

¹⁹⁴² The CMA responded to specific concerns from Waymade and AMCo in relation to interviews in letters dated 25 September 2020 and 11 September 2019, respectively.

¹⁹⁴³ Document 204922, AMCo's RSSO, paragraphs 5.24, 5.42, 5.46, 5.93-5.94 and 5.105. Compare Document 204903, Waymade's RSSO, paragraph 7.136.

¹⁹⁴⁴ Document 204922, AMCo's RSSO, paragraphs 2.13-2.17. Document 204967, Cinven's RSSO, paragraphs 2.37 and 2.40. See also Document 205217, Auden/Actavis's RSSO, paragraph 5.16.5.

¹⁹⁴⁵ Compare *Lexon (UK) Limited v CMA* [2012] CAT 5, paragraph 221.

¹⁹⁴⁶ See, for example, Document 204922, AMCo's RSSO, paragraph 5.105.

establish the infringement the authority has alleged. An alternative explanation for the facts found by the authority does not suffice¹⁹⁴⁷ – indeed, where documentary evidence establishes an infringement, an alternative explanation is irrelevant.¹⁹⁴⁸ Where the CMA puts forward positive evidence of an infringement, as it has done below, it is for the undertaking concerned to prove to the requisite legal standard, on the one hand, the existence of the circumstance relied on by it and, on the other, that that circumstance calls into question the probative value of the evidence relied on by the CMA.¹⁹⁴⁹

- 6.59. For the avoidance of doubt, the parties have not provided a plausible alternative explanation for the evidence relied on by the CMA, or *a fortiori* proven to the requisite legal standard the existence of a circumstance that calls into question the probative value of that evidence.

C. Legal and economic context

- 6.60. In order to determine whether an agreement reveals a sufficient degree of harm as to constitute a restriction of competition by object, regard must be had to the economic and legal context of which it forms a part. This includes:

- a. the nature of the goods affected; and
- b. the real conditions of the functioning and structure of the relevant market.¹⁹⁵⁰

- 6.61. The economic and legal context also includes whether the parties are actual or potential competitors at the time of entering into the agreement.¹⁹⁵¹

I. Legal framework relevant to potential competition

- 6.62. The examination of conditions of competition on a given market must be based not only on existing competition between undertakings already present in the relevant market, but also on potential competition, in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves

¹⁹⁴⁷ T-305/94 *Limburgse Vinyl v Commission*, EU:T:1999:80, paragraphs 727-728: where an authority's case 'is based not on a mere finding of parallel market conduct but on documents which show that the practices were the result of concerted action ... the burden is on the applicants not merely to submit an alleged alternative explanation for the facts found by the [authority] but to challenge the existence of those facts established on the basis of the documents produced by the [authority]'.

¹⁹⁴⁸ C-239/11 *Siemens v Commission*, EU:C:2013:866, paragraphs 220 and 224.

¹⁹⁴⁹ C-89/11 *E.ON Energie v Commission*, paragraph 76.

¹⁹⁵⁰ C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 53, citing C-32/11 *Allianz Hungaria v Commission*, EU:C:2013:160, paragraph 36 and the case law cited. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 27.

¹⁹⁵¹ See, for example, CMA decision in case CE-9531/11 *Paroxetine*, sections 5.C.vi and vii.

or for a new competitor to enter the relevant market and compete with established undertakings.¹⁹⁵²

- 6.63. In examining potential competition, the critical assessment is whether the potential entrant had '*real concrete possibilities*' of entering the market.¹⁹⁵³
- a. The assessment of this issue must be carried out having regard to '*the structure of the market and the economic and legal context in which [the agreement] operates*'.¹⁹⁵⁴ The '*perception of the established operator*', ie, whether it perceived the potential entrant as a competitive threat, is a factor that is relevant to the assessment of the existence of a competitive relationship between the incumbent and the potential entrant since '*if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market*'.¹⁹⁵⁵
 - b. Against that background, the first key element to assess is whether the potential entrant had a '*firm intention and an inherent ability*' to enter the market at the time at which the relevant agreement was concluded. A '*firm intention and an inherent ability to enter the market*' is established where the potential entrant has taken '*sufficient preparatory steps to enable it to enter the market concerned within such a period of time as to impose competitive pressure*' on the incumbent.¹⁹⁵⁶ These preparatory steps '*permit the conclusion that [an undertaking] has a firm intention and an inherent ability to enter the market*'.¹⁹⁵⁷
 - c. The second key element to assess is whether there were any insurmountable barriers to market entry.¹⁹⁵⁷
 - d. Third, the finding that a potential entrant has a firm intention and an inherent ability to enter the market, if not called into question by the

¹⁹⁵² T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 99; as upheld by the ECJ in C-591/16 P *Lundbeck v Commission* ECLI:EU:C:2021:243 paragraphs 54-55; T-374/94 *European Night Services and Others v Commission*, EU:T:1998:198, paragraph 137; T-461/07 *Visa Europe and Visa International v Commission* EU:T:2011:181, paragraph 68; and T-360/09 *E.ON Ruhrgas and E.ON v Commission*, EU:T:2012:332, paragraph 85.

¹⁹⁵³ C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 54.

¹⁹⁵⁴ C-307/18, *Generics (UK) and others v CMA*, paragraph 39.

¹⁹⁵⁵ C-307/18, *Generics (UK) and others v CMA*, paragraph 42.

¹⁹⁵⁶ C-307/18, *Generics (UK) and others v CMA*, paragraph 43 and the CAT's supplementary judgment in *Generics (UK) and others v CMA* [2021] CAT 9, paragraphs 11-12; C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraphs 56-57.

¹⁹⁵⁷ C-307/18, *Generics (UK) and others v CMA*, paragraph 45; C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraphs 56-57.

existence of insurmountable barriers to market entry, can be '*confirmed by additional factors*'.¹⁹⁵⁸

- 6.64. When examining whether an undertaking was a potential competitor, the analysis should be conducted principally on contemporaneous evidence.¹⁹⁵⁹ However, although subsequent evidence '*cannot be decisive*', it can be taken into account to the extent that it is '*capable of clarifying those parties' positions at the time, confirming or challenging their arguments in that respect as well as allowing a better understanding of the market concerned*'.¹⁹⁶⁰ Evidence relating to events subsequent to the conclusion of that agreement cannot be taken into consideration in order to assess and retrospectively to rebut the claim that the parties to that agreement were potential competitors at the time when it was concluded.¹⁹⁶¹

a. Sufficient preparatory steps / firm intention and inherent ability to enter

- 6.65. As stated above, in order to determine whether an undertaking is a potential competitor in the market, it must be determined whether there are '*real and concrete possibilities [of that undertaking] joining that market and competing with [the incumbent]*'.¹⁹⁶²
- 6.66. In assessing this issue, it is necessary first to determine whether, at the time the agreement was concluded, the undertaking had taken '*sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure [on the incumbent]*' such as to permit the conclusion that the potential entrant in fact had a firm intention and an inherent ability to enter the market.¹⁹⁶³
- 6.67. In the pharmaceutical industry, taking into account any regulatory constraints or applicable intellectual property rights, these '*sufficient preparatory steps*' may include the measures taken by the undertaking to put itself in a position to have, within that period, the required administrative authorisations for the marketing of the relevant drug, and an adequate stock of that medicine either through its own production or through supply contracts with third

¹⁹⁵⁸ C-307/18, *Generics (UK) and others v CMA*, paragraph 54 and the CAT's supplementary judgment in *Generics (UK) and others v CMA* [2021] CAT 9, paragraph 14; C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 74 as confirmed by the Court of Justice in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 57.

¹⁹⁵⁹ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 138, citing – by analogy – T-540/08 *Esso and Others v Commission* EU:T:2014:630, paragraph 75.

¹⁹⁶⁰ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 141, as confirmed by the Court of Justice in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 67.

¹⁹⁶¹ C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 68.

¹⁹⁶² C-307/18, *Generics (UK) and others v CMA*, paragraph 36.

¹⁹⁶³ C-307/18, *Generics (UK) and others v CMA*, paragraphs 43–44.

parties (eg CMOs). Such measures evidence a ‘*firm intention and an inherent ability*’ to enter the market.¹⁹⁶⁴

- 6.68. For example, in *Lundbeck*, the General Court stated that a potential entrant requires only ‘*real concrete possibilities and the capacity to enter the market*’ which ‘*is certainly the case when those undertakings had made significant investments in order to enter the market and when they had already obtained MAs or had taken the necessary steps to obtain them within a reasonable period.*’¹⁹⁶⁵
- 6.69. The CAT has held that an undertaking which holds a MA and ‘*with a declared intention of entering the market in the near future*’ should be regarded as a potential competitor.¹⁹⁶⁶
- 6.70. Further, an undertaking can be a potential competitor before it has even obtained a MA. The General Court explained that ‘*potential competition includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market...*’.¹⁹⁶⁷
- 6.71. Specifically, in *Lundbeck*, Merck and Ranbaxy were considered potential competitors even though Merck did not hold an MA in every relevant market, and Ranbaxy did not hold an MA at all. In such circumstances, ‘*the path to obtaining such an MA, when it is taken by an undertaking which has for a long time been seriously preparing its market entry, constitutes potential competition, even though it may in fact take longer than envisaged by the interested parties.*’¹⁹⁶⁸ Potential competition is likely to be exerted throughout the MA application process unless the applicant encounters ‘*objectively insurmountable difficulties*’.^{1969, 1970}
- 6.72. Similarly, and contrary to a representation made by Cinven,¹⁹⁷¹ an undertaking can be a potential competitor before it has obtained stock. For

¹⁹⁶⁴ C-307/18, *Generics (UK) and others v CMA*, paragraphs 43-44.

¹⁹⁶⁵ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 131. See also paragraph 157, which shows that the Commission also took into account the strength of the incumbent’s process patents, the fact that one generic undertaking had actually entered, and the significant amounts the incumbent paid to the generic undertakings to keep them out of the market.

¹⁹⁶⁶ *Lexon (UK) Limited v Competition and Markets Authority* [2021] CAT 5, paragraph 234.

¹⁹⁶⁷ *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 158, citing T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 171 and 180, as upheld by the Court of Justice in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 83.

¹⁹⁶⁸ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraphs 178 to 80, 230, 293, 299, 314 and 320, as upheld by the Court of Justice in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 84.

¹⁹⁶⁹ T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 149.

¹⁹⁷⁰ The fact that a potential entrant holds an MA is not a *sufficient* condition for the existence of potential competition (cf. Document 205217, *Auden/Actavis’ RSSO*, paragraph 7.13); it is plainly, however, highly *relevant* evidence to the question of whether there are real and concrete possibilities of entering the market, and the CMA has treated it accordingly in its analysis of potential competition below.

¹⁹⁷¹ Document 204967, *Cinven’s RSSO*, paragraphs 6.3(d) and 6.48(a).

example, in *Lundbeck*, Ranbaxy was found to be a potential competitor to Lundbeck without having either stock available to sell at the time of the agreement nor an MA, but the possibility to obtain the MA within a short period of time.¹⁹⁷² The General Court found that: *it must be stated that the steps necessary for obtaining MAs and preparing for market entry constitute potential competition, when they are carried out by generic undertakings which have made significant investments in terms of human and economic resources in order to launch their generic medicinal product.*¹⁹⁷³ The fact that Ranbaxy also had begun to develop a process to produce the generic product and had the ability to sell its API to a customer who could then enter the market and who may have needed to vary its MA to do so was an expression of potential competition, upheld by the Court of Justice.¹⁹⁷⁴

- 6.73. The position of a potential competitor also cannot depend on whether the potential entry would certainly have taken place or proved to be successful, only whether the potential entrant *‘had real concrete possibilities in that respect. To assert the contrary would amount to denying any distinction between actual and potential competition.’*¹⁹⁷⁵ Contrary to a representation made by Cinven, there is *‘no requirement’* to demonstrate *‘with certainty’* that the undertaking *‘will in fact enter the market concerned, and, a fortiori, that it will be capable, thereafter, of retaining its place there.’*¹⁹⁷⁶
- 6.74. Further, potential entry by a product which is less commercially attractive than the incumbent’s product again does not mean that a potential entrant does not have real concrete possibilities to enter the market and compete with the incumbent.¹⁹⁷⁷
- 6.75. An assessment of whether a potential entrant had *‘real concrete possibilities’* of entering the market to compete with the incumbent and a *‘firm intention*

¹⁹⁷² The Court of Justice in *Paroxetine* recognised this as well, stating that *‘sufficient preparatory steps’* to enter the market within a short period of time as would impose competitive pressure on the incumbent included the measures taken by the generic manufacturer *‘to put itself in a position to have, within that period, the required administrative authorisations for the marketing of a generic version of the medicine concerned and an adequate stock of that generic medicine either through its own production or through supply contracts concluded with third parties.’* See C-307/18, *Generics (UK) and others v CMA* EU:C:2020:52, paragraphs 43 and 44. See also C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 86.

¹⁹⁷³ Case T-460/13, *Sun Pharmaceuticals and Ranbaxy v Commission* EU:T:2016:453, paragraph 77.

¹⁹⁷⁴ Judgment of the General Court in Case T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraphs 308-310, upheld by the Court of Justice in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraphs 88-89 and in Case C-586/16 P *Sun Pharmaceuticals and Ranbaxy v Commission* EU:C:2021:241, paragraph 44: *‘Sun Pharmaceutical had, at the time when the agreement at issue was concluded, real and concrete possibilities of entering the market with its API within a sufficiently short period of time for it to be characterised as a potential competitor of Lundbeck and did not meet any insurmountable barrier to entry.’*

¹⁹⁷⁵ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 159 as upheld by the Court of Justice in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 63; T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 91.

¹⁹⁷⁶ C-307/18, *Generics (UK) and others v CMA* EU:C:2020:52, paragraph 38; see also C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 63.

¹⁹⁷⁷ T-679/14 *Teva v Commission*, EU:T:2018:919, paragraphs 155 to 157.

and an inherent ability to do so also includes an examination of the timeframe for potential entry, ie whether entry was possible *‘within such a period of time as would impose competitive pressure’*¹⁹⁷⁸ on the incumbent *‘on the basis of costs which would have been economically viable’*.¹⁹⁷⁹

- 6.76. With respect to the timeframe within which potential entry could take place, it is only required to be capable of taking place *‘with sufficient speed to form a constraint on market participants’*,¹⁹⁸⁰ in *‘such a period of time as would impose competitive pressure’*,¹⁹⁸¹ *‘without fixing a specific limit in that respect.’*¹⁹⁸² A potential competitor does not have to have *‘a readily marketable product as long as the company is able to enter within a “short period of time”’*.¹⁹⁸³
- 6.77. The European Commission’s Guidelines on Horizontal Cooperation Agreements explain that a potential competitor is able to enter the market *‘within a short period of time’*. In the case of a potential competitor that is a party to the agreement concerned, the Guidelines explain that the Commission would normally consider a longer period of time to be a *‘short period of time’* than in a case where the potential competitor is a third party.¹⁹⁸⁴ The Guidelines also state that both the R&D and Specialisation

¹⁹⁷⁸ C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 57. See also T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 203 and C-307/18, *Generics (UK) and others v CMA*, paragraph 43.

¹⁹⁷⁹ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 104.

¹⁹⁸⁰ T 461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraph 189.

¹⁹⁸¹ C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 57.

¹⁹⁸² *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 155, citing T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 131.

¹⁹⁸³ Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 226.

¹⁹⁸⁴ In *Visa v Commission* (referred to by the CAT in *Paroxetine*), the General Court had referred to the previous set of Guidelines (in force at the time) as follows: *‘the Commission refers to a period of one year while stating that ‘in individual cases longer time periods can be taken into account’ and the ‘[t]he time period needed by companies already active in the market to adjust their capacities can be used as a yardstick to determine this period.’* (see *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 92 to 93, citing Case T-461/07 *Visa Europe and Visa International v Commission* EU:T:2011:181, paragraph 171). Auden/Actavis submitted that because Auden could reduce its capacity with its CMO (Tiofarma) in six months, the CMA should take six months as the ‘yardstick’ to determine whether the other parties to the relevant agreements were able to enter within a sufficiently short period of time to constitute potential competitors to Auden. The CMA does not accept this representation. The previous Guidelines refer to one year normally being a *‘sufficiently short’* period for these purposes, but add that in individual cases the period may be *longer*, and that the ability of existing market participants to adjust their capacities may be used as a ‘yardstick’. Nothing in the Guidelines, or the relevant case law, supports the proposition that a period of significantly *shorter* than one year may be considered to be *‘sufficiently short’* for these purposes, as Auden/Actavis claims. Nor do the Guidelines or the case law support the suggestion that the time it would take for an existing market participant to *reduce* its capacity is a relevant ‘yardstick’, as Auden/Actavis suggests: as the previous version of the Guidelines make clear, the relevant ‘yardstick’ when considering potential competition is the length of time it would take an existing market participant to *increase* its capacity. In any event, the specific six-month period to which Auden/Actavis refers is simply a contractual term in its contract with Tiofarma. It cannot in itself be indicative of how long it may take a different undertaking to enter the market. Finally, the current version of the Guidelines does not refer to the ‘yardstick’ approach at all and refers to much longer periods than one year being appropriate where the question to be determined is whether a party to an agreement is a potential competitor to the other party to that agreement. The CMA therefore rejects Auden/Actavis’ ‘six-month’ approach (see Document 205217, Auden/Actavis’ RSSO, paragraphs 7.8-7.12).

Block Exemption Regulations ‘*consider a period of not more than three years a ‘short period of time’.*’¹⁹⁸⁵

- 6.78. Indeed, the General Court has also recognised that the timeframe over which competitive pressure may be exercised by a potential entrant may be longer, but this will depend on the company’s objective ability to enter the market, even if it encounters delays in entering the market. Specifically, ‘*[t]he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place, particularly since...the cost and time necessary for entering a new product market may be considerable*’.¹⁹⁸⁶
- 6.79. Finally, it is not necessary to prove that the potential entrant would have entered the market before the expiry of an agreement in order to establish the existence of potential competition.¹⁹⁸⁷

b. Insurmountable barriers to entry

- 6.80. Where specific market characteristics exist that may have an impact on potential entry, it is necessary to assess whether those characteristics form an ‘*insurmountable barrier*’ to the potential entrant which ‘*rule out*’ any potential competition.¹⁹⁸⁸
- 6.81. It is relevant, in this context, to assess whether there are any ‘*significant regulatory hurdles*’ preventing a potential competitor from launching its product.¹⁹⁸⁹

c. Additional factors

- 6.82. As noted above, a finding that a potential entrant has a firm intention and an inherent ability to enter the market, if not called into question by the existence of insurmountable barriers to market entry, can be ‘*confirmed by additional factors*’.¹⁹⁹⁰ In that regard, the ‘*conclusion of an agreement*

¹⁹⁸⁵ Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements, paragraph 10 and footnote 3 to that paragraph, which was in force at the time of the Agreements. The CMA has had regard to these Guidelines on the basis of section 60A(3) of the Act.

¹⁹⁸⁶ T-114/02 *BaByliss SA v Commission* EU:T:2003:100, paragraph 102. The Court also stated that ‘*[t]he fact ... that the applicant’s actual entry ... was deferred several times, by comparison with its announcements, is not a sufficient reason for concluding that BaByliss cannot be regarded as a potential competitor*’.

¹⁹⁸⁷ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 163.

¹⁹⁸⁸ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 124, citing T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 230. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 31: ‘*...since Article 101 TFEU also concerns potential competition, the Gentlemen’s Agreement was capable of restricting competition, unless insurmountable barriers to entry to the European market existed that ruled out any potential competition from Japanese producers*’. See also T-112/07 *Hitachi and Others v Commission* EU:T:2011:342, paragraph 230. The requirement to consider the existence of any insurmountable barriers to entry was confirmed in C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 54.

¹⁹⁸⁹ Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 232.

¹⁹⁹⁰ C-307/18, *Generics (UK) and others v CMA*, paragraph 54; C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 74.

*between a number of undertakings, operating at the same level in the production chain, constitutes a **strong indication** that a competitive relationship existed between those undertakings'* (emphasis added)¹⁹⁹¹. This additionally provides a strong indication that the market in question is '*not impenetrable*'¹⁹⁹² and that the incumbent '*perceived those undertakings as a potential threat at the time the agreements at issue were concluded*'.¹⁹⁹³

- 6.83. A further such indication is the intention, made known and acted upon by the incumbent, to make '*transfers of value to a manufacturer of generic medicines in exchange for the postponement of the latter's market entry*'. '*[T]he greater the transfer of value, the stronger the indication.*'¹⁹⁹⁴ Such transfers of value provide an indication of the incumbent's perception of the commercial threat that a potential entrant poses and therefore of a competitive relationship between them (even in a situation where there is a claim to a patent infringement).
- 6.84. As noted above, the CMA may '*rely inter alia on the perception of the undertaking present on the market in order to assess whether other undertakings are potential competitors.*'¹⁹⁹⁵ A potential competitor may exert competitive pressure on the incumbent by its existence alone, '*a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive.*'¹⁹⁹⁶
- 6.85. This is relevant to assessing the existence of a competitive relationship between an incumbent and an undertaking not on the market at that time as '*if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market.*'¹⁹⁹⁷
- 6.86. For instance, in *Lundbeck* itself, the fact that an incumbent transferred value under an agreement demonstrated that Lundbeck perceived the recipient as

¹⁹⁹¹ C-307/18, *Generics (UK) and others v CMA*, paragraph 55, citing, by analogy, C-373/14 P *Toshiba Corporation v Commission* EU:C:2016:26, paragraphs 33 and 34. See also C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 78.

¹⁹⁹² T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 103, citing T-112/07 *Hitachi and Others v Commission* EU:T:2011:342, paragraph 226; and T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 231, confirmed by the Court of Justice in C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraphs 30 to 35.

¹⁹⁹³ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 181, citing T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 231.

¹⁹⁹⁴ C-307/18, *Generics (UK) and others v CMA*, paragraph 56.

¹⁹⁹⁵ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 104. See also T-360/09 *E.ON Ruhrgas and E.ON v Commission* EU:T:2012:332, paragraph 106, which adds, consistent with the case law quoted above, that '*the purely theoretical possibility of market entry is not sufficient to establish the existence of potential competition*'.

¹⁹⁹⁶ T-461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraph 169; and T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 102.

¹⁹⁹⁷ C-307/18, *Generics (UK) and others v CMA*, paragraph 42; see also C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 76.

a potential competitor. This was particularly so given that the incumbent occupied a more informed position in the market and *'it would be surprising if an undertaking as experienced as Lundbeck would have decided to pay several million euros to the generic undertakings in exchange for their commitment not to enter the market during a certain period if the possibility that those generic undertakings could enter the market was purely theoretical.'*¹⁹⁹⁸

i. Relevance of the patent context in the 'pay-for-delay' case law

- 6.87. Auden/Actavis, Cinven and AMCo have submitted that the legal framework for assessing potential competition referred to above is inappropriate as it derives from the case law on 'pay-for-delay' agreements in the context of patents.¹⁹⁹⁹ The CMA disagrees. The case law on potential competition applied by the CMA in this case and also applied in the 'pay-for-delay' case law derives from earlier judgments in which patents did not feature. These cases established the key areas to be determined for a relationship of potential competition, ie, *'in the light of the structure of the market and the economic and legal context within which it functions, [whether] there are real concrete possibilities for the undertakings concerned to compete amongst themselves or for a new competitor to enter the relevant market and compete with established undertakings'*.²⁰⁰⁰ The cases this proposition is based on are clearly not restricted to a patent context.
- 6.88. This is apparent from the European Commission's own application of the same legal framework in *Lundbeck* and *Servier* (cases involving a patent) and in *Fentanyl* (which did not involve a patent). Similarly, the CMA applied the same legal framework in *Paroxetine* (which involved a patent)²⁰⁰¹ and in *Nortriptyline* (information exchange) (which did not involve a patent). Both decisions were upheld by the CAT. In particular, in *Nortriptyline* the product had a *'homogenous commodity'* nature and the CAT upheld the CMA's

¹⁹⁹⁸ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 161

¹⁹⁹⁹ Document 205217, Auden/Actavis's RSSO, paragraphs 6.17 to 6.36 and 7.58 to 7.59; Document 204967, Cinven's RSSO, paragraphs 6.48, 7.101 to 7.112

²⁰⁰⁰ For example, the General Court in case T-461/07, *Visa Europe Ltd and Visa International Service v Commission*, paragraph 68, citing the General Court in cases T-374/94, T-375/94, T-384/94 and T-388/94, *European Night Services and Others v Commission*, paragraph 137. Both cases were cited in the General Court's judgment in case T-360/09, *E.ON Ruhrgas and E.ON AG v Commission*, paragraph 85, along with Case C-234/89 *Delimitis*, paragraph 21. These cases are wholly outside the pharmaceutical patent context: beer supply agreements, payment card systems, international rail passenger services and the markets for natural gas.

²⁰⁰¹ See the CMA's decision in *Paroxetine* (Case CE-9531/11) paragraphs 6.14 to 6.17, the findings of which on potential competition were upheld by the CAT in *Generics (UK) Limited and others v CMA* [2021] CAT 9, paragraphs 8 to 32.

conclusions on the economic and legal context in which the infringement occurred.²⁰⁰²

- 6.89. Cinven and AMCo also submitted that the existence of the orphan designation distinguishes the present case as it affected the conditions of competition,²⁰⁰³ and meant that there was no option of entry 'at risk', which distinguishes the present case from the patent context. The relevance of the orphan designation is considered in detail at sections 3.D.III, 3.E.III, 3.E.IV, Annex D, and paragraphs 6.297 to 6.298 below. For present purposes, it is sufficient to note that the fact that the alleged barrier to entry in the present case (the orphan designation) is different from the barrier to entry that often arises in the patent context (the risk that an entrant will be found to have infringed the patent concerned) does not mean that the pay-for-delay case law is somehow irrelevant.
- 6.90. In addition, the CMA has carried out detailed analysis of the impact of the orphan designation on the competitive process with respect to 10mg hydrocortisone tablets, which demonstrates that skinny label tablets do compete with full label tablets. See also the CMA's assessment of the drug lifecycle (at section 3.B of this Decision) and its assessment of competition in generic markets.

II. The legal and economic context to the Agreements

- 6.91. In this section, the CMA summarises the economic and legal context to the Agreements, including:
- a. the nature of the goods affected; and
 - b. the real conditions of the functioning and structure of the market(s) for the supply of hydrocortisone tablets in the UK, including:
 - i. the market conditions prior to Waymade, AMCo and Auden entering into the Agreements; and
 - ii. Waymade's and AMCo's positions as potential competitors to Auden.
- 6.92. This section should be read in conjunction with section 3.B above.

²⁰⁰² See the CMA's decision in *Nortriptyline Tablets: Information Exchange*, 4 March 2020, paragraphs 5.17 – 5.23, and 5.34 – 5.40 on the assessment of potential competition. The CAT upheld the CMA's findings that Alissa was a potential competitor to Lexon and King as Alissa held an MA and had a '*declared intention of entering the market in the near future*', see *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 199-201, 234.

²⁰⁰³ Document 204967, Cinven's RSSO, paragraphs 6.40-6.46; Document 204922, AMCo's RSSO, 6.53-6.56.

6.93. In summary, as explained below, the economic and legal context at the time the parties entered into the Agreements was that:

- a. Hydrocortisone tablets are a very old drug. They were long off-patent and were in the third stage of the drug lifecycle.
- b. They were unbranded generics (as a result of Auden's action in de-branding them): as such, price would have been the key driver of any competition that might materialise (see paragraphs 6.94 to 6.106 below);
- c. The market was highly concentrated: Auden was the sole supplier (see paragraph 6.99 below);
- d. Auden had exploited that position to increase prices very significantly (see section 3.F.I (*Facts relevant to the Unfair Pricing Abuses*) above);
- e. Auden's high prices meant that it was attractive for other generic manufacturers to develop their own hydrocortisone tablets to enter the market. These competing tablets were homogenous (bioequivalent) with Auden's (see section 3.D above).
- f. Waymade and AMCo were the first two generics to develop their own hydrocortisone tablets. Both were potential competitors to Auden. The potential for entry represented a competitive threat to Auden's monopoly position and created scope for volume loss and price falls, including (in the case of 10mg tablets) through off-label dispensing (see paragraphs 6.107 to 6.113 and sections 6.C.II.b.ii, iii and iv below),²⁰⁰⁴ but
- g. Each of the parties stood to gain if competition was avoided. Price falls would be avoided and prices would remain high or increasing, with them sharing what continued to be monopoly profits (see paragraphs 6.114 to 6.115 below).²⁰⁰⁵

a. The nature of the goods affected

6.94. Hydrocortisone tablets are a very old drug. They were first sold in the UK in 1955. Auden acquired the MAs from their originator, MSD, 53 years later in April 2008. By that point any patents relating to hydrocortisone tablets had long since expired. MSD was selling the drugs for less than £1 per pack.

²⁰⁰⁴ Compare *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 69 and 244.

²⁰⁰⁵ Compare *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 200 and 83.

- 6.95. Auden immediately de-branded the drug: it discontinued the *Hydrocortone* brand and launched its own generic versions.
- 6.96. As explained in section 3.B (*The Drug Lifecycle*) above, during the third stage of the drug lifecycle, when exclusivity is lost and generic competition is possible, the price of even essential drugs is expected to fall. Hydrocortisone tablets were in this stage of the lifecycle throughout the period covered by this Decision. With unbranded generic drugs the main parameter of competition is price.
- 6.97. As explained in section 3.E.III above, prescriptions for hydrocortisone tablets are 'open', meaning they do not specify a particular manufacturer or supplier. Auden's decision to de-brand removed the last potential blockage to generic competition.
- 6.98. As a result of Auden's own actions, hydrocortisone tablets are therefore essentially homogeneous, fungible commodities. Any generic supplier with the necessary resources and know how could develop its own hydrocortisone tablets and enter the market and expect to win market share provided they were competitively priced (in the absence of action by the incumbent, Auden, to prevent this).

b. The real conditions of the functioning and structure of the market(s)

i. The market conditions prior to Waymade, AMCo and Auden entering into the Agreements

- 6.99. At the time the parties entered into each of the Agreements, Auden was the sole supplier of hydrocortisone tablets in the UK. Auden had exploited that position to impose significant price increases for hydrocortisone tablets. From its initial entry in April 2008 until the points that it entered into the Agreements:
- a. Auden increased its price for 20mg hydrocortisone tablets by 533%, from £5.14 a pack in April 2008 to £32.56 a pack in July 2011, when the 20mg Agreement began.
 - b. Auden increased its price for 10mg hydrocortisone tablets by 595%, from £4.53 a pack in April 2008 to £31.55 a pack in October 2012, when the 10mg Agreement began.
- 6.100. Overall demand for hydrocortisone tablets was finite: while the number of prescriptions issued each year varied, the total volume of demand for the product was limited by the number of prescriptions. As explained in section

3.C above, 98% of prescriptions for hydrocortisone tablets are repeat prescriptions, creating a stable core customer base. Prescriptions were open (specifying only 'hydrocortisone tablets' and a strength), so that dispensers were free to switch between suppliers if competition emerged.

6.101. As [Auden Senior Employee 2] of Auden explained:

*'I suppose there's a finite number of prescriptions there, so if [Waymade] had their own manufacture and brought product into the market we would then naturally reduce our volumes.'*²⁰⁰⁶

6.102. [Actavis Senior Employee 2] of Actavis explained: *'there's a finite bucket, the market is a finite size'*.²⁰⁰⁷

6.103. [Waymade Senior Employee 1] of Waymade also noted: *'They [Auden] make a certain amount for a finite market and when there is a second player in it, his [[Auden Senior Employee 1]'s] sales would be diminished.'*²⁰⁰⁸

6.104. [Waymade Senior Employee 3] of Waymade explained: *'obviously there was little or no competition to keep the price down and therefore the price was drifting up and that becomes..., irrespective of the fact that the number of prescriptions written for hydrocortisone tablets would be relatively limited, the fact that there was a high selling price would make it an attractive proposition.'*²⁰⁰⁹

6.105. AMCo also noted in relation to 10mg hydrocortisone tablets: *'market volumes steady for more than 2 years'*; ²⁰¹⁰ *'Very stable and slowly growing (circa 2% yr on yr) IMS market'*.²⁰¹¹

6.106. If competitors entered the market, the main parameter of competition would be price. In order to win a share of the finite total market, entrants would expect to undercut the price of the incumbent, Auden.

6.107. Independent entry to the market would therefore be expected to result in erosion of Auden's sales volumes and/or prices. As [Waymade Senior

²⁰⁰⁶ Document 00717, transcript of [Auden Senior Employee 2] interview dated 21 September 2016, part 2, page 4, lines 14 to 16.

²⁰⁰⁷ Document 203351, transcript of [Actavis Senior Employee 2] interview dated 20 July 2019, page 51, line 13.

²⁰⁰⁸ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 34, lines 19 to 20.

²⁰⁰⁹ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 17, lines 20 to 25.

²⁰¹⁰ Document 200153, AMCo Commercial Session report August 2015, slide 5.

²⁰¹¹ Document 200034, AMCo 'Run rate analysis' August 2015, slide 5.

Employee 1] of Waymade noted, *‘when we came to the market, they could have actually lost a lot of the market share to us.’*²⁰¹²

6.108. [Waymade Employee] of Waymade explained:

*‘we would track pricing up to launch and then, obviously expect that post-launch, the price would drop ... depending on how many competitors there are, you would expect them to obviously keep their share of the market by obviously having to drop the price to be more competitive’.*²⁰¹³

6.109. The orphan designation granted to Plenadren, which affected the market from November 2011 onwards, did not change any of these essential facts.

6.110. As explained in section 3.D.III above, the effect of the centralised European MA granted to Plenadren on 3 November 2011 was that – because of the orphan designation already granted to Plenadren – for 10 years after that date any MA for hydrocortisone tablets approved by the MHRA could not include the indication *‘adrenal insufficiency in adults’*. MAs without this full indication are known as ‘skinny label’ (as opposed to ‘full label’).

6.111. The orphan designation is not relevant to the nature of hydrocortisone tablets. All forms of hydrocortisone tablets are bioequivalent (see section 3.D.I above). The orphan designation is relevant only to the labelling and marketing of the product and resulting demand. The orphan designation is also not relevant to the 20mg Agreement: Plenadren’s MA, which triggered the 10-year exclusivity period, was not granted until after the 20mg Agreement was concluded (and in any event both Auden and Waymade benefited).

6.112. The orphan designation is relevant to the 10mg Agreement in that it meant Waymade – and AMCo, which acquired Waymade’s 10mg development on 31 October 2012 – could only obtain a skinny label 10mg MA. However, as explained in section 3.E.IV.a above and Annex D to this Decision, each of the undertakings involved in the Agreements (Auden/Actavis, Waymade and AMCo) anticipated that there would be demand for skinny label hydrocortisone tablets throughout the period prior to their launch in October 2015 and appreciated the possibility of off-label dispensing:

²⁰¹² Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 15 to 16.

²⁰¹³ Document 302405, transcript of [Waymade Employee] interview dated 23 November 2018, page 39, lines 21 to 26.

- a. Waymade and AMCo predicted that their skinny label 10mg hydrocortisone tablets could win between 10,000 packs and 18,000 packs per month from Auden, equating to a volume market share between 13% and 24%.
- b. Auden was particularly concerned about the threat AMCo's entry posed to its position as sole supplier, going so far as to launch Project Guardian in a bid to discourage off-label dispensing specifically of AMCo's 10mg tablets (see section 3.F.III.h above). However, as explained in section 3.E.III.c above, off-label dispensing of hydrocortisone tablets did not raise any concerns with pharmaceutical regulators. For example, in a letter dated 20 May 2014, [Chief Pharmaceutical Officer for NHS England] (the Chief Pharmaceutical Officer of NHS England) informed [Auden Senior Employee 1] that there were '*no material differences*' between skinny and full label tablets and that there were no '*risks to patient safety*' from off label supply. Consequently, [Chief Pharmaceutical Officer for NHS England] explained that he saw no reason to correspond with senior pharmacists to discourage off-label supply for adult adrenal insufficiency (as Auden had requested).²⁰¹⁴ This view was shared by the MHRA, which advised [Chief Pharmaceutical Officer for NHS England] and assisted him in responding to Auden's correspondence.²⁰¹⁵ Actavis subsequently '*modeled [sic] competitors entering in 2015 without indication for adrenal insufficiency and being launched and dispensed off label*' and found that this would result in '*share erosion of 60% and price erosion of 90% over 3 yrs*'.²⁰¹⁶

6.113. There was therefore no doubt that there would be demand for skinny label tablets once they were launched – as the number of suppliers that sought to enter with skinny label tablets attests – even if the extent of such potential demand was uncertain.

6.114. If independent entry could be avoided, however, Auden could expect to maintain its position as sole supplier – to maintain its 100% volume market share – and its ability to charge high prices.

6.115. Auden therefore had a reason to prevent or delay independent entry into the market. It could do so by 'buying off' its potential competitors. Its potential

²⁰¹⁴ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden Senior Employee 1], [Auden Senior Employee 4] and [Auden's External Consultant], dated 20 May 2014.

²⁰¹⁵ Document 206640, note of call between the CMA and the MHRA on 31 March 2021, paragraph 2.1 and Document 206557, note of call between the CMA and NHS England and NHS Improvement on 22 March 2021, paragraph 2.1.

²⁰¹⁶ Document 00706, slide deck titled 'Project Apple: Auden McKenzie (UK)' dated January 2015.

competitors also had a reason to agree to this: by allowing Auden to remain the sole supplier and avoid price competition, they could share in the monopoly profits Auden was making while avoiding the uncertainties and diminishing prices inherent in competition from independent entry. Both parties could continue sharing increasing monopoly profits for as long as Auden remained the sole supplier.

- 6.116. Any arrangements that aimed to frustrate the process of merits-based competition in this way, and thus the benefits for patients and the NHS that flow from it, should be subject to particular scrutiny.
- 6.117. It is fundamental to fair and merits-based competition that undertakings must determine their commercial conduct independently. It is for this reason that competition law prohibits any form of coordination which deliberately substitutes practical cooperation for the risks of competition.²⁰¹⁷
- 6.118. In principle, therefore, undertakings should not engage in regular or detailed discussions with potential competitors – especially where a potential competitor is at or near the point of launching its own product. Such a context means that undertakings should be especially cautious about engaging in this type of contact.
- 6.119. However, as explained below:
- a. Waymade approached Auden in early 2011 to negotiate a supply deal for 20mg hydrocortisone tablets, with the aim of coming to an agreement at the time when it would be ready to launch its own product.
 - b. AMCo negotiated a renewed supply arrangement for 10mg hydrocortisone tablets with Auden at a time when it anticipated its own 10mg tablets were ready to launch.
- 6.120. As the European General Court explained in *Lundbeck* (cited with approval by the CAT in *Paroxetine*):

'If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that progress, effective competition would never take place, or would suffer

²⁰¹⁷ C-209/07 *BIDS*, EU:C:2008:643, paragraphs 32 to 34. See also C-307/18 *GSK v Commission*, paragraph 83.

*significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes.*²⁰¹⁸

6.121. The European Court of Justice has further held that in the UK:

*‘the medicines sector is particularly sensitive to a delay in the market entry of the generic version of an originator medicine. Such a delay leads to the maintenance on the market of the medicine concerned of a monopoly price, which is very appreciably higher than the price at which generic versions of that medicine would be sold following their market entry and which has considerable financial consequences, if not for the final consumer, at least for social security authorities*²⁰¹⁹

6.122. Those observations were made in the context of generic entry following the expiry of an originator’s patent. As explained above, that was not the context to the Agreements: there was no patent and Auden was not an originator. These statements therefore apply *a fortiori*.²⁰²⁰

6.123. At the time of entering into each of the Agreements, Waymade and AMCo were each taking the necessary steps to prepare for the launch of generic hydrocortisone tablets, including obtaining an MA, and had made significant investments to that end. Each of Waymade and AMCo was a potential competitor of Auden.

ii. Waymade was a potential competitor to Auden when it entered into the 20mg Agreement

6.124. For the reasons set out below, the CMA concludes that Waymade was a potential competitor to Auden at the time it entered into the 20mg Agreement in July 2011:

- a. Waymade had taken ‘*sufficient preparatory steps*’ to show its ‘*firm intention and inherent ability*’ to enter the market independently (paragraphs 6.125 to 6.213);
- b. there were no insurmountable barriers to Waymade’s entry (paragraphs 6.214 to 6.216);

²⁰¹⁸ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 171; *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 158.

²⁰¹⁹ C-307/18, *Generics (UK) and others v CMA* EU:C:2020:52, paragraph 70.

²⁰²⁰ Compare *Lexon (UK) v CMA* [2021] CAT 5, which also involved a purely generic market, at paragraph 244: ‘*in this market context, reducing strategic uncertainty and coordination on matters such as volumes and market entry, as well as prices in some instances, could reasonably be expected to have an effect on price levels applying in the market*’ (emphasis added).

- c. the existence of the 20mg Agreement between Auden and Waymade itself and the value transfer are a strong indication that a competitive relationship existed (paragraphs 6.217 to 6.218); and
- d. Auden perceived Waymade to be a competitive threat (paragraphs 6.219 to 6.226).

Waymade had taken sufficient preparatory steps to show its firm intention and inherent ability to enter the market independently

- 6.125. The CMA concludes that Waymade had real concrete possibilities of entering the market and had taken ‘*sufficient preparatory steps*’ to show a ‘*firm intention and an inherent ability*’ to do so at the time it entered into the 20mg Agreement with Auden in July 2011.²⁰²¹
- 6.126. This is because, by July 2011, Waymade held a 20mg MA and had saleable stock from the Third Batch in its possession, meaning it was in a position where it could have entered the market and competed with Auden: there was nothing standing in its way from becoming an actual competitor (other than the negotiations with Auden which resulted in the 20mg Agreement), and this exerted a competitive threat on Auden as the undertaking already present on the market. As explained below, this finding is not undermined by the fact that Waymade had decided it would need to reformulate its product to achieve ongoing market presence after it had exhausted its stock from the Third Batch (because the Fourth Batch had failed a dissolution test). Waymade could have entered with the Third Batch and reformulated without its supply to the market being interrupted. Even if Waymade could not have entered with the Third Batch (which the CMA does not accept), entry after reformulation remained possible in the short term.
- 6.127. In the sub-sections below, the CMA explains its findings in more detail:
- a. Waymade had taken ‘*sufficient preparatory steps*’ to prepare for independent entry;
 - b. Entry was possible in the short term; and
 - c. Entry was economically viable.

Waymade had taken ‘*sufficient preparatory steps*’ to prepare for entry

- 6.128. At the time Waymade entered into the 20mg Agreement, it had taken sufficient preparatory steps to enter the market independently with its own

²⁰²¹ See section 6.C.I.a above.

20mg hydrocortisone tablets: it was able to enter with the Third Batch and although it decided it needed to reformulate the product and submit it for re-testing before producing future batches beyond the Third Batch, it already had experience with reformulation and considered the process to be straightforward.

- 6.129. Waymade targeted developing and launching its own 20mg hydrocortisone tablet product as early as September 2008. For example, on 2 September 2008, [Waymade Senior Employee 1] emailed [Waymade Senior Employee 3] to inform him that he [Waymade Senior Employee 1] had a firm intention to launch a 20mg tablet:

*'hydrocortisone tabs 20mg we have a license and I want to launch. the brand by MSD has been discontinued.'*²⁰²²

- 6.130. In October/November 2008, Waymade started discussions with Aesica and began developing its own 20mg hydrocortisone tablet.²⁰²³ Waymade subsequently made significant investments to develop its 20mg tablet (for example, it paid Aesica approximately [X] in 2009 to cover some of the initial developments costs for both the 10mg and 20mg hydrocortisone tablet projects).²⁰²⁴
- 6.131. By December 2010 the development process had reached an advanced stage with Aesica having manufactured four batches of 20mg hydrocortisone tablets in accordance with Waymade's instructions. Each batch manufactured by Aesica contained approximately 113,000-144,000 20mg hydrocortisone tablets.²⁰²⁵ There were no production issues with the first three batches. However, the Fourth Batch failed a dissolution test (see paragraphs 3.344 to 3.355).
- 6.132. On 13 December 2010, Waymade instructed Aesica to pack stock from the Third Batch as it had the longest shelf life of the first three batches expiring in November 2013 (see paragraphs 3.357 and 3.361).^{2026, 2027}

²⁰²² Document 300705, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 3] dated 2 September 2008

²⁰²³ Document 200292, paragraph 3.2, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

²⁰²⁴ Document 200296, purchase requisition from Waymade to Aesica dated 12 February 2009; and Document 200295, 'Offer – Hydrocortisone 10 and 20mg Tablet Business' from Aesica to Waymade dated 23 December 2008.

²⁰²⁵ Document 302554, paragraph 2.1, Aesica's response to the CMA's section 26 notice dated 12 February 2019.

²⁰²⁶ Document 300127, email from [Waymade Senior Employee 3] to [X], [Waymade Employee], [X] and others dated 13 December 2010, see also Document 300177, Minutes update of joint Aesica Sovereign review 31/3/11, page 1.

²⁰²⁷ Waymade's decision is consistent with what wholesalers and dispensers told the CMA, that they typically require stock purchases to have a shelf life of at least one year. However, they may accept stock with a shorter

- 6.133. The first three batches passed process validation testing on 22 February 2011. This meant that the product had been found to be able to be produced consistently and to specification on a commercial scale.²⁰²⁸
- 6.134. By 28 March 2011, Waymade had received approval from the MHRA to launch its Aesica-manufactured 20mg hydrocortisone tablets.²⁰²⁹ On 9 May 2011, Aesica delivered 3,560 saleable bottles of 20mg hydrocortisone tablets (106,800 tablets in total) to Waymade using tablets from the Third Batch.²⁰³⁰
- 6.135. Accordingly, by 9 May 2011, Waymade was in a position where it could have actually entered the market with the stock from the Third Batch.²⁰³¹ This of itself demonstrates that Waymade had taken ‘*sufficient preparatory steps*’ to prepare for entry at the time it entered into the 20mg Agreement with Auden in July 2011. The threat of entry with the Third Batch alone was sufficient to exert competitive pressure on Auden.
- 6.136. As explained at paragraph 3.354 and 3.355, in December 2010 Waymade was made aware that the Fourth Batch failed its dissolution tests. As a

shelf life if offered on agreeable commercial terms. See for example Document 206612, note of call with Mawdsleys on 3 March 2021, paragraph 4.1; Document 206344, note of call with Resolution, paragraphs 5.1 to 5.3; Document 206416, note of call with Day Lewis on 16 March 2021, paragraphs 4.1 to 4.2; Document 206580, note of call with DE Pharma on 17 March 2021, paragraphs 3.1 to 3.2. As such the First and Second Batches would have also been saleable in at least early 2011 had they been packed for sale. These batches were instead stored at Aesica until they were destroyed in September 2015.

²⁰²⁸ Document 206641, note of call with the MHRA dated 30 March 2021.

²⁰²⁹ Document 200003, paragraph 10.4, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016. See also Document 301469, email from [Waymade Employee] to Regulatory Dept, Medical, Sovereign Group, Artwork Mailbox and Technical dated 23 March 2011; Document 301478, [REDACTED] Projects April 2011, slide 2, attachment to Document 301477, email from [REDACTED] to [REDACTED], [Waymade Senior Employee 2], [REDACTED] and others dated 5 April 2011. See also Document 300159, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [REDACTED] and others dated 21 March 2011. Between November 2010 and February 2011 Waymade had applied to the MHRA for variations to its 20mg MA in around August 2010: ‘*variation to 20mg Licence to add site of manufacture, packaging, QC and release*’ (Document 300094, Project Brief version date 17 August 2010) and in December 2010: ‘*the variation for the generic name, 30 pack size, with artwork for carton and label was submitted to the MHRA on 06 December*’ (Document 300127, email from [Waymade Senior Employee 3] to [REDACTED], [Waymade Employee] and others dated 13 December 2010). Waymade also submitted its updated Patient Information Leaflet to the MHRA which included the current formulation in February 2011 (Document 300609) and Waymade also obtained the MHRA’s approval of Aesica as the manufacturer, approval of new packaging artwork and approval of a new API source by March 2011 (Document 200003, paragraph 10.4, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016).

²⁰³⁰ Document 206378, email from the MHRA to the CMA dated 13 April 2021 and Document 206642, note of call with the MHRA dated 30 March 2011. The MHRA confirmed that the batches would be saleable unless there were any GMP or finished product specification issues identified. No such issues were identified and these tablets were approved to be released by Aesica (see Document 206623, note of call with [Aesica Employee] dated 30 March 2021). The MHRA explained that the batches would be saleable provided that there were no inconsistencies between the original process validation protocol and the later process validation protocol. [Aesica Employee] reviewed the records and subsequently confirmed to the CMA that the process validation protocols were the same (see Document 206648, note of call with [Aesica Employee] dated 5 May 2021). Auden/Actavis submitted that the CMA’s case is undermined by not proving that the same process validation protocols were used (Document 206667, Auden/Actavis’s RLOF, paragraph 3.24.4). As set out, the protocols were the same and process validation was therefore complete and valid.

²⁰³¹ Indeed, Waymade had foreseen the use of the validation batches for commercial purchases from as early as February 2009. See Document 300094, Project Brief for Hydrocortistab Tablets 20mg, page 9.

result, Waymade decided to reformulate the product and submit it for re-testing before producing future batches beyond the Third Batch.²⁰³²

- 6.137. Waymade's decision to reformulate for future supply does not undermine the CMA's finding that Waymade had taken '*sufficient preparatory steps*' to prepare for entry.
- 6.138. At the time of concluding the 20mg Agreement, Waymade had recently completed reformulation of its 10mg hydrocortisone tablets (see paragraph 3.404), which involved the same steps that were required for the 20mg reformulation. Waymade therefore had experience with reformulating hydrocortisone tablets when it concluded the 20mg Agreement. It could have carried out reformulation while supplying the market with the Third Batch without supply being interrupted.
- 6.139. However, Waymade did not carry out the reformulation work at this time due to the negotiations with Auden and successful conclusion of the 20mg Agreement, as set out at paragraphs 6.174 to 6.177 below. Waymade only commenced reformulation work in February 2014 (see section 3.F.II.c) when it was negotiating the sale of its 20mg MA to AMCo and Waymade reviewed the status of its development of 20mg hydrocortisone tablets.
- 6.140. Documentary evidence contemporaneous with the period when Waymade actually started to take steps to reformulate in 2014 to 2015 indicates that key Waymade staff understood that reformulation was a straightforward matter, would not take long, and did not affect the economic viability of the Aesica-manufactured product going forward. The CMA has no reason to believe the process would have been considered more difficult or time-consuming in 2011.²⁰³³ The process was neither complex nor cost-prohibitive and merely involved the replacement of maize starch with pre-gelatinised starch. This was the same switch that had already been carried out successfully for Waymade's 10mg product. As explained in section 3.F.II.c Waymade only re-engaged with the 20mg development work after it began negotiations in February 2014 to sell its 20mg MA to AMCo. This contemporary view is clear from:
- a. An email from Waymade's [Waymade Employee] dated 10 March 2014 concerning Waymade's proposal for supply which considered the option of changing the starch, stated that '*[a]lthough this change is minor it will still require a license [MA] variation*' and acknowledged that

²⁰³² See paragraphs 3.354 to 3.365.

²⁰³³ In fact, since reformulation had just been completed for the 10mg product in 2010, carrying out this work in 2011 would likely have been less complicated than picking it up again in 2014 after four years of inaction.

Waymade would subsequently need '*validation samples taken during manufacture of both batches*'.²⁰³⁴

- b. an internal Waymade email dated 6 May 2014, where [Waymade Senior Employee2] informed [Waymade Senior Employee 1] and [X] that reformulation work would be '*very straight forward*' involving only '*a minor change in formulation*':

*'There is a minor change in formulation that is required – I am told by [Waymade Employee] that these are very straight forward and simply a matter of swapping one form of starch for another and then submitting a variation. Aesica are due to produce and implement the change in July.'*²⁰³⁵

- c. [X] also reported to [Waymade Senior Employee 1] and [Waymade Senior Employee 2] on 8 May 2014 that '*Technical– advised that the issues were minor and the work virtually complete*' in the context of a possible sale of Waymade's 20mg to AMCo.²⁰³⁶

6.141. The view that reformulation was straightforward and would not take long is supported by witness evidence from interviews conducted by the CMA - for example, [Aesica Employee] of Aesica told the CMA that reformulation would likely only have taken between six and twelve months²⁰³⁷, and [Waymade Employee] thought this was '*straightforward*'.²⁰³⁸

6.142. [Waymade Employee] was also clear that the decision whether to reformulate Waymade's 20mg hydrocortisone tablet did not impact on the commercial decisions it was taking with respect to the Third Batch. As [Waymade Employee] states, this batch could '*continue to be sold*' while '*the decision whether to reformulate*' was being made.²⁰³⁹

6.143. It is clear from the evidence discussed above that there is no reason to believe that when Waymade concluded the 20mg Agreement it viewed

²⁰³⁴ Document 301707, email from [Waymade Employee] to [Aesica Employee] copied to [Waymade Senior Employee 2], dated 10 March 2014, and its attachment Document 301708, Aesica Investigation Report. See also Document 300482, email from [Waymade Employee] to [Waymade Senior Employee 4] and [Waymade Senior Employee 2] dated 27 October 2014: '*We have valid MA for this product. The reason for us going through a validation process is that we had to change the grade of starch from maize to pre-gelatinised. Although this change is a minor one it still requires process validation on 3 batches all of which can be commercialised*'.

²⁰³⁵ Document 300453, email from [Waymade Senior Employee 2] to [X] and [Waymade Senior Employee 1] dated 6 May 2014 (emphasis added).

²⁰³⁶ Document 300456, email from [X] to [Waymade Senior Employee 1], [Waymade Senior Employee 2] and [X] dated 8 May 2014

²⁰³⁷ Document 206623, note of call between the CMA and [Aesica Employee], 30 March 2021, paragraph 2.5

²⁰³⁸ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 55, lines 3 to 5.

²⁰³⁹ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 24, lines 6-9.

reformulation as complex or time-consuming. In fact, it had experience reformulating its 10mg product and the evidence from 2014 confirms that Waymade viewed reformulation as a straightforward matter.

6.144. Therefore, at the time when it concluded the 20mg Agreement, Waymade had taken 'sufficient preparatory steps' to prepare for entry:

- a. It could have entered the market with the stock from the Third Batch and considered that the process of reformulation would be straightforward; and
- b. Even if it could not have entered the market with the Third Batch and needed to reformulate first (which the CMA does not accept, as discussed further in paragraphs 6.146 to 6.162), it had experience reformulating the product and considered it to be a straight-forward process that would take only six to 12 months.

Entry was possible in the short term

6.145. When it entered into the 20mg Agreement, Waymade had the possibility to enter the market sufficiently quickly such that it exerted competitive pressure on Auden. In particular:

- a. Waymade was in a position where it could have actually entered the market with the stock from the Third Batch by the time it entered into the 20mg Agreement with Auden/Actavis; and
- b. Even if it could not have entered the market with the Third Batch and needed to reformulate first (which the CMA does not accept), it had experience reformulating the product and this could be carried out sufficiently quickly to exert competitive pressure on Auden.

Waymade could have entered with the stock from the Third Batch

6.146. It is clear from the analysis of the preparatory steps Waymade took to prepare for independent entry (paragraphs 6.128 to 6.135 above) that by May 2011 Waymade was in a position where it could have entered the market independently with the Third Batch. It follows that at the time Waymade concluded the 20mg Agreement in July 2011, it could have entered the market sufficiently quickly to exert competitive pressure on Auden.

6.147. However, Waymade and Auden/Actavis submitted that Waymade would not have been able to sell stock from the Third Batch given the dissolution issue that had been identified with the Fourth Batch:

- a. Waymade told the CMA that the dissolution failure in the Fourth Batch resulted in a 'Corrective and/or Preventative Action' ('**CAPA**')²⁰⁴⁰ being raised against the product in 2011, meaning that in Waymade's view it would have needed to reformulate the product before producing further commercial batches.²⁰⁴¹ Waymade also referred to Aesica's section 26 response which refers to the successful validation status of the 20mg product having been '*annulled*' at some stage following successful process validation on 22 February 2011.²⁰⁴²
- b. Waymade also submitted that the open CAPA on the Fourth Batch called into question the entire manufacturing process of the 20mg hydrocortisone tablet product, meaning that it would have been '*poor and unusual conduct*' leading to '*concerns from a safety and quality perspective*' and against '*good practice*'²⁰⁴³ had Waymade marketed product from the '*annulled*' validation batches. Waymade also stated that even if a small portion of batches produced with the same formulation had an open CAPA, Waymade could not safely sell any of the finished goods.²⁰⁴⁴
- c. Auden/Actavis went further than Waymade, submitting that it would have been a criminal offence for Waymade to sell the 20mg tablets it received in May 2011, and that the CMA should consider this to be an insurmountable barrier to entry.²⁰⁴⁵

6.148. As explained below, these representations cannot be sustained.

6.149. First, the MHRA confirmed that the three validation batches including the Third Batch were saleable.²⁰⁴⁶ They had passed process validation and the

²⁰⁴⁰ Waymade describes a CAPA as a '*formal record of a problem identified in the manufacturing process or with a product, 'opened' when the issue is identified and 'closed' when the issue is resolved*' – Document 204903, Waymade's RSSO, footnote 135.

²⁰⁴¹ Document 204903, Waymade's RSSO, paragraphs 2.15, 7.54(a). The CMA does not dispute that Waymade decided to reformulate for future batches as a result of the dissolution failure, although it is noted that the MHRA queried whether reformulation was necessary to resolve the dissolution issue, see Document 206378, note of call between the MHRA and the CMA.

²⁰⁴² Document 200292, Aesica's response to the CMA's section 26 notice dated 15 June 2016, page 9.

²⁰⁴³ Document 204903, Waymade's RSSO, paragraph 2.16(a).

²⁰⁴⁴ Document 204903, Waymade's RSSO, paragraph 7.64, Waymade repeats this representation in Document 206661, Waymade's RLOF, paragraphs 3.1(c), 4.2, 4.4, 4.9, 6.1).

²⁰⁴⁵ Document 205217, Auden/Actavis's RSSO, paragraphs 2.93-2.94, 2.96-2.98, 7.15-7.24

²⁰⁴⁶ Document 206378, email from the MHRA to the CMA dated 13 April 2021 and Document 206642, note of call with the MHRA dated 30 March 2011. The MHRA confirmed that the batches would be saleable unless there were any GMP or finished product specification issues identified. No such issues were identified and these tablets were approved to be released by Aesica (see Document 206623, note of call with [Aesica Employee] dated 30 March 2021). The MHRA explained that the batches would be saleable provided that there were no inconsistencies between the original process validation protocol and the later process validation protocol. [Aesica Employee] reviewed the records and subsequently confirmed to the CMA that the process validation protocols were the same (see Document 206648, note of call with [Aesica Employee] dated 5 May 2021). Auden/Actavis submitted that the CMA's case is undermined by not proving that the same process validation protocols were

dissolution issue with the Fourth Batch had no impact on the status of the successful process validation and saleability of the three previous batches. Aesica corroborated that the batch appeared to be technically saleable in a call with the CMA.²⁰⁴⁷ [Aesica Employee] also explained to the CMA that the process validation report was signed off by Aesica's 'Qualified Person' (ie the individual responsible for batch release) on the basis that the Third Batch was suitable for commercial sale.^{2048, 2049}

6.150. In addition, with respect to the reference in Aesica's section 26 response to the successful process validation having been '*annulled*', there are no contemporaneous records indicating that the process validation had somehow been '*annulled*' or invalidated – this language was first used some four years after the dissolution was identified, in the process validation report that was written when the product was eventually redeveloped in June 2015.²⁰⁵⁰ Further, [Aesica Employee] explained to the CMA that the 2015 report recorded that the new process validation had been completed on the revised formulation, and that this did not impact the earlier process validation for the first three validation batches.²⁰⁵¹ As such, [Aesica Employee] considered that '*superseded*' would have been a more appropriate choice of words than '*annulled*'.²⁰⁵² Waymade's reliance on this reference to the earlier process validation having being '*annulled*' is therefore artificial – it was not in the purview of Waymade at the time it entered into the 20mg Agreement, and in any case it did not have any adverse impact on the validation status of the three validation batches or their saleability in 2011.

6.151. Furthermore, there is no contemporaneous evidence on the CMA's file (nor has Auden/Actavis nor Waymade provided any) that would indicate that

used (Document 206667, Auden/Actavis's RLOF, paragraph 3.24.4). As set out, the protocols were the same and process validation was therefore complete and valid. See also Document 302140, transcript of the CMA's interview with [Amdipharm Senior Employee] dated 7 June 2018, page 59, lines 1-21.

²⁰⁴⁷ Document 206077, note of call between the CMA and Aesica dated 10 December 2020, paragraph 24, where Aesica provided their expert opinion on the basis of records available.

²⁰⁴⁸ Document 206623, note of call between the CMA and [Aesica Employee], 30 March 2021, paragraph 3.5.

²⁰⁴⁹ Waymade made representations on this further evidence set out in the Letter of Facts which restated its position as set out in its RSSO, that as no root cause of the failure of the Fourth Batch had been identified, Waymade could not sell the Third Batch (Document 206661, Waymade's RLOF, paragraphs 3.1-3.8).

Auden/Actavis made the same representation and also stated that the process validation was undermined by the failure of the Fourth Batch (Document 206667, Auden/Actavis's RLOF, paragraphs 3.27-3.29). However, as the MHRA has made clear, the process validation of the Third Batch was not affected by the dissolution issue with the Fourth Batch. The fact that the root cause for the Fourth Batch failing had not been identified does not undermine the finding that Waymade had real and concrete possibilities to enter the market with the Third Batch, such that Waymade imposed competitive pressure on Auden when negotiating and concluding the 20mg Agreement. Auden/Actavis also submitted that at the time Waymade and Aesica considered that '*there was a real risk the products could not safely or legally be sold*' (Document 206667, Auden/Actavis's RLOF, paragraphs 1.4.5 and 3.29). The CMA does not accept this representation as there is no contemporary evidence to support that position and Recipharm did not confirm this point. Instead the contemporary evidence unambiguously shows that Waymade was preparing to launch the product (see paragraph 6.152).

²⁰⁵⁰ Document 302086, process validation report dated 5 June 2015.

²⁰⁵¹ Document 206623, note of call between the CMA and [Aesica Employee], 30 March 2021, paragraph 4.3.

²⁰⁵² Document 206623, note of call between the CMA and [Aesica Employee], 30 March 2021, paragraph 4.2.

Waymade was concerned that selling tablets from the Third Batch was an illegal act, contrary to good practice or raised safety concerns.

6.152. In fact, the contemporaneous evidence shows that Waymade understood that the failed dissolution test on the Fourth Batch did not affect the saleability of the Third Batch and that it was planning to sell those tablets in the UK. It also shows that Aesica was aware that Waymade wanted to place the batch on the market and on no occasion informed Waymade that doing so would be problematic or risky from a compliance perspective. For example:

- a. The notes for the internal meeting of 13 December 2010 specified that *'Aesica has confirmed that batch four of the 20mg tablets has now formally failed the dissolution test. [X] has advised Aesica in writing that [...] batch three of the 20mg strength should be packed in week 51 as planned'*.²⁰⁵³
- b. Waymade's internal report for December 2010 illustrates that it intended to launch its product regardless of the dissolution failure of the Fourth Batch: *'Launch of 20mg tablet is still on track for May or June 2011'*.²⁰⁵⁴
- c. Waymade's internal report for January 2011 shows that Waymade continued to progress the packaging of the Third Batch notwithstanding the dissolution issue affecting the Fourth Batch: *'Aesica has been asked to hold a packing slot for the 20mg (into glass) in late April. The timing of the packing is dependent on approval of the PIL and receipt of the printed PIL from Aesica's supplier. [...] Launch of 20mg tablet is still on track for May or June 2011'*.²⁰⁵⁵
- d. Waymade's internal report for February 2011 reiterates the confidence Waymade had in its ability to sell tablets from the Third Batch: *'Aesica has provided 18 months stability data for the 20mg strength. The data is robust and should support the continuation of the 36 months shelf life. [...] Launch of the 20mg tablet is still on track for May or June 2011'*.²⁰⁵⁶

²⁰⁵³ Document 300127, email from [Waymade Senior Employee 3] to [X], [Waymade Employee], [X] and [X] dated 13 December 2010.

²⁰⁵⁴ Document 300136, Monthly Report Sovereign Generics December 2010, page 2.

²⁰⁵⁵ Document 300149, Monthly Report Sovereign Generics, January 2011.

²⁰⁵⁶ Document 300158, Monthly Report Sovereign Generics, February 2011.

- e. By 28 March 2011,²⁰⁵⁷ a contemporaneous internal report confirms that Waymade understood it was *'free to launch'* its 20mg tablets and compete with Auden and it would reformulate for future batches:

'We are now free to launch the 20mg strength in glass bottles. The focus is now Aesica to ensure that the components are ordered and received in a timely fashion, and that packing occurs at Aesica at an early opportunity. [...] Existing stocks of 20mg tablets can only be sold in glass bottles. It is proposed that the next manufacture of 20mg will be with a revised formulation [...] This will require a variation to the formulation.'^{2058 2059}

- f. On 31 March 2011 Waymade held a meeting with Aesica where Aesica's slides for the meeting covered the following: *'20mg old formula: 3x20 mg Validation completed and approved. Batches on stability in 100s bottles. Blister packaging withdrawn. Post validation batch failed dissolution – needs PGS'*. In the project timeline *'20mg in 30s bottles'* Aesica planned to package *'end April'* and *'supply market'* in May/June subject to *'Reg approval?'*. This evidences that despite the dissolution failure of the Fourth Batch, Aesica did not find any issues in Waymade supplying the market with the Third Batch subject to the MHRA approving the outstanding variations to the MA.²⁰⁶⁰
- g. The minutes of the meeting Waymade held with Aesica on 31 March 2011 provide further support for the fact that Waymade knew it was in a position to start selling its 20mg tablets in the UK: *'Hydrocortisone 20 mg regulatory approval obtained and can now start selling in 30 bottles'*.²⁰⁶¹
- h. Waymade's meeting notes of 11 April 2011 reported that *'Launch of 20mg strength in Bottles of 30 tabs to be launched on 04 May 2011. Actions to required now: [Waymade Employee] to take the lead in planning/reviewing bar code; carton integrity; current market prices; establishment of PIP code; communications to sales colleagues'*.²⁰⁶²
- i. Waymade's meeting notes of 18 April 2011 indicated that *'Launch of 20mg strength in Bottles of 30 tabs to be launched after delivery from*

²⁰⁵⁷ See also paragraph 6.134..

²⁰⁵⁸ Document 300736, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [☒] and others dated 28 March 2011.

²⁰⁵⁹ See also paragraph 6.134.

²⁰⁶⁰ Document 300164, Aesica Sovereign meeting presentation, 31 March 2011

²⁰⁶¹ Document 300166, Minutes of joint Aesica Sovereign review 31/3/11, page 2.

²⁰⁶² Document 300171, email from [Waymade Employee] to [☒], [Waymade Employee], [Waymade Employee] and others dated 26 April 2011, recording meeting notes of meeting on 18 April 2011.

*Aesica expected on 4th May 2011. Launch activities including pricing and communication to sales colleagues underway. Full cog established.*²⁰⁶³

- j. On 27 April 2011, [Aesica Employee] shared an updated version of the joint Waymade/Aesica meeting minutes that had taken place on 31 March 2011: *'20mg stock being packaged as agreed with Sovereign. Order will be ca 65% fulfilled using Dec 20 batch; earlier batches have reduced shelf-life and it was directed not to use. 20mg formulation switch to pre gel starch to be planned following urgent RFP [request for proposal] agreement. Hydrocortisone 20mg shipping plan for beginning May on track. Actions from 31/3 joint meeting all in progress. Hydrocortisone 20mg supply risk – urgent progress of pre gel starch RFP and plan required'*.²⁰⁶⁴

6.153. Members of Aesica and Waymade's QA teams attended the joint Waymade-Aesica meetings and are not recorded as having raised any issues.²⁰⁶⁵

6.154. The following later evidence further confirms that there were no safety or regulatory concerns with the Third Batch that affect the CMA's conclusion that this batch was saleable:

- a. Waymade packed tablets from the Third Batch and stored the batch of tablets in its warehouse. An internal email from [Waymade Senior Employee 4] in 2013 said that even though the batch was going out of date they *'need it available just in case'*.²⁰⁶⁶ [Waymade Senior Employee 4] explained that he had checked with [Amdipharm Senior Employee] but could not explain why the stock was to be retained. Auden/Actavis submitted that one reason for Waymade to keep the Third Batch in its warehouse was for stability studies and further testing.²⁰⁶⁷ However, the contemporaneous evidence presented at paragraph 6.152 above shows that Waymade intended to launch these onto the market. Moreover, the contemporaneous evidence indicates

²⁰⁶³ Document 300171, email from [Waymade Employee] to [X], [Waymade Employee], [Waymade Employee] and others dated 26 April 2011.

²⁰⁶⁴ Document 300171, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2] and others dated 11 April 2011.

²⁰⁶⁵ Therefore, statements made by [Amdipharm Senior Employee] in interview with the CMA that process validation may be called into question by a subsequent batch failure (as an explanation why the Third Batch was 'frozen') cannot be sustained and can have no impact on this analysis (i) when read in light of the volume of contemporary evidence set out above showing that Waymade considered it could enter the market with the Third Batch notwithstanding the dissolution failure of the Fourth Batch, and (ii) the fact that the MHRA has confirmed that the first three batches were saleable (see paragraph 6.149 above) (Document 302140, transcript of the CMA's interview with [Amdipharm Senior Employee] dated 7 June 2018, page 55, lines 8-10).

²⁰⁶⁶ Document 300790, emails (i) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; (ii) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; and (iii) from [Waymade Senior Employee 4] to [Waymade Employee] dated 8 April 2013.

²⁰⁶⁷ Document 205217, Auden/Actavis' RSSO, paragraph 2.94.5.

that Aesica packed practically all of the Third Batch in bottles despite the fact that only a marginal amount is needed for the purpose of testing/stability studies.²⁰⁶⁸

- b. As set out in paragraph 3.373, Waymade tried to sell 1,500 of the bottles packed for sale from the Third Batch to Yemen on the basis that these were for export and could not be sold in the UK. Waymade's claim that it had '*concerns from a safety and quality perspective*' is inconsistent with the decision that the tablets were suitable for export: a responsible pharmaceutical company would not seek to export tablets where it had any concerns about the safety of these.²⁰⁶⁹

6.155. Interview evidence from the CMA's interview with [Waymade Employee] [X] corroborates this contemporaneous and later documentary evidence. For example, [Waymade Employee] stated that Waymade could have sold tablets from any of the first three validation batches:

*'the three validation batches that had been produced initially, they had all passed the test and, were compliant, so they could continue to be sold while we [...] made the decision whether to reformulate.'*²⁰⁷⁰

6.156. Later in the same interview [Waymade Employee] added:

*'...as I understood [...] in May [2011], we had the product, we'd received it, we'd received the packed product from Aesica and it was in a condition ready to be released.'*²⁰⁷¹

²⁰⁶⁸ See Document 301707, correspondence between Aesica and Waymade in February and March 2014: '3 validation batches were originally produced and part of each bulk batch was hand packed for stability in 100 tablet bottles. The stability study was completed and all bulk batches are now expired. A portion of the 3rd batch was also packed for stability in 3x10 blisters, although the study never was initiated. The remainder of the 3rd batch was hand packed in 30 tablet bottles for commercial supply'; and Document 302554, Aesica's response to the CMA's section 26 notice dated 12 February 2019 (in reference to the Third Batch): 'An initial fraction (3,031 tablets) of this batch was taken as a sample for testing in November 2010. The vast majority (109,056) was then prepared for supply to the Waymade Group around six months later in May 2011. Following process control checks, the actual number of tablets supplied to the Waymade Group was 106,800 (in 3,560 bottles at 30 tablets per bottle). The remaining portion (3,030 tablets) of this batch was taken as a sample for testing in May 2012'.

The only document Auden/Actavis cites in support of its submission is a section 26 response from Aesica in which it stated, with respect to batches of 10mg hydrocortisone tablets for which Waymade did not yet have a MA when the batches were produced, that those batches were not destroyed prior to September 2012 (when Waymade obtained that MA) in case samples might be required for the MA application. The circumstances relating to the Third Batch were entirely different, since Waymade already had a MA, and the batch had passed process validation such that it could therefore be sold under that MA. Aesica's statement does not relate in any way to Waymade's decision to have tablets from the Third Batch packaged and Waymade has not itself given this as the reason for packaging tablets from that batch.

²⁰⁶⁹ Waymade submitted that no '*reasonable and experienced pharmaceutical company*' would sell a product in the UK in respect of which there are safety concerns (see for example Document 204903, Waymade's RSSO, paragraphs 2.16-2.17). The same must be true of a pharmaceutical company selling on an export basis.

²⁰⁷⁰ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 24, lines 6 to 9.

²⁰⁷¹ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 54, lines 4 to 6.

- 6.157. It is clear from these two quotations that [Waymade Employee] believed that Waymade could have sold tablets from the Third Batch notwithstanding the issues encountered with the Fourth Batch.
- 6.158. [Amdipharm Senior Employee] also explained in interview that the Third Batch was saleable even in the context of possible reformulation on future batches: *'so we had one batch, and we could have put that onto the market and sold it'*, and later in interview again confirmed his understanding that the Third Batch was saleable.²⁰⁷²
- 6.159. In addition to the reference to the process validation being *'annulled'*, which is discussed at paragraph 6.150 above, Waymade rely on comments made by [Waymade Senior Employee 1], [Amdipharm Senior Employee] and [Waymade Employee] (all Waymade) during interviews with the CMA to support that Waymade could not enter with the Third Batch.²⁰⁷³
- 6.160. These comments however directly contradict a large number of contemporaneous documents from different sources within Waymade and Aesica (all discussed above), which are not ambiguous or unclear and which contain no indication of any concerns over safety and confirm that Waymade was preparing to enter the market with this stock. The comments are also contradicted by statements made by other members of Waymade staff during interview with the CMA, for example those made by [Waymade Employee] set out in paragraphs 6.155 and 6.156 above.²⁰⁷⁴
- 6.161. Waymade and Auden/Actavis also rely on selective quotes from the CMA's interviews with [Aesica Employee] and [Aesica Employee] of Aesica which, when read in context and in light of later evidence described above obtained from Aesica and [Aesica Employee], clearly do not assist Waymade and Auden/Actavis:
- a. Auden/Actavis argues that [Aesica Employee] was clear in interview that if it was not possible to identify the root cause of the dissolution failure and determine that the same failure could not subsequently occur to the first three batches, that the Third Batch could not be safely sold.²⁰⁷⁵ Waymade makes a similar argument and quotes from the transcript of the CMA's interview with [Aesica Employee] to state that he indicated to the CMA that the stock should not have been sold in

²⁰⁷² Document 302140, transcript of the CMA's interview with [Amdipharm Senior Employee] dated 7 June 2018, page 59, lines 9 to 10, and page 60, lines 17 to 24.

²⁰⁷³ Document 204903, Waymade's RSSO, paragraph 7.62; citing the CMA's interview with [Waymade Senior Employee 1] (Document 302145), the CMA's interview with [Amdipharm Senior Employee] (Document 302140) and the CMA's interview with [Waymade Employee] (Document 302543).

²⁰⁷⁴ Citing Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018.

²⁰⁷⁵ Document 205217, Auden/Actavis's RSSO, paragraph 2.91.

light of the open CAPA and in light of the fact that a specific reason for the failure of the Fourth Batch had not been identified.²⁰⁷⁶ However, when the interview is read in full, [Aesica Employee] was clear that the Third Batch was marketable following an extensive quality review process approving the tablets: *'there must have been a technical or a QA – there must have been a reason why those tablets were considered okay'*, that *'there must have been an extensive QA, Quality Assurance review and approval'*, and *'there must have been a review as to why the three batches..., the first three batches were deemed ok'* ie these batches *'met the specifications'*. [Aesica Employee] explained that though he did not know what the reason was for differentiating between the first three batches and the Fourth Batch, *'for those first three batches to have been allowed to have been marketed, there must have been a quality technical review which said, "those three batches are okay. There is a unique problem with the fourth batch and we're going to discount it."*²⁰⁷⁷

- b. Waymade quotes from the transcript of the CMA's interview with [Aesica Employee] to argue that Waymade could not have sold the Third Batch due to the open CAPA on the Fourth Batch²⁰⁷⁸ and to argue that the dissolution failure on the Fourth Batch had an impact on the validation status and saleability of the Third Batch.²⁰⁷⁹ Again, when these quotes are read in the context of the interview as a whole [Aesica Employee] was clear that it was the stock subject to the CAPA, ie the Fourth Batch, that should not have been sold while the CAPA was open. It is not the CMA's case that Waymade could have sold the Fourth Batch. Further, as explained above at paragraph 6.149, the MHRA confirmed to the CMA that the dissolution failure of the Fourth Batch had no impact on the saleability of the Third Batch²⁰⁸⁰ and a large amount of contemporary evidence shows Waymade understood this to be the position at the time. Further, Waymade cites [Aesica Employee]' interview where he clearly speculates on the timing of the CAPA and selling the Third Batch and a link to prioritising the 10mg product (*'I think' 'there may have been a, a halt'...*)²⁰⁸¹ and which is not

²⁰⁷⁶ Document 204903, Waymade's RSSO, paragraph 7.61(b) and 7.61(c), citing Document 302483, transcript of the CMA's interview with [Aesica Employee], pages 41, 43-45 and 60.

²⁰⁷⁷ Document 302483, transcript of the CMA's interview with [Aesica Employee], page 48, lines 1-10 and page 49, lines 8-21, and page 60, lines 16-21. See also Document 206623, note of call with [Aesica Employee], paragraph 3.4.

²⁰⁷⁸ Document 204903, Waymade's RSSO, paragraph 7.65, citing Document 204903, transcript of the CMA's interview with [Aesica Employee], pages 19 and 22.

²⁰⁷⁹ Document 204903, Waymade's RSSO, paragraphs 7.54, 7.60 – 7.61.

²⁰⁸⁰ Document 206378, email from the MHRA to the CMA dated 13 April 2021 and Document 206642, note of call with the MHRA dated 30 March 2011.

²⁰⁸¹ Document 204903, Waymade's RSSO, paragraph 7.61 (g), citing Document 204903, transcript of the CMA's interview with [Aesica Employee], page 40, lines 975 to 980.

consistent with the fact pattern where Waymade readied the Third Batch for sale in the full knowledge of the dissolution failure of the Fourth Batch.

- 6.162. Therefore by May 2011, Waymade was in a position where it could have entered the market with the Third Batch and competed with Auden: there was nothing standing in its way from becoming an actual competitor (other than the negotiations with Auden which resulted in the 20mg Agreement). When it negotiated and concluded the 20mg Agreement, Waymade had saleable stock at its disposal. For this reason alone, Waymade was able to enter the market sufficiently quickly such that it exerted competitive pressure on Auden at that time. After such entry, Waymade could have reformulated its product while making sales from the Third Batch (see in particular paragraph 6.206 below).

Waymade's decision to reformulate for future supply does not undermine the CMA's finding that entry was possible in the short term

- 6.163. Waymade and Auden/Actavis both submitted that the CMA underestimated the time required to reformulate, pointing to evidence from the time reformulation eventually took place in 2014/2015 (when the period from approval of the reformulation project to delivery by Aesica of a commercial batch was approximately 15 months) to argue that they were not potential competitors.²⁰⁸²
- 6.164. In making these submissions, which are conditional on Waymade and Auden/Actavis first rebutting the CMA's findings that Waymade could have entered with the Third Batch (which they failed to do), Waymade²⁰⁸³ and Auden/Actavis²⁰⁸⁴ have misstated the legal test for potential competition. The test is whether Waymade could have entered sufficiently quickly to exert competitive pressure on Auden at the time the 20mg Agreement was entered into. As a matter of law, there is no fixed period within which a potential entrant is considered to exert competitive pressure on an incumbent. As explained above, the CMA finds that Waymade's objective position vis-à-vis Auden at the time the 20mg Agreement was entered into

²⁰⁸² Document 204903, Waymade's RSSO, paragraphs 7.74-7.76 in relation to 15 months when it actually took place; Document 206661 Waymade's RLOF, paragraphs 5.1-5.4; See also Document 205217, Auden/Actavis' RSSO paragraphs 7.17-7.24. Waymade argued that reformulation timescales are 'highly unpredictable' and 'that eighteen months would be a sensible 'best case' estimate' (Document 206661, Waymade's RLOF, paragraph 5.4). There is no evidence on the CMA's case file indicating that Waymade considered reformulation to be 'unpredictable' or would take 18 months – indeed, had it considered this to be the case, then that was all the more reason to have commenced redevelopment as soon as possible rather than delay it.

²⁰⁸³ In its RSSO and RLOF Waymade addressed the wrong question: it focused on arguing that it could not have entered with the Third Batch, rather than arguing that it did not have real concrete possibilities of entry (Document 204903, Waymade's RSSO and Document 206661, Waymade's RLOF, paragraph 2.4).

²⁰⁸⁴ Document 205217, Auden/Actavis' RSSO, paragraphs 7.8 to 7.12.

was that it could have entered immediately with the Third Batch and this threat of entry exerted competitive pressure on Auden. It could have reformulated its 20mg product while make supplies from the Third Batch. However, even if Waymade could not have entered with the Third Batch (which the CMA does not accept), Waymade was in a position to reformulate and enter sufficiently quickly to exert competitive pressure on Auden:

- a. As already discussed at paragraphs 6.136 to 6.144 above, Waymade viewed reformulation as straightforward. [Waymade Senior Employee 2] stated in the May 2014 email cited above: '*Aesica are due to produce and implement the change in July*' – ie within three months of his email. [Aesica Employee] estimated in interview that the process would take six to 12 months. These time estimates are all sufficiently short periods to exert competitive pressure on Auden even if Waymade was not able to enter with the Third Batch. There is no reason to believe that longer time periods were being considered by Waymade in 2011; and
- b. When reformulation was actually carried out almost three years after entering into the 20mg Agreement, it took only 15 months to complete. There is no evidence that the parties thought reformulation would take as long as 15 months when they entered into the 20mg Agreement, but in any case that period is also in itself sufficiently short for Waymade to exert competitive pressure on Auden. The CMA's findings with respect to this 15-month period are further set out below.

6.165. When the work was eventually undertaken in 2014 (nearly three years after entering into the 20mg Agreement),²⁰⁸⁵ reformulation itself was relatively quick: Waymade submitted a purchase order for the manufacture of three validation batches of 20mg hydrocortisone tablets with a change in the formulation in April and Aesica manufactured those in August. The process validation was completed in November, receiving approval from the MHRA for the variation to its MA early the following February.²⁰⁸⁶

6.166. Notwithstanding the above, as set out in paragraph 3.393, between April 2014 and July 2015 (when Waymade entered the market with its Aesica-

²⁰⁸⁵ The Third Batch had expired in November 2013.

²⁰⁸⁶ Document 301899, email from [Waymade Employee] to [Waymade Employee] and [Waymade Senior Employee 2] dated 9 February 2015. See also Document 300899, email from [Waymade Employee] to [Waymade Employee] dated 6 February 2015. [Waymade Senior Employee 2] then told [Waymade Senior Employee 1] '*stock will now be packed off*', see Document 301900, email from [Waymade Senior Employee 2] to [Waymade Senior Employee 1] dated 9 February 2015.

manufactured tablets) Waymade did experience some extraordinary delays to the production and delivery of the reformulated batches.

- 6.167. The 15-month timeframe wholly allows for these extraordinary delays and was how long the work took when the project was reignited some three years after the dissolution issue was identified, following a three-year period of inactivity due to Waymade's agreement with Auden.²⁰⁸⁷ Because it had to be restarted after a long hiatus, the time it eventually took Waymade when it restarted the project is not reflective of how long it may have taken Waymade if it had pursued reformulation and independent entry in 2011.
- 6.168. Further and as a matter of principle, evidence from after the 20mg Agreement was concluded must be approached with caution as the 20mg Agreement had reduced Waymade's incentive to reformulate swiftly and bring its own product to market: it was receiving a steady revenue stream from the 20mg Agreement which would fall away and be replaced by the uncertainty of competition if it entered the market independently. The long period between identifying the need to reformulate and actually carrying out that reformulation is indicative of this.
- 6.169. Indeed, the full effect of these extraordinary delays was not anticipated by Waymade at the time the reformulation project was initiated in 2014 as set out at paragraphs 6.139 and 6.140. For example, [Waymade Senior Employee 2] thought it would take no more than three months for Aesica to implement the change as is clear from the email cited above.
- 6.170. The delays in reformulation and entering the market that Waymade encountered in 2014 in any event do not undermine Waymade's position as a potential competitor when it entered into the 20mg Agreement in July 2011.²⁰⁸⁸ The fact is that Waymade could have commenced the reformulation project when it first became aware of the dissolution issue affecting the Fourth Batch in December 2010 but instead waited to see if its negotiations with Auden were successful (as set out from paragraph 6.174). It is clear therefore that Waymade could have reformulated earlier than it eventually did: even using the 15 month time period, Waymade could have obtained reformulated stock by mid-2012 if it had carried out this work at the time. It is reasonable to conclude that 15 months would be the outside estimate for how long reformulation would have taken (indeed, had the full effect of these extraordinary delays been in the purview of Waymade at the

²⁰⁸⁷ [Aesica Employee] of Aesica explained to the CMA that when a product development is halted, particularly over a handful of years, there is a risk that restarting the development will entail further work (Document 302539, transcript of interview with [Aesica Employee] dated 30 October 2018, pages 16-18, lines 359-393).

²⁰⁸⁸ See paragraphs 6.71 and 6.78.

time, then that was all the more reason to have commenced redevelopment as soon as possible rather than postpone it as Waymade did).

6.171. For the avoidance of doubt, however, even if 15 months represented a reasonable estimate - at the time at which the 20mg Agreement was entered into - of the time that it would take Waymade to obtain a saleable batch to enter the market with, that would still satisfy the requirement that entry be possible within a sufficiently short period to exert competitive pressure. In particular:

- a. Waymade already held a MA for 20mg hydrocortisone tablets: the MA only had to be updated when the formulation was revised. The revised formulation was in line with the switch from maize to pre-gelatinised starch that had already successfully been carried out on the 10mg hydrocortisone tablet.
- b. It had experience with reformulating hydrocortisone tablets from the successful reformulation of its 10mg product.
- c. It had made significant investments into the development of its 20mg product and this product was at an advanced stage of the development.
- d. Auden was willing from July 2011 to provide favourable terms of supply to Waymade because it considered Waymade could enter the market sufficiently quickly to take market share from Auden. This forms in itself evidence of the fact that Waymade exerted competitive pressure on Auden at the time the 20mg Agreement was entered into, regardless of whether it could have entered with the Third Batch or had to spend up to 15 months to reformulate. By contrast, there is no evidence that either Waymade or Auden thought that Waymade was so far away from independent entry that it did not exert competitive pressure on Auden.
- e. The contemporary views of Waymade staff when it did reformulate in 2014 show that it was not expected to be a difficult process.

6.172. The CMA reiterates that the European Commission's Guidelines on Horizontal Cooperation Agreements specifically refer to three years as being a short period of time, and note that even a '*longer period*' may be sufficiently short where the potential entrant is a party to the agreement in question (as Waymade is in this case).²⁰⁸⁹

²⁰⁸⁹ See paragraphs 6.75 to 6.78.

6.173. Therefore, even if 15 months represented a reasonable estimate - at the time at which the 20mg Agreement was entered into - of the time that it would take Waymade to be ready to enter the market independently, this would be sufficiently short for Waymade to exert competitive pressure on Auden.

The fact that Waymade only independently entered in 2015 was because of the negotiation and conclusion of the 20mg Agreement

6.174. Despite the position as just described, Waymade did not enter the market in May 2011 and nor did it reformulate its product. Waymade only commenced reformulation in 2014 and independently entered the market as late as July 2015. For the avoidance of doubt, these delays are not representative of the time spent on preparing to enter the market: they are the result of the negotiation and conclusion of the 20mg Agreement, as further set out below.

6.175. With respect to reformulation, Aesica recommended reformulation in December 2010.²⁰⁹⁰ However, Waymade did not carry out the reformulation work at this time, instead deciding in January 2011 to '*re-formulate [...] at a later date.*'²⁰⁹¹ On 7 January 2011, Waymade informed Aesica that '*reformulation will be considered in approximately 12 to 18 months*'.²⁰⁹²

6.176. Contemporaneous evidence shows that the decision of when to reformulate depended on the outcome of negotiations with Auden, as set out below:

- a. Internal Waymade meeting notes of 9 May 2011: '*Stock will not be released for sale pending outcome of commercial negotiations with third party. The outcome of these discussions will inform the decision as to whether the 20mg tablet is reformulated in line with the 10mg tablet*'.²⁰⁹³
- b. Internal Waymade meeting notes of 6 June 2011: '*Question raised as to whether we want to reformulate 20mg strength tablet (i.e. inclusion of 'pre-gelatinised starch' in line with the fix for the 10mg formulation).*

²⁰⁹⁰ See paragraphs 3.355.

²⁰⁹¹ Document 300133, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Employee], [Waymade Employee] and others dated 10 January 2011. See also Document 301462, Operations Monthly Report January 2011, pages 19 to 20.

²⁰⁹² Document 205963, Exception Report number 1010997 for Lot number 6013367 (ie the Fourth Batch). Waymade submitted that this document is evidence that there was no link between the decisions on reformulation and the agreement and instead was due to its prioritisation of the 10mg product. The CMA does not accept this representation given the weight of contemporary evidence set out here showing the link between postponing reformulation work and the agreement with Auden (Document 206661, Waymade's RLOF paragraph 7.1-7.6)

²⁰⁹³ Document 300178, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2] and others dated 9 May 2011

Actions: [X] to check status of negotiations with third party. This will inform decision as whether we undertake reformulation.²⁰⁹⁴

- c. Internal Waymade correspondence of 23 June 2011: *'Do we want to reformulate the 20mg strength to bring it in line with the 10mg formulation? We know that the 20mg formulation is somewhat 'knife-edge'. If you [Amdipharm Senior Employee] and [Waymade Senior Employee 1] are confident that the Auden Mckenzie trading relationship is going to stick then I would suggest that we do not need to reformulate at the current time [...]. We can come back to the reformulation at a later date if we want to although costs and timing might not be to our liking*'.²⁰⁹⁵
- d. Internal Waymade correspondence of February 2014: *'There are no regulatory issues preventing us from producing packs of 30 tablets in amber glass bottles. Any other pack size or type would require prior approval of variations by the MHRA. An issue with the formulation was identified by Aesica, which could cause failure of future batches. They proposed a reformulation, which would also require a variation with stability data. A decision was made not to proceed with the blister pack and re-formulation due to the commercial arrangement we'd entered into which prevented us marketing our product*'.²⁰⁹⁶
- e. Document called: 'Hydrocortisone 20mg Tablets – Regulatory Status February 2014': *'Three commercial scale batches successfully manufactured by Aesica for validation. Formulation change to replace maize starch with pregelatinized starch was proposed due to dissolution failure on 4th batch. Change was not progressed as 20mg tablets were not marketed due to agreement with 3rd party. 3 months stability data on 2 batches (pilot or commercial) will be required if we are to proceed with this change. [X] advised that there is a risk that future batches will fail if not re-formulated. Aesica are best placed to advise on the degree of risk. There are no outstanding variations, change controls, deviations or CAPAs. Pending satisfactory quality review of validation status and stability data, production of Hydrocortisone 20mg Tablets in amber glass bottles of 30 tablets can*

²⁰⁹⁴ Document 300184, email from [Waymade Senior Employee 3] to [X], [Waymade Senior Employee 2] and others dated 6 June 2011 (emphasis added)

²⁰⁹⁵ Document 200017, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] dated 23 June 2011 (emphasis added).

²⁰⁹⁶ Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2], dated 25 February 2014 (emphasis added)

*proceed, according to the currently approved formulation and manufacturing process’.*²⁰⁹⁷

- 6.177. Evidence from when Waymade restarted the project in 2014 confirms that it did not continue with reformulation in 2011 because of the 20mg Agreement. Waymade had decided not to *‘proceed with the [...] re-formulation due to the commercial arrangement [it had] entered into which prevented [Waymade] from marketing [its] product’*;²⁰⁹⁸ *‘[r]eformulation was not completed on the 20mg product as there was no subsequent demand for commercial supply until now’*;²⁰⁹⁹ and *‘no further batches’* were made as Waymade was *‘no longer going to market the tablets’*.²¹⁰⁰
- 6.178. With respect to the decision not to enter with the Third Batch, contemporaneous documentary evidence, corroborated by information provided by key Waymade staff in interviews with the CMA, similarly indicates that Waymade took this decision because of its negotiations with Auden. Specifically:
- a. An excerpt from Waymade’s Medical Monthly Report for April 2011 shows the clear link between Waymade not launching its 20mg tablets and the ongoing negotiations with Auden:

‘[t]he product will be released into stock and then frozen pending the outcome of the negotiations with Auden McKenzie’.^{2101,2102}
 - b. The minutes of a meeting held on 09 May 2011 also recorded that the *‘stock [from the Third Batch] will not be released for sale pending the outcome of commercial negotiations with Auden Mckenzie’*.²¹⁰³
 - c. In his interview with CMA officials, [Waymade Employee] also explained that he: *‘knew that [...] we [Waymade] had stock, at the time,*

²⁰⁹⁷ Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014 attached to Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014 (emphasis added).

²⁰⁹⁸ Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2], dated 25 February 2014. See also Document 300438, Hydrocortisone 20 mg Tablets – Regulatory Status February 2014 attached to Document 300439, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014, *‘Formulation change [...] not progressed as 20mg tablets were not marketed due to agreement with 3rd party’*.

²⁰⁹⁹ Document 301709, email from [Aesica Employee] to [Waymade Employee] dated 28 February 2014.

²¹⁰⁰ Document 301693, email from [Waymade Employee] to [Waymade Employee] dated 28 February 2014.

²¹⁰¹ Document 300180, Monthly Report Sovereign Medical April 2011, page 2, attached to Document 300179, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1], [Waymade Employee], [Amdipharm Senior Employee] and [Waymade Employee] dated 11 May 2011.

²¹⁰² [Amdipharm Senior Employee] told the CMA in interview that released into stock meant: *‘it would be released because it’s got a QP certificate that says that it meets the finished product specification, therefore the product can be released’*, (Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 10).

²¹⁰³ Document 300178, email from [Waymade Senior Employee 3] to various Waymade personnel dated 9 May 2011.

we had stock that was suitable for release and [...] that release was put on hold, or delayed, due to the negotiations with the third party.²¹⁰⁴ He also stated that it was these commercial negotiations that were *‘the only thing that was preventing us from releasing our stock’*.²¹⁰⁵

- 6.179. The evidence is therefore clear that Waymade did not enter the market with the Third Batch and it did not reformulate its product because of the negotiations for and conclusion of the 20mg Agreement, and not because of a defect in Waymade’s 20mg hydrocortisone tablets.
- 6.180. Waymade submitted that concerns around the cost of reformulation influenced its decision to reformulate the product in the future.²¹⁰⁶
- 6.181. In making this submission Waymade relied only on quotations from the transcripts of the CMA’s interviews with Waymade personnel held in 2018 and cited no contemporaneous evidence in support.
- 6.182. Further, when these quotations are read in their proper context, it is clear that they do not assist Waymade’s case:
- a. First, Waymade selectively quotes from the transcript of the CMA’s interview with [Waymade Employee] to argue that she told the CMA that *‘reformulation was “extremely costly and time-consuming”*’.²¹⁰⁷ However when this quote is read in its full context, it is clear that [Waymade Employee] was merely speculating in making this comment: when asked why Waymade did not pursue reformulation straight away, she answered *‘I don’t know the answer to that question, but again, my assumption would be that all of this is extremely costly and time-consuming*’²¹⁰⁸ (emphasis added). This is acknowledged by Waymade in a footnote in its representations.²¹⁰⁹
 - b. Second, Waymade quotes from the transcript of the CMA’s interview with [Waymade Employee] in which he commented that *“there were issues with the cost of reformulation”*. Again, when this quote is read in

²¹⁰⁴ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 57, lines 16 to 18.

²¹⁰⁵ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 58, line 10. [Waymade Senior Employee 3] also stated in interview that it was *‘very unusual for a product to be developed, manufactured and received into stock and then not launched’*: Document 301315, transcript of [Waymade Senior Employee 3] interview, dated 27 March 2018, part 2, page 34, lines 3 to 5.

²¹⁰⁶ Document 204903, Waymade’s RSSO, paragraphs 7.83, 10.18-10.19 (extracting from Document 302405, transcript of the CMA’s interview of [Waymade Employee] on 23 November 2018 and Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018).

²¹⁰⁷ Document 204903, Waymade’s RSSO, paragraph 7.83, quoting Document 302405, transcript of the CMA’s interview of [Waymade Employee] on 23 November 2018, page 51, lines 27-28

²¹⁰⁸ Document 302405, transcript of [Waymade Employee] interview dated 23 November 2018, page 51, lines 26-28.

²¹⁰⁹ Document 204903, Waymade’s RSSO, footnote 210.

the context of the exchange as a whole, it is clear that [Waymade Employee] was uncertain as to the relevance of cost to the decision: “*I think there were issues with the cost of reformulation*” (emphasis added). In fact, elsewhere [Waymade Employee] told the CMA that reformulation was not carried out due to Waymade’s negotiations with Auden: “*those negotiations would inform the decision on whether to go ahead with the reformulation*”.²¹¹⁰

- 6.183. The assertion concerning the costs of reformulation is also difficult to reconcile with Waymade’s other submission that it remained incentivised throughout the term of the agreement to enter the market with its own 20mg tablets,²¹¹¹ nor the fact that Waymade later elected to reformulate the product in 2014.
- 6.184. In fact, the only contemporaneous email on the CMA’s file in which the cost of reformulation is discussed estimates that the reformulation work would have cost approximately £50,000,²¹¹² which would have been more than covered by the revenue Waymade would have made had it sold the Third Batch (of 3,560 packs) at the prevailing market price in 2011 of £34.50 per pack. In any event, concerns with respect to the cost of reformulation do not mean that entry was not economically viable, particularly since Waymade could have entered with the Third Batch and in any event Waymade eventually achieved successful entry in 2015 after incurring the cost of reformulation.
- 6.185. This representation by Waymade must therefore be dismissed.
- 6.186. Auden/Actavis²¹¹³ and Waymade²¹¹⁴ also submitted that the delays to the reformulation of Waymade’s 20mg product were not a consequence of the 20mg Agreement but rather the result of Waymade’s limited resources and the lack of engagement from Aesica, including because Waymade was unsure whether Aesica would be able to successfully produce the product.
- 6.187. However, these claims must be dismissed as contemporaneous evidence (see paragraphs 6.176 and 6.177 above) shows that Waymade decided not to enter the market with the stock from the Third Batch and to refrain from reformulating the 20mg tablets due to the agreement with Auden (and not due to other reasons).

²¹¹⁰ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 46 line 21 – page 47 line 14.

²¹¹¹ Document 204903, Waymade’s RSSO, paragraphs 2.9(d), 2.21-2.22, 7.35-7.37, 7.46-7.47.

²¹¹² Document 200017 email from [X] (Aesica) to [Waymade Senior Employee 3] dated 11 May 2011.

²¹¹³ Document 205217, Auden/Actavis’s RSSO, paragraphs 7.126 to 7.129

²¹¹⁴ Document 204903, Waymade’s RSSO paragraphs 7.75 and 7.101 to 7.104.

- 6.188. With respect to Auden/Actavis's and Waymade's submissions²¹¹⁵ that Waymade did not have enough resources to engage with the 20mg development, these parties did not present any evidence that supports this as a plausible reason for Waymade's suspension of the redevelopment of its 20mg product.
- 6.189. To the contrary, the contemporaneous evidence shows that the 10mg and 20mg hydrocortisone tablets were being developed alongside one another and functional team meetings were being held to deal with both developments in 2010 and the first half of 2011 (until the 20mg development was parked). It therefore is not credible to state (a) that there were no resources to manage both products or (b) that the 20mg product was left aside in order to develop the 10mg product, in circumstances where both were being developed simultaneously up until entering the 20mg agreement with Auden.
- 6.190. Furthermore, Waymade only lost personnel in the sale of Amdipharm to Cinven in October 2012, over a year after it entered into the 20mg Agreement. As such, that transaction had no impact on Waymade's ability to conduct the reformulation of its 20mg product, particularly since Waymade decided it would need to reformulate the product in December 2010. The evidence presented above indicates that reformulation was paused by Waymade as early as 10 January 2011.
- 6.191. With respect to Auden/Actavis's and Waymade's submissions²¹¹⁶ that Waymade delayed its reformulation efforts due to [REDACTED].
- 6.192. As explained in detail above, the contemporaneous evidence shows that the reason for Waymade not to engage with Aesica on reformulation was that it had entered into the 20mg Agreement with Auden. Contemporaneous evidence and Aesica's response to the CMA's section 26 notice dated 15 June 2016²¹¹⁷ also show that when Aesica provided Waymade with a proposal to reformulate its 20mg product in May 2011, Waymade did not engage with it until August 2013.²¹¹⁸ [REDACTED].

²¹¹⁵ Document 205217, Auden/Actavis' RSSO, paragraphs 7.126 and 7.127; Document 204903, Waymade's RSSO paragraphs 7.101 to 7.104.

²¹¹⁶ Document 205217, Auden/Actavis' RSSO, paragraphs 7.128 and 7.129; Document 204903, Waymade's RSSO paragraph 7.75.

²¹¹⁷ Document 200292, Aesica's response to the CMA's section 26 notice dated 15 June 2016, paragraph 3.7.

²¹¹⁸ Document 200017, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] dated 23 June 2011.

Entry was economically viable

- 6.193. Finally, the CMA concludes that Waymade's entry was economically viable.
- 6.194. Waymade purchased an MA for 20mg hydrocortisone tablets in 1998 as part of a basket of assets.²¹¹⁹ Although it initially decided not to commercialise the asset, Waymade's strategy changed in October 2008 following a significant increase in the NHS Reimbursement Price of 20mg hydrocortisone tablets (from [£1-£4] per pack in January to £13.86 in September 2008),²¹²⁰ after which launching its own 20mg tablets became a '*high priority*' for the company,^{2121, 2122} reflecting the commercial opportunity that the price increase presented. At that time, Waymade's estimated cost of producing its own 20mg hydrocortisone tablets (via Aesica) was significantly lower than the NHS Reimbursement Price: in December 2008, Aesica had proposed a '*[f]ull inclusive price for Hydrocortisone 20mg tablets in 2 x 30 tablet blister:GB [£1-£4] per pack*'.²¹²³ In July 2011, when Waymade entered into the 20mg Agreement with Auden, the NHS Reimbursement Price of 20mg hydrocortisone tablets had risen to £45.90. Therefore, there is no question that entry was economically viable.
- 6.195. Auden/Actavis cites the interview evidence of certain Waymade personnel as demonstrating that Waymade was concerned that its product would not be commercially viable as a result of being packaged in bottles rather than blister packs.
- 6.196. The contemporaneous evidence on the CMA's file indicates, however, that Waymade considered the Third Batch (packed in bottles) was saleable, and that Waymade believed it could enter the market with them: see paragraphs 6.152 and 6.187 above.

²¹¹⁹ See paragraph 3.345.

²¹²⁰ Document 200003, paragraph 1.1, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

²¹²¹ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 9, lines 17 to 18. See in addition page 18, lines 8 to 9.

²¹²² See, in addition, Document 300124, Sovereign Generics Key Technical Transfer and Support Projects for 2011, attachment to Document 300123, email from [X] to [Waymade Senior Employee 2] and [X] dated 24 November 2010, in which projects to develop hydrocortisone tablets were referred to as '*Key Projects*' in Waymade's internal documents, and were assigned '*Priority Rating 1*', meaning '*High-Critical*'. In addition, [Amdipharm Senior Employee] confirmed during an interview with the CMA that the development of the 20mg hydrocortisone tablets was a '*priority project*' (Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 46, line 10). See also Document 200006, in relation to both the 20mg and 10mg development projects, Waymade's response to the CMA's section 26 notice dated 5 May 2016, Annex 10(A), page 1, email from [X] to [X] (Aesica), [Aesica Employee] (Aesica) and [X] (Aesica) dated 9 April 2010: '*Discussed recent additional pressure to progress re [X] and [Amdipharm Senior Employee]'s request to accelerate!*'

²¹²³ Document 200295, 'Offer – Hydrocortisone 10 and 20mg Tablet Business' from Aesica to Waymade dated 23 December 2008.

- 6.197. Further, when Waymade eventually independently entered the market in 2015 it did so with its product packed in bottles.²¹²⁴ Moreover, certain wholesalers informed the CMA that some customers even prefer to purchase hydrocortisone tablets in bottles rather than blister packs.²¹²⁵
- 6.198. In fact, Waymade used the fact it had real concrete possibilities to launch its own 20mg hydrocortisone tablets and the competitive threat this posed to Auden as ‘leverage’ in those negotiations (and also as an insurance policy should these negotiations fail). As [Waymade Senior Employee 3] explained in his interview with the CMA: *‘the fact that the product is there in the warehouse in Basildon, is the leverage in that Waymade could have placed that product on the market.’*²¹²⁶ Such a strategy is only possible if Waymade’s product exerted a competitive threat on Auden’s position in the market.
- 6.199. In any case, the legal test for potential competition does not require that the CMA proves that Waymade would have in fact entered, or *a fortiori*, that it would have been capable of retaining its place on the market after entry.²¹²⁷ Rather, the CMA must show that Waymade had ‘*real concrete possibilities*’ of entry within such a period of time as would impose competitive pressure on Auden. It is the threat of entry that is relevant in a case like the present one, not the threat of Waymade with certainty obtaining a permanent position in the market.
- 6.200. Auden/Actavis’s submission relating to Waymade’s 20mg hydrocortisone tablets being packaged in bottles must therefore be dismissed.
- 6.201. Waymade further submitted that, even assuming the Third Batch had been saleable (which it was, as explained above), it would not have been commercially rational for Waymade to enter with the Third Batch because:
- a. the CAPA meant that the product was not robust or reproducible, meaning the product may have faced recall (which would be a ‘*commercial disaster*’);²¹²⁸ and

²¹²⁴ Auden/Actavis has stated that evidence gathered by the CMA shows that blister packs are preferred to glass bottles (Document 206667, Auden/Actavis’s RLOF, paragraph 3.38-3.40). For the reasons set out above, that Waymade entered with its product in glass bottles, and that it was preparing to enter the market in 2011 with its glass bottles, the CMA does not accept this representation.

²¹²⁵ Document 206582, note of call with Sigma on 4 March 2021 and Document 206612, note of call with Mawdsleys on 3 March 2021.

²¹²⁶ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 12, line 27; page 13, lines 1 to 2.

²¹²⁷ C-307/18, *Generics (UK) and others v CMA*, paragraph 38: ‘...there is no requirement that it must be demonstrated with certainty that that manufacturer will in fact enter the market concerned and, a fortiori, that it will be capable, thereafter, of retaining its place there’.

²¹²⁸ Document 204903, Waymade’s RSSO, paragraph 7.69(a)(4).

- b. Waymade had no certainty of supply once the stock from the Third Batch was exhausted, because the stock was insufficient to provide stock cover for the likely duration of reformulation and there was no guarantee that reformulation would be successful.²¹²⁹ Waymade says that *'no company would enter the market with a product it couldn't replicate'*²¹³⁰ as this would cause reputational damage.
- 6.202. It is important to note, first, that the CMA has sought to establish whether at the point of entering into the 20mg Agreement, Waymade had real concrete possibilities to enter the market within a sufficiently short period of time to exert competitive pressure on Auden. Since Waymade could have entered with the Third Batch, this test is clearly met, regardless of whether – with hindsight – Waymade now considers that doing so would not have been its preferred option. What matters is whether it had a clear route to market within a sufficiently short period of time so as to exert competitive pressure on Auden. The Third Batch gave it an immediate route to market. Waymade believed at that time that it had to reformulate to secure future supplies once that batch had been fully dispensed, which (as described above) is a process Waymade could have started in January 2011 but delayed in favour of negotiating the 20mg Agreement with Auden.
- 6.203. Furthermore, there is no contemporaneous evidence demonstrating that these concerns were a relevant factor in Waymade's decision-making at the time. Indeed as set out above, it follows from the contemporaneous evidence that Waymade decided not to enter the market with the Third Batch because of the negotiation and conclusion of the 20mg Agreement, not because of concerns around a product recall or security of supply.
- 6.204. With respect to the risks of product recall, as discussed above Waymade considered that the Third Batch was saleable and there is no contemporaneous evidence to suggest that Waymade had any safety or quality concerns with the product, nor that it perceived there to be a risk of product recall. In fact, Waymade retained the Third Batch in stock in case it would need it, and considered whether the Third Batch could be sold in Yemen (see paragraphs 3.373 and 6.154.b above).
- 6.205. With respect to continuity of supply, the CMA does not contest that Waymade decided to reformulate for future supply, but the impact of this on Waymade's ability to enter the market with the Third Batch has been significantly overstated by Waymade. In particular and as set out below, Waymade had options with respect to both reformulation and its supply to

²¹²⁹ Document 204903, Waymade's RSSO, paragraphs 2.15-2.17, 7.54 and 7.69-7.76.

²¹³⁰ Document 204903, Waymade's RSSO, paragraph 7.69.

the market in the interim to limit this impact. In any event, had a stock outage occurred this would not have been terminally damaging to Waymade's position in the market. These credible options do not mean Waymade could not have decided to wait until reformulation had been carried out, they simply mean Waymade had real and concrete possibilities to enter with the Third Batch and to manage supplies from that batch while reformulating its product.

- 6.206. As at May 2011, Waymade had a stock of 3,560 bottles of 20mg hydrocortisone tablets with an expiry date of November 2013. This was sufficient stock to make Waymade's entry possible and sustainable:
- a. Contemporaneous documents show that Waymade concluded that it would have '*sufficient stock from the validation batches for 2011*' due to the '*low market volume for the 20mg strength*', and so Aesica would '*not be required to manufacture the 20mg strength during the remainder of [...] 2011.*'²¹³¹
 - b. In fact, since this stock had a shelf life of approximately 30 months it was open to Waymade to manage its supply to the market so as to provide coverage for the longer term had it wanted to: wholesalers and dispensers typically require stock purchases to have a shelf life of at least one year but may accept stock with a shorter shelf life if offered on agreeable commercial terms,²¹³² and as such the stock would have been saleable until at least late 2012.²¹³³ As described at paragraph 6.170 above, it was open to Waymade to obtain reformulated stock by mid-2012, meaning that it could have obtained reformulated supplies before its stock from the Third Batch was exhausted.
 - c. Market entry with limited stock was not extraordinary. In fact, when Waymade entered the market in July 2015, it told customers that it had '*limited stocks*' and decided to '*allocate sensibly*' per customer giving

²¹³¹ Document 300120, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2], [X] and others dated 8 November 2010.

²¹³² Document 206612, note of call with Mawdsleys on 3 March 2021, paragraph 4.1; Document 206344, note of call with Resolution, paragraphs 5.1 to 5.3; Document 206416, note of call with Day Lewis on 16 March 2021, paragraphs 4.1 to 4.2; Document 206580, note of call with DE Pharma on 17 March 2021, paragraphs 3.1 to 3.2; Document 206582, note of call with Sigma on 4 March 2021, paragraphs 5.1 to 5.2.

²¹³³ In respect of this new evidence gathered by the CMA, Waymade stated that it has accepted that the shelf life of the Third Batch was '*sufficient to be considered marketable*'. It also repeated that there are other reasons such as the open CAPA why it could not sell these tablets (Document 206661, Waymade's RLOF, paragraph 4.2). That particular argument is responded to above at paragraphs 6.148 to 6.192. Waymade in addition stated that due to the shelf life on the First and Second Batches these could not have been sold: the CMA does not assert that this was the case. Auden/Actavis submitted that the shelf life of the Third Batch would be a 'potential barrier to customer uptake' and that going out of stock would have an impact on a small supplier such as Waymade (Document 206667 Auden/Actavis's RLOF, paragraph 3.31-3.37). For the reasons set out above, the CMA does not accept these representations.

preference to short-line.²¹³⁴ A similar strategy was followed by Alissa when it entered the market in October 2015 as it had to '*ring fence a quantity*'²¹³⁵ for the first few customers it had secured supply for.²¹³⁶ Nothing prevented Waymade from proceeding on this same basis in May 2011 until it received additional stock post-reformulation.

- d. In any case, when Waymade entered the market with the Auden product in July 2011 it only supplied the market with 200 packs of Auden's product available to it each month. Waymade has submitted that supply from Auden at this level enabled it to achieve some market presence,²¹³⁷ and indeed, [Waymade Senior Employee 4], [REDACTED] told the CMA that Waymade would not have been able to sell more than 200 packs to its retail customer base.²¹³⁸ Measured by this volume, the packs that were produced using tablets from the Third Batch would have lasted until around November 2012, with the latest sold packs still carrying a shelf life of approximately 1 year.

6.207. Therefore, at the time it entered into the 20mg Agreement in July 2011, Waymade could have launched these tablets and simultaneously undertaken reformulation to secure longer term supply (and this is what it planned to do in the absence of the 20mg Agreement),²¹³⁹ and it was open to Waymade to manage the reformulation work and its supply to the market with its Aesica product in such a way so as secure this ongoing supply prior to the packs produced using tablets from the Third Batch being exhausted.

6.208. Even had those packs been exhausted prior to Waymade having obtained stock for future supply, this would not have been terminally damaging to Waymade's position in the market. A number of wholesalers and suppliers²¹⁴⁰ have confirmed to the CMA that it is common in the generics

²¹³⁴ Document 300912, email from [REDACTED] to [Waymade Senior Employee 1] dated 28 July 2015; and Document 300917, email from [Waymade Senior Employee 4] to [REDACTED] (DE Pharma) dated 16 August 2015.

²¹³⁵ See, for instance, Document 206108, email from [Alissa Senior Employee] to [REDACTED] ([wholesaler]) dated 20 October 2015.

²¹³⁶ Document 206124, note of call between [Alissa Senior Employee] and the CMA of 23 December 2020, paragraph 12.

²¹³⁷ Document 204903, Waymade's RSSO, paragraphs 7.26, 7.28, and 7.49 which cites the witness evidence of [Amdipharm Senior Employee] (citing Document 200348, transcript of CMA interview with [Amdipharm Senior Employee], p. 10-11).

²¹³⁸ Document 301313, transcript of CMA interview with [Waymade Senior Employee 4], p.20, lines 5-26 and p.21, lines 4-9 and 18-20. [Waymade Senior Employee 4] confirmed that '*I wouldn't have enough retail customers on my books to move the whole thousand into retail*'.

²¹³⁹ Document 300166, Minutes of joint Aesica Sovereign review 31/3/11: it was reported that at that point in time Waymade could '*now start selling in 30 bottles*' (page 2) and that '*20 mg formulation switch to pre gel starch to be planned following agreement, ca mid-year*' (page 1).

²¹⁴⁰ Document 206413, note of call between [REDACTED] (Alissa) and the CMA of 22 February 2021, paragraphs 4.1 and 4.3; Document 206579, note of call between DE Pharma and the CMA of 23 February 2021, paragraph 5.1; Document 206612, note of call between Mawdsleys and the CMA of 3 March 2021, paragraphs 5.1 to 5.3; Document 206344, note of call between Resolution Chemicals and the CMA of 4 March 2021, paragraphs 6.1 to 6.3; and Document 206582, note of call between Sigma Pharmaceuticals and the CMA of 4 March 2021, paragraph 4.4.

market for stocks not to be supplied continuously to the market (for example, AMCo managed to continue to make sales despite having stock outages following its independent entry with its 10mg hydrocortisone tablet).²¹⁴¹ The CMA understands that price is the critical factor for generic medicines and customers are not brand-loyal.²¹⁴²

6.209. In any case, Waymade had options to manage the risk of a stock outage if it had decided to enter the market with the Third Batch. For example:

- a. As discussed above, Waymade could have rationed its supply of tablets in the market so that it could supply consistently while it reformulated. [Waymade Senior Employee 4] explained to the CMA that selling 200 packs per month was sufficient to establish a presence in the retail market.²¹⁴³ In some months Waymade was unable even to sell 200 packs.²¹⁴⁴
- b. Equally Waymade could have supplied the market in a manner so as to anticipate a future gap in its supply (for example by dealing with its customers accordingly) since, as noted above, there would have been demand for the product and a gap in supply would not have been terminally damaging to Waymade.

6.210. Waymade was a wholesaler itself so had a direct route to market to sell its products in whichever manner it pleased. Given that Waymade had these options available to it, it is notable that Waymade did not pursue any of them - some sales, even at a discount, would at least have allowed Waymade to recoup some of the production costs rather than write this off which would appear to be a commercially rational strategy. [Waymade Senior Employee 3] also told the CMA in interview that *'it is very unusual for a product to be developed, manufactured and received into stock and then not launched'* and that *'the expectation would normally be that we would sell it for all we could, you know, to start to, to start to pull back money against the investment which has been made. So, it's unusual'*.²¹⁴⁵

²¹⁴¹ Document 03113, Concordia's response to the CMA's section 26 notice dated 1 May 2018, response to question 1.

²¹⁴² Document 206413, note of call with Alissa [§] Document 206612, note of call with Mawdsleys on 3 March 2021, Document 206582, note of call with Sigma on 4 March 2021, Document 206579, note of call with DE Pharma on 23 February 2021, Document 206580, note of call with DE Pharma on 17 March 2021, Document 206416, note of call with Day Lewis on 16 March 2021 and Document 206418, note of call with Day Lewis on 8 February 2021.

²¹⁴³ Document 301313, transcript of [Waymade Senior Employee 4]'s interview dated 28 March 2018, page 20, lines 5 to 26.

²¹⁴⁴ See table 3.26 above.

²¹⁴⁵ Document 301315, transcript of interview with [Waymade Senior Employee 3] dated 27 March 2018, part 2, page 34, lines 3-11.

- 6.211. Further, the risk of a stock outage (if one existed) only arose because the prospect of the agreement with Auden meant that Waymade did not prioritise reformulation in a timely manner and eventually postponed reformulation when negotiations were successful, as set out above. But for the 20mg Agreement, the commercially rational thing to do would have been to take steps to reformulate the product as quickly as possible and not to delay doing so in favour of negotiations with a competitor.²¹⁴⁶
- 6.212. Accordingly the CMA dismisses these representations.

Conclusion

- 6.213. In conclusion, when Waymade entered into the 20mg Agreement it had taken sufficient preparatory steps to enter the market independently, entry was possible within a sufficiently short period of time to exert competitive pressure on Auden and entry was economically viable. Waymade therefore had a '*firm intention and an inherent ability*' to enter the market independently. Waymade decided neither to launch with the Third Batch nor to reformulate, and this was because of its negotiations with Auden.

There were no insurmountable barriers to entry

- 6.214. The CMA concludes that there were no '*insurmountable barriers*' to Waymade's entry.
- 6.215. There were no legal barriers to entry to the market for the supply of 20mg hydrocortisone tablets in the UK which would have precluded Waymade's entry. Regulatory and manufacturing hurdles to obtaining an MA and supply do not amount to an '*insurmountable barrier*' which would have '*ruled out*' potential competition.²¹⁴⁷ In any case as set out above, Waymade had an MA for 20mg hydrocortisone tablets since 1998 and had then overcome any further regulatory and manufacturing hurdles at the time of entering into the 20mg Agreement. It had a product it could have sold to the market in May 2011.
- 6.216. The absence of any insurmountable barrier is further confirmed by Waymade's ultimate entry with its 20mg hydrocortisone tablets in July 2015.

²¹⁴⁶ In its representations on the Letter of Facts Waymade repeated its position that a reasonable supplier would not have launched a single batch of product in the knowledge that it would not be able to maintain supply (Document 206661, Waymade's RLOF, paragraphs 6.1-6.5). Waymade '*acknowledges*' that the CMA has evidence that being out of stock would not act as an '*absolute bar*' to a generic company being able to sell its product. In any case as set out here Waymade had options to manage its independent market entry while it reformulated.

²¹⁴⁷ C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 31.

Had there been any barrier that was '*insurmountable*', Waymade would not have been able to enter the market, which was clearly not the case.

Additional factors which indicate the existence of potential competition: the 20mg Agreement and the value transfer

- 6.217. The very fact that Auden sought to conclude agreements with Waymade and made value transfers to Waymade when it was not yet on that market provides a strong indication that a competitive relationship existed between Auden and Waymade.²¹⁴⁸
- 6.218. The very generous terms of the 20mg Agreement and the fact that Auden entered into an agreement with Waymade offering supply of its 20mg hydrocortisone tablets at a significant discount to the rest of the market (nearly 90%, as set out in, for example, paragraph 6.456) and to make monthly cash payments to Waymade under the Buyback shows in itself that a '*competitive relationship existed*' between them, ie that Waymade's potential entry with 20mg hydrocortisone tablets exerted competitive pressure on Auden.²¹⁴⁹ As explained at section 6.D.II.c.i ('*Negotiating the 20mg Agreement 21 June to 11 July 2011*') below, in June 2011 Auden had offered Waymade 20mg hydrocortisone tablets at market rate (ie £34.50 per pack).²¹⁵⁰ Within a week, however, it substantially reduced the supply price offered to Waymade by 87%, to £4.50 per pack (while keeping prices charged to other customers at their original levels). Auden offered this enormous price reduction to Waymade because it perceived that Waymade posed a competitive threat to its market position and offered to buy off the anticipated competition from Waymade before it materialised. Over the term of the 20mg Agreement Auden paid Waymade £1.8 million not to enter the market to buy off this competitive threat.

Auden perceived Waymade to be a competitive threat

- 6.219. In addition to the evidence of the existence of the agreement and the value transfer, the CMA has further evidence to show that Auden perceived Waymade to be a competitive threat at the time it entered into the 20mg Agreement in July 2011.²¹⁵¹
- 6.220. Auden sought to justify its reasons for the very low supply price as allowing it to maintain its '*volumes with Tiofarma*' as explained further below, which is

²¹⁴⁸ See section 6.C.I.c.

²¹⁴⁹ C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 33.

²¹⁵⁰ Document 300186, email from [Auden Senior Employee 2] to [Amdipharm Senior Employee] dated 21 June 2011.

²¹⁵¹ See section 6.C.I.c.

evidence that it perceived Waymade to be its potential competitor. In interview, [Auden Senior Employee 1] recalled *'having an internal discussion which acknowledged Waymade was our competitor'*²¹⁵² and explained that the reason Auden offered Waymade a very low supply price compared to the rest of the market was *'to maintain [Auden's] volumes with Tiofarma'*.²¹⁵³

- 6.221. In interview, [Auden Senior Employee 2] of Auden also explained that the 20mg Agreement was intended to protect Auden's manufacturing volumes with its CMO Tiofarma:

*'It [the 20mg Agreement] was all about maintaining the volumes with Tiofarma. [...] I suppose there's a finite number of prescriptions there, so if [Waymade] had their own manufacture and brought product into the market we would then naturally reduce our volumes.'*²¹⁵⁴

- 6.222. This is tantamount to saying that the purpose of the 20mg Agreement was to buy off the anticipated competition from Waymade, which, if it had materialised, would have resulted in a potentially significant decline in Auden's market share and hence its *'volumes with Tiofarma'*. In other words, [Auden Senior Employee 2] expected that if Waymade had independently entered the market with its Aesica-manufactured product, it would have gained market share from Auden (and reduced Auden's volumes with its CMO).²¹⁵⁵
- 6.223. [Auden Senior Employee 1] similarly confirmed that if Waymade had entered the market with its own product, Auden's volumes *'could have dropped'* and it was to avoid this risk that Auden offered Waymade a £30 (87%) discount (when compared to its other customers) to supply Waymade with Auden product.²¹⁵⁶
- 6.224. [Auden Senior Employee 2]'s and [Auden Senior Employee 1]'s observations indicate that Auden was concerned that Waymade would take market share from it if Waymade independently entered the market – and that was the commercial rationale for Auden entering into the 20mg Agreement. This indicates, in turn, that Auden perceived Waymade to be a competitive threat.

²¹⁵² Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.17.

²¹⁵³ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.16.

²¹⁵⁴ Document 00717, transcript of [Auden Senior Employee 2] interview dated 21 September 2016, page 4, lines 6 to 16.

²¹⁵⁵ [Waymade Senior Employee 1] (of Waymade) confirmed that he did not tell Auden that Waymade had to reformulate its hydrocortisone tablets for future supply. Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 13, lines 4 to 19 and page 15, line 19 to page 16, line 26.

²¹⁵⁶ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 36, lines 1 to 9.

[Amdipharm Senior Employee] also told the CMA in interview that Auden would have been aware that Waymade had a MA and that this '*would put Waymade in a stronger competitive position in the market*'.²¹⁵⁷

6.225. This evidence is corroborated by contemporaneous documentary evidence of Auden's negotiating strategy in the build up to the 20mg Agreement. An email from [Auden Senior Employee 2] to [Auden Senior Employee 1] on 28 June 2011 (at the time Waymade and Auden were negotiating the terms of the 20mg Agreement) shows that Auden thought that Waymade could generate 50% market share on entry: '*[i]f Waymade had their own licence and achieved 50% mkt share at current pricing then they would net £50K per mth.*'²¹⁵⁸ In the same email [Auden Senior Employee 2] said that he had adjusted the deal he proposed to offer Waymade to reflect the cost savings Waymade would make in '*not bringing the product* [Waymade's 20mg tablet] *to market*'.

6.226. In conclusion, for the reasons set out above the CMA has found that Waymade was a potential competitor to Auden when it entered into the 20mg Agreement.

iii. Waymade was a potential competitor of Auden when it entered into the 10mg Agreement in October 2012

6.227. For the reasons set out below, the CMA concludes that the Waymade undertaking (at the time comprising Waymade plc and Amdipharm UK Limited) was a potential competitor to Auden at the time it entered into the 10mg Agreement in October 2012. This is because:

- a. Waymade had taken '*sufficient preparatory steps*' to show its '*firm intention and inherent ability*' to enter the market;
- b. there were no insurmountable barriers to entry;
- c. the existence of the 10mg Agreement itself and the value transfer are a strong indication that a competitive relationship existed; and
- d. Auden perceived Waymade to be a competitive threat.

²¹⁵⁷ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29, lines 24 and 25; page 31, lines 11 to 12.

²¹⁵⁸ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

Waymade had taken sufficient preparatory steps to enter the market to show it had a firm intention and an inherent ability to do so

6.228. The CMA concludes that Waymade had real concrete possibilities of entering the market independently and had taken '*sufficient preparatory steps*' to show its '*firm intention and an inherent ability*' to do so at the time it entered into the 10mg Agreement with Auden in October 2012.

6.229. This is because, by October 2012, Waymade had made significant investments and taken '*sufficient preparatory steps*' to prepare for entry, entry was possible in the short term, and entry was economically viable, as set out below.

Waymade had taken '*sufficient preparatory steps*' to prepare for entry

6.230. The CMA concludes that Waymade had taken '*sufficient preparatory steps*' to show its '*firm intention and an inherent ability*' to enter the market independently at the time it entered into the 10mg Agreement with Auden in October 2012.

6.231. Obtaining a 10mg MA was a priority for Waymade. For example, on 8 April 2010, [Amdipharm Senior Employee] asked [X], [X], to '*significantly accelerate*' the project, explaining that '*obtaining a licence for a 10mg strength is the major objective*'.²¹⁵⁹

6.232. Waymade submitted its 10mg MA application to the MHRA on 9 June 2011 and the MA was granted on 27 September 2012, just weeks before concluding the 10mg Agreement.

6.233. Waymade commenced work on developing 10mg hydrocortisone tablets with Aesica in October/November 2008, at the same time as it commenced the development of 20mg hydrocortisone tablets.²¹⁶⁰ Waymade subsequently made significant investments to develop its 10mg hydrocortisone tablet (for example, Waymade paid Aesica approximately [X] in 2009 to cover some of the initial developments costs for both the 10mg and 20mg hydrocortisone tablet projects).²¹⁶¹

²¹⁵⁹ Document 300038, email from [Amdipharm Senior Employee] to [X] dated 8 April 2010.

²¹⁶⁰ Document 200292, paragraph 3.2, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

²¹⁶¹ Document 200296, purchase requisition from Waymade to Aesica dated 12 February 2009; and Document 200295, 'Offer – Hydrocortisone 10 and 20mg Tablet Business' from Aesica to Waymade dated 23 December 2008.

- 6.234. By July 2010, Aesica had manufactured 500,000 10mg hydrocortisone tablets (the July 2010 10mg Validation Batches). Those tablets were packaged and placed on stability.²¹⁶²
- 6.235. The 10mg tablets were ready for commercial production as early as October 2010, when the process validation²¹⁶³ was completed and approved.²¹⁶⁴
- 6.236. The only outstanding step was the optimisation of the testing (assay) method for 10mg hydrocortisone tablets,²¹⁶⁵ which Waymade identified in July 2012 *'as the only issue (...) preventing us from launch'*²¹⁶⁶ and which AMCo quickly addressed within weeks in early 2014 (as set out further below). Had Waymade carried out optimisation at the time, it would not have needed to do any further work to be able to produce saleable batches of tablets in bottles once it had obtained its 10mg MA.²¹⁶⁷
- 6.237. The assay optimisation work does not indicate that either Waymade or AMCo would not be considered a potential competitor, particularly since it was not material to the intrinsic qualities of the tablets themselves. Nor does AMCo's later decision to purchase a tablet feeder considered further below.²¹⁶⁸ In fact, the 10mg tablets that Aesica produced in July 2010 and placed on stability were the same in terms of *'drug substance, composition, specification (including quality) and stability'* as the later batches that Aesica

²¹⁶² Document 200292, response to question 5, Aesica's response to the CMA's section 26 notice dated 15 June 2016. See paragraph 3.350 above for an explanation of the concept of 'stability testing'.

²¹⁶³ See paragraph 3.348 for an explanation of the concept of 'process validation', a mandatory step in drug development in which the manufacturer must prove that the manufacturing process is capable of producing consistently good product at the intended commercial scale.

²¹⁶³ Batches 6002398 and 6002893. See Document 301886, Analytical Development Report headed '20mg Hydrocortisone 20mg Tablet Comparative Dissolution Profiles' dated 7 December 2010 and Document 302554, paragraphs 1.1 and 2.1, Aesica's response to the CMA's section 26 notice dated 12 February 2019.

²¹⁶⁴ Document 200292, response to question 5, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

²¹⁶⁵ Essentially, Waymade realised that the assay method had to be optimised to improve the testing method's accuracy in producing stability data, which in turn determined the shelf life of the product. Waymade commissioned DSG to come up with a new assay method in July 2012. Eventually, AMCo addressed this with Aesica within weeks in early 2014 when it finally engaged with the product development. It then submitted a type 1A variation to the MHRA which was registered within less than a month.

²¹⁶⁶ Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012. [Waymade Employee] explained that *'[t]he problem is the assay method not the product [...]. This is the only issue I can see at the moment preventing us from launch'*. Document 202238, email from [X] to [X] dated 27 July 2012. In this email [X] asks DSG *'to develop a method for the assay of Hydrocortisone, validate it and transfer it to Aesica Queenborough in the UK'*. Document 301592, Amdipharm's Technical Monthly Report – July 2012. The Report records that *'DSG have been commissioned to improve the Hydrocortisone assay method to eliminate the low assay results that are causing the assay on stability being borderline above 95%'*. Document 301620, Amdipharm's Technical Monthly Report – October 2012. The Report records that *'Aesica have supplied samples to DSG to complete the Hydrocortisone assay improvement process'*.

²¹⁶⁷ In fact, before the 10mg MA was transferred, Waymade's strategy was to manufacture commercial batches and market them irrespective of optimising the assay method: *'On reviewing the stability data with [Waymade Employee] and [Waymade Senior Employee 1] the decision was to market now with the approved shelf life accept the limitations and not wait to change things'* (emphasis added). Document 300319, email from [X] to [Amdipharm Senior Employee] dated 19 October 2012.

²¹⁶⁸ Aesica did not consider this work to be a material difficulty for the development of 10mg hydrocortisone tablets. See Document 200292, paragraph 11.2, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

produced and with which AMCo entered the market in 2016.²¹⁶⁹ Accordingly, by October 2010, once process validation was completed and approved,²¹⁷⁰ Waymade had passed all the required steps to be in a position to produce a commercial supply of 10mg hydrocortisone tablets (with the exception of the optimisation of the assay method) – two years before it entered into the 10mg Agreement with Auden.²¹⁷¹ All Waymade required to launch the product was a MA and to produce a stock of tablets. It acquired that MA in the month before entering into the 10mg Agreement.

Entry was possible in the short term

- 6.238. The CMA concludes that when it entered into the 10mg Agreement, Waymade had the possibility independently to enter the market sufficiently quickly such that it exerted competitive pressure on Auden before actual entry into the market.
- 6.239. Waymade obtained its 10mg MA on 27 September 2012, thereby clearing the most important regulatory hurdle for market entry.
- 6.240. Although Waymade did not have any stock to supply the market at this stage, it did have an approved development process to produce 10mg hydrocortisone tablets on a commercial scale having completed process validation in October 2010.
- 6.241. Waymade explained to the CMA that [REDACTED].²¹⁷² Thus, on the basis of Waymade's own submission and assuming it had no hydrocortisone API in September 2012, Waymade was only around 5 to 6 months away from obtaining product it could sell onto the market.
- 6.242. This timeline is consistent with Aesica's estimates. During an interview with the CMA, [Aesica Employee] (a former Aesica employee) estimated that it would ordinarily only take six months from completion of process validation to produce a 10mg batch ready for sale.²¹⁷³ Aesica also told the CMA that it *'would likely not have needed to take further steps before it could supply to Waymade, but for the fact Waymade had not yet been granted a MA for the product.'*²¹⁷⁴

²¹⁶⁹ Document 200302, paragraph 5.1, Aesica's response to the CMA's section 26 notice dated 25 August 2016.

²¹⁷⁰ Document 200292, response to question 5, Aesica's response to the CMA's section 26 notice dated 15 June 2016.

²¹⁷¹ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 141.

²¹⁷² Document 01563, response to question 7, Waymade's response to the CMA's section 26 notice dated 4 May 2017.

²¹⁷³ Document 302539, transcript of [Aesica Employee] interview dated 30 October 2018 page 96, lines 2436 to 2437.

²¹⁷⁴ Document 200302, paragraph 1.3, Aesica's response to the CMA's section 26 notice dated 25 August 2016.

- 6.243. Contemporaneous documents also indicate that Waymade anticipated entering the market in the short term. Due diligence documents prepared for Project Ampule²¹⁷⁵ in October 2012 show that both Waymade's management and Cinven believed that Amdipharm's 10mg hydrocortisone tablets would be launched in 2013 and take market share from Auden. Deloitte reported that Amdipharm's management's plans with respect to skinny label tablets that these were '*planned to be launched in the UK in 2013, taking market share from the incumbent supplier*'.²¹⁷⁶
- 6.244. Therefore, by the time the MA was granted (on 27 September 2012) Waymade and Aesica considered that they were in a position to manufacture the product on a commercial scale enabling Waymade to enter the market. However, despite having previously treated the development of a 10mg hydrocortisone tablet as a priority, Waymade did not instruct Aesica to commence commercial production.²¹⁷⁷ In fact, had Waymade been committed to market entry, it could have asked Aesica to commence commercial manufacture prior to receiving its MA (since its product had passed process validation). If it had done this, it would have been in a position to launch its 10mg hydrocortisone tablet upon obtaining its MA (in the same way as Resolution did in 2016) (see Table 3.4).
- 6.245. Accordingly, the CMA concludes that, when it entered into the 10mg Agreement in October 2012, Waymade had the possibility to enter the market sufficiently quickly that it exerted competitive pressure on Auden before actual entry into the market, as is supported by the payments Auden agreed to make pursuant to the terms of the 10mg Agreement.
- 6.246. Any subsequent delays in manufacturing the product that were encountered by AMCo (discussed in section 6.C.II.b.iv ('*AMCo had taken sufficient preparatory steps to enter the market to show it had a firm intention and an inherent ability to do so*') below) were not foreseen by Waymade and Aesica at this time and therefore did not have an impact on the competitive pressure exerted by Waymade in October 2012. In any event, as explained below

²¹⁷⁵ Cinven's proposed acquisition of Amdipharm.

²¹⁷⁶ Document 202506, Deloitte report: 'Project Ampule' dated 23 October 2012, page 9.

²¹⁷⁷ Developing and registering a new assay method was not an impediment for Waymade to order a commercial batch of the product, as the assay method had no impact on the attributes of the tablets but rather on how to test and measure stability results, as explained at section 3.F.III.j.ii. Having positively identified the assay method as the reason behind the low stability results in July 2012 and being aware that the grant of the 10mg MA was imminent, it was open to Waymade to order a batch of commercial product to secure rapid entry. After several months of inactivity, Waymade's product development team intended to manufacture commercial batches of product in October 2012 but were told not to because the 10mg MA had already been included in the sale to Cinven. See Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012; Document 202238, email from [X] to [X] dated 27 July 2012; Document 202251, email from [Waymade Employee] to [Waymade Senior Employee 1] and others dated 14 August 2012 and Document 300319, email from [X] to [Amdipharm Senior Employee], [X], [X] and [Waymade Employee] dated 19 October 2012.

those delays do not undermine the CMA's finding that Waymade and subsequently AMCo were a potential competitor of Auden.

Entry was economically viable

- 6.247. The CMA concludes that Waymade's independent entry was economically viable.
- 6.248. The NHS Reimbursement Price of 10mg hydrocortisone tablets increased significantly during the course of 2008 from 70 pence per pack in January to £13.15 per pack in September 2008. At that time, Waymade's cost of producing its own 10mg hydrocortisone tablets (via Aesica) would have been significantly lower than the NHS Reimbursement Price: in December 2008, Aesica's initial proposal to Waymade for development and manufacture of hydrocortisone tablets set out '*[f]ull inclusive price for Hydrocortisone 10mg tablets in 1 x 30 tablet blister:GB [£1-£4] per pack*'.²¹⁷⁸ By October 2012, the Reimbursement Price had risen to £46.76 for 10mg hydrocortisone tablets. Waymade was fully aware of the profit margin by then: '*[t]he COG's are [£1-£4] a pack (3 years old). The selling price is currently over £40 a pack with a shortage in the market*'.²¹⁷⁹
- 6.249. Given the significant profit margin available from the level of the NHS Reimbursement Price, entry clearly was economically viable.
- 6.250. Unsurprisingly, Waymade's management considered the project a '*very hot priority*',²¹⁸⁰ and when Waymade was considering entering the market in February 2012, an internal email stated that '*[n]o matter what market share I use this [10mg hydrocortisone tablets] is a clear winner*'.²¹⁸¹
- 6.251. Waymade's 10mg MA post-dated the orphan designation protection afforded to Plenadren and therefore did not include the 'adrenal insufficiency in

²¹⁷⁸ Document 200295, 'Offer – Hydrocortisone 10 and 20mg Tablet Business' from Aesica to Waymade dated 23 December 2008.

²¹⁷⁹ Document 300319, email from [X] to [Amdipharm Senior Employee] dated 19 October 2012.

²¹⁸⁰ For example, in an email to Aesica on 9 April 2010, [X] forwarded his exchange with [Amdipharm Senior Employee] emphasising that '*this is a very hot priority. Within minutes a mail from [Amdipharm Senior Employee] and two calls from [Waymade Senior Employee 1]!!! [Waymade Senior Employee 1] has clearly told me this is a personal priority for him, he would appreciate we progress asap and appreciate this is very competitor sensitive, so must be completed discretely*' (Document 300039, email from [X] to [X] (Aesica) and [Aesica Employee] (Aesica) dated 9 April 2010). In addition to wanting to maintain pressure on Aesica to deliver saleable product, Waymade sought to ensure that its own actions did not cause unnecessary delays. For example, on 8 September 2010, [Waymade Senior Employee 3] chased [X] and [X]: '*Aesica sent this proposal through on 16 June. We are returning our first response on 08 September, a gap of precisely 12 weeks. This gap does not support the proposition that this is a key project for Waymade / Amdipharm and that we are progressing it with a sense of urgency whilst Aesica is being slow in progressing its actions. Please could we do our very best to execute actions in a timely fashion*' (Document 201696, email from [Waymade Senior Employee 3] to [X] and [X] dated 8 September 2010).

²¹⁸¹ Document 300222, Excel spreadsheet attached to Document 300221, email from [X] to [Amdipharm Senior Employee] dated 29 February 2012.

adults' indication. Nevertheless, as further described at sections 3.E.III and 3.E.IV and Annex D:

- a. the orphan designation did not preclude market demand for the skinny label product: not only did the orphan designation not cover the whole market, there was also the possibility of off-label dispensing, which was appreciated by key market players at the time. It is notable that the MHRA took no steps that would have prevented off-label dispensing prior to skinny label tablets being launched (for example by requiring a brand name to be used), as it was not concerned about patients switching from full to skinny label tablets;²¹⁸²
- b. various contemporaneous internal email exchanges between key Waymade staff indicate that they did not consider that the lack of an orphan indication would affect the economic viability of its skinny label 10mg tablets;
- c. documents related to the Fifth Cinven Fund's acquisition of Amdipharm, which post-date the MHRA's refusal to grant the '*adrenal insufficiency in adults indication*', show that Waymade expected to launch 10mg hydrocortisone tablets in 2013 '*with sales reaching £4.2m in the year after launch*';²¹⁸³
- d. Auden's conduct at the time of entering into the 10mg Agreement with Waymade clearly indicates that it perceived that Waymade could have successfully entered the market; and
- e. the economic viability of skinny label 10mg tablets is supported by the evidence of subsequent successful market entry by skinny label suppliers.

There were no insurmountable barriers to entry

- 6.252. The CMA concludes that there were no '*insurmountable barriers*' to Waymade's entry with 10mg hydrocortisone tablets, as Waymade understood at the time (otherwise it would not have developed the product to the brink of entry) and as corroborated by AMCo's subsequent entry into the market in May 2016.
- 6.253. The orphan designation afforded to Plenadren did not constitute an '*insurmountable*' barrier to Waymade and its real concrete possibilities of entering the market. As discussed at sections 3.E.III and 3.E.IV, Annex D

²¹⁸² See paragraphs 3.220 and 3.240-3.241

²¹⁸³ Document 202511, Pharmacloud report: 'Amdipharm: review of key products' dated 25 July 2012, page 10.

and paragraph 6.251 above, at the time, the orphan designation did not preclude market demand for the skinny label product; Waymade and Auden did not consider that it did so, and nor did they consider that it would prevent Waymade's entry into the market; and despite lacking the '*adrenal insufficiency in adults*' indication, suppliers of the skinny label product have subsequently successfully entered the market.

Additional factors which indicate the existence of potential competition: the 10mg Agreement and the value transfer

- 6.254. The very fact that Auden sought to conclude agreements with Waymade and made value transfers to Waymade when it was not yet on that market provides a strong indication that a competitive relationship existed between Auden and Waymade.^{2184, 2185}
- 6.255. The very generous terms of the 10mg Agreement and the fact that Auden entered into an agreement with Waymade offering supply of its 10mg hydrocortisone tablets at a significant discount to the rest of the market shows in itself that a '*competitive relationship existed*' between them, ie that Waymade's potential entry with 10mg hydrocortisone tablets exerted competitive pressure on Auden.²¹⁸⁶
- 6.256. Prior to the grant of Waymade's 10mg MA, Auden charged Waymade the market price of around £31.55 per pack for the supply of 10mg hydrocortisone tablets. However, this was reduced to £1 per pack from October 2012 – very shortly after Waymade obtained its 10mg MA. Prices charged to Auden's other customers remained at their original levels (ie around £31.55).

Auden perceived Waymade to be a competitive threat

- 6.257. In addition to the evidence of the existence of the agreement and the value transfer, the CMA has further evidence to show that Auden perceived Waymade to be a competitive threat at the time it entered into the 10mg Agreement in October 2012.
- 6.258. The timing of the price reduction set out at paragraph 6.256 above is no coincidence. It occurred because, once Waymade obtained a 10mg MA, Auden perceived it as a competitive threat that was worth buying off in order

²¹⁸⁴ See section 6.C.I.c.

²¹⁸⁵ Waymade recognised the competitive position between Waymade and Auden when it explained that '*[i]t is also not unusual for an MA holder to buy product from a competing MA holder where that competitor has developed a more reliable source of supply for the particular product.*' Document 200003, paragraph 11.4, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

²¹⁸⁶ C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 33.

to avoid having to compete which [Auden Senior Employee 1] explained: *'[w]e did not offer this price to other customers as those other customers would have been pure wholesalers, whereas Amdipharm [Waymade]²¹⁸⁷ was not only a wholesaler, but carried out a range of work including product development and product marketing and sales. [...] We wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well'*.²¹⁸⁸

- 6.259. Auden therefore clearly entered the 10mg Agreement in order to buy off Waymade's competitive threat.
- 6.260. Cinven and Auden/Actavis submitted that the CMA placed undue reliance on the incumbent's perception in relation to the question of the existence of potential competition.²¹⁸⁹ However, the case law is clear that the subjective perception of the incumbent is a relevant factor (as Auden/Actavis recognises):²¹⁹⁰ see, in this regard, paragraphs 6.83 to 6.86 of the legal framework section above. In line with the case law, the CMA has treated the incumbent's perception as a relevant consideration, albeit not a decisive one. As set out above, there is strong evidence to show that Auden/Actavis perceived a competitive threat from Waymade/AMCo, and, in concluding that there was a relationship of potential competition between the parties to the 10mg Agreement, the CMA has considered that evidence **alongside** the strong evidence as to Waymade/AMCo's objective ability to enter the market sufficiently quickly to exert a competitive threat.

The position in October 2012

- 6.261. Finally, Waymade submitted that it could not be a potential competitor to Auden in October 2012 having agreed to divest its MA with the Amdipharm group and being subject to a non-compete clause that precluded Waymade from commercialising 10mg tablets.²¹⁹¹
- 6.262. This representation cannot be accepted. In the agreement for the sale of the Amdipharm group, dated 13 October 2012, [Waymade Senior Employee 1] and [Waymade Employee] and the top company of the Waymade group (Verdot Limited) agreed that they would not for three years from the '*Completion Date*' be engaged in the business of selling or competing with

²¹⁸⁷ As set out at section 3.D.VI.a, Amdipharm was first a subsidiary of Waymade. It was transferred to Cinven in October 2012.

²¹⁸⁸ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 and 1.20.

²¹⁸⁹ Document 204967, Cinven's RSSO paragraphs 6.3(f), 6.53-6.59, Document 205217, Auden/Actavis's RSSO, paragraphs 7.7, 7.50-7.52.

²¹⁹⁰ Document 205217, Auden/Actavis' RSSO, paragraph 7.50

²¹⁹¹ Document 204903, Waymade's RSSO, paragraph 8.117; Document 206661, Waymade's RLOF, paragraph 1.7.

'Protected Products'.²¹⁹² This included those products sold under licences transferred from Waymade plc to Amdipharm UK Limited by the intra-group agreement of the same date. As explained in section 3.F.III.d.ii above, the parties treated 10mg tablets sold under Waymade plc's newly-obtained 10mg MA as covered by that intra-group agreement.

- 6.263. The sale of the Amdipharm group completed on 31 October 2012.
- 6.264. The CMA has found that Waymade, an undertaking including both Amdipharm UK Limited and Waymade plc, obtained the 10mg MA in September 2012, entered into the 10mg Agreement by 23 October 2012 at the latest and transferred that agreement to AMCo on 31 October 2012, when the sale of the Amdipharm group completed. The fact that [Waymade Senior Employee 1] and [Waymade Employee] and Verdot Limited agreed not to sell 10mg hydrocortisone tablets in competition with AMCo after the sale completed is irrelevant to that finding. Any commitment with respect to 10mg hydrocortisone tablets in the agreement for the sale of the Amdipharm group only had effect from 31 October 2012 and cannot therefore affect whether the Waymade undertaking was a potential competitor between obtaining the MA on 27 September 2012 and transferring that MA (and the 10mg Agreement) to AMCo on 31 October 2012. Until that date, the 10mg MA and associated product development – and therefore the competitive threat to Auden – remained within the Waymade undertaking.
- 6.265. This is demonstrated by the fact that in October 2012, shortly after Waymade had obtained its 10mg MA, Waymade received around £70,000 from Auden via the transfer of its margin on 2,000 packs. This deal was possible because the Waymade undertaking represented a competitive threat to Auden which materialised when Waymade plc obtained its MA on 27 September 2012. By 23 October 2012 at the latest, Waymade had leveraged that competitive threat to obtain a 97% discount on the price it had been paying to date for 10mg tablets. That discount was only available to Waymade in October 2012, in between obtaining the 10mg MA and transferring the MA to AMCo. After that the discount was exclusively available to AMCo.
- 6.266. The CMA has found that in exchange, Waymade agreed not to launch its 10mg tablets. However, in the absence of the 10mg Agreement, the Waymade undertaking was not restricted from launching 10mg tablets before the sale of the Amdipharm group completed.

²¹⁹² Document 200476, Sale and Purchase Agreement between Verdot Limited, [Waymade Senior Employee 1] and [Waymade Employee] (as sellers) and CCM Pharma Midco Limited (as buyer) of 13 October 2012.

6.267. This is demonstrated by the fact that contemporary documents show that Waymade's product development staff, before realising that the 10mg MA was included in the sale to Cinven, planned to produce commercial batches and begin selling Waymade's 10mg tablets.²¹⁹³

iv. AMCo was a potential competitor of Auden when it succeeded Waymade as counterparty to the 10mg Agreement on 31 October 2012

6.268. As described above, on 31 October 2012 the sale of the Amdipharm group to the Fifth Cinven Fund completed. Amdipharm UK Limited (and with it Waymade's 10mg MA, product development and relevant staff) ceased to be a part of the Waymade undertaking, and became part of the AMCo undertaking, from this date.

6.269. From 31 October 2012 until 24 June 2016 the 10mg Agreement continued, with the AMCo undertaking replacing the Waymade undertaking as Auden's counterparty.

6.270. For the reasons set out below, the CMA concludes that AMCo was a potential competitor to Auden at the time it succeeded Waymade as a counterparty to the 10mg Agreement with Auden on 31 October 2012. By that point in time, the Waymade undertaking had already taken '*sufficient preparatory steps*' to show its '*firm intention and an inherent ability*' to enter the market (as discussed in section 6.C.II.b.iii above), and these attributes were transferred to the AMCo undertaking by virtue of the sale of Amdipharm UK Limited. In other words, all the factors which made Waymade a potential competitor to Auden were transferred to AMCo. The AMCo undertaking effectively stepped into the Waymade undertaking's shoes as a potential competitor to Auden effective from 31 October 2012 and from this point onwards:

- a. AMCo had taken '*sufficient preparatory steps*' to show its '*firm intention and inherent ability*' to enter the market;
- b. there were no insurmountable barriers to entry;
- c. the existence of the agreement between Auden and AMCo and the value transfer are a strong indication that a competitive relationship existed; and
- d. Auden perceived AMCo to be a competitive threat.

²¹⁹³ Document 300319, email from [X] to [Amdipharm Senior Employee] dated 19 October 2012.

6.271. This conclusion is supported by the subsequent evidence contemporaneous with the period when AMCo remained a potential competitor up to its actual market entry in May 2016, which included the re-negotiation of the 10mg Agreement and the entry into the First Written Agreement and the Second Written Agreement, which is set out below.

AMCo had taken sufficient preparatory steps to enter the market to show it had a firm intention and an inherent ability to do so

6.272. The CMA concludes that AMCo had real concrete possibilities of entering the market and had taken '*sufficient preparatory steps*' to show its '*firm intention and an inherent ability*' to do so at the time it succeeded Waymade as a counterparty to the 10mg Agreement with Auden on 31 October 2012, having acquired a business with real concrete possibilities of entering the market (as set out in section 6.C.II.b.iii above) from this date.

Entry remained possible in the short term

6.273. The CMA concludes that AMCo had the possibility to launch its 10mg hydrocortisone tablet sufficiently quickly such that it exerted competitive pressure on Auden. The existence of such competitive pressure is supported by fact of the payments Auden made to AMCo from 31 October 2012 onwards in exchange for AMCo not launching its tablets (these payments are discussed section 6.D.II.b.ii ('*The payments to AMCo*'). Moreover, the (relatively minor) delays encountered during AMCo's further development with Aesica do not undermine this conclusion.

6.274. As discussed at paragraphs 6.238 to 6.246 above, at the time Waymade and Auden entered into the 10mg Agreement, Waymade had obtained an MA, and Waymade and Aesica considered that they were in a position to manufacture 10mg hydrocortisone tablets on a commercial scale. As such, Waymade was in a position to enter the market sufficiently quickly such that it exerted competitive pressure on Auden before actual entry into the market.

6.275. From the moment that Waymade's activities with respect to 10mg hydrocortisone tablets transferred to AMCo (that is, from 31 October 2012), AMCo replaced Waymade as the undertaking that had the ability to independently enter the market within a sufficiently short period to impose competitive pressure on Auden.²¹⁹⁴ Waymade's 10mg MA, the product development and relevant staff involved in the 10mg product development (see section 3.F.III.d.ii) all transferred from Waymade to AMCo, facilitating AMCo's ability to independently enter the market. (While AMCo did not have

²¹⁹⁴ See paragraphs 6.75 to 6.78.

any stock when it entered into the 10mg Agreement, that was because Waymade, despite developing a successful manufacturing process with Aesica and obtaining a MA, failed to order stock from Aesica to sell under that MA).²¹⁹⁵

- 6.276. However, AMCo did not take steps towards entering the market at this time because of the 10mg Agreement. In fact, AMCo did not meaningfully engage with the development of its 10mg hydrocortisone tablet until January 2014 and this engagement was only prompted by concerns that Auden would pull the plug on the 10mg Agreement and stop supplying 10mg tablets to AMCo, as set out further below.
- 6.277. When AMCo did engage with the development of its 10mg hydrocortisone tablet, it is striking exactly how close it (and its predecessor Waymade) were to being able to enter the market. In January 2014 AMCo engaged with the work on the optimisation of the assay method which Waymade had identified in July 2012 and which had been left outstanding by AMCo since the purchase of the 10mg MA in October 2012. This work was dealt with very quickly, taking Aesica less than a month to update the assay method and confirm that there were no inherent stability issues affecting AMCo's 10mg hydrocortisone tablets (see sections 3.F.III.f.i and 3.F.III.f.ii). It also took AMCo less than a month to register the '*minor changes in the test procedure, assay, for the finished product*'.²¹⁹⁶
- 6.278. In January 2014, AMCo also took the decision that it wished to sell its 10mg hydrocortisone tablets in blister packs, rather than the glass bottles Waymade had planned. Therefore, in addition to optimising the assay method, AMCo also bought and installed an automated tablet feeder at Aesica's facilities to enable the 10mg tablet to be blister packed.²¹⁹⁷ Despite encountering some difficulties, the installation and commissioning of the blister feeder was achieved within two months.²¹⁹⁸
- 6.279. None of this further work undermines the CMA's finding that AMCo (and Waymade before it) was a potential competitor to Auden, or supports the

²¹⁹⁵ As noted above in the legal framework section at paragraph 6.72, it is not a pre-requisite for the existence of potential competition that AMCo itself possessed any stock at the time at which it became a party to the 10mg Agreement.

²¹⁹⁶ Document 201871, letter from the MHRA to AMCo dated 1 May 2014.

²¹⁹⁷ Document 200292, response to question 11, Aesica's response to the CMA's section 26 notice dated 15 June 2016. Aesica considered that '*there were no material difficulties in the development of 10mg hydrocortisone tablets*' as explained at paragraph 11.2 of its response.

²¹⁹⁸ The blister feeder was ordered on 17 February 2014, delivered to Aesica on 29 April 2014 and installed on 30 April 2014. The commissioning of the feeder was initially unsuccessful but, after further testing, it was successfully commissioned on 2 July 2014. See, for example, Document 200292, response to question 11, Aesica's response to the CMA's section 26 notice dated 15 June 2016; Document 201865, email from [Aesica Employee] to [AMCo Employee] dated 1 May 2014; and Document 202705, email from [Aesica Employee] to [AMCo Senior Employee 7] dated 2 July 2014.

contention that AMCo's ability to enter the market was no more than a '*hypothetical possibility*'.²¹⁹⁹

- 6.280. First, in order to determine whether an undertaking is a potential competitor in the market, it is necessary to determine whether, at the time the relevant agreement was concluded, the undertaking in question had taken '*sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure* [on the incumbent]'.²²⁰⁰ As discussed above, at the point at which the 10mg Agreement was entered into, Waymade was already imposing competitive pressure on Auden and this position passed to AMCo from 31 October 2012 onwards (as indicated by the payments Auden made pursuant to the 10mg Agreement, first to Waymade and then to AMCo).
- 6.281. Second, although further development work was necessary before AMCo would have been able to launch its own 10mg tablet, that work was limited in nature and meant that throughout the relevant period AMCo was in a position to enter the market '*within such a period of time as would impose competitive pressure*'²²⁰¹ on Auden. From 31 October 2012 AMCo was never further away than around six to eight months from having market-ready 10mg hydrocortisone tablets with which it could have independently entered the market as set out further below. This is supported by each instance where AMCo made a serious push for obtaining market-ready product. In January 2014, following concerns that Auden may stop supply to AMCo, AMCo significantly stepped up its efforts to develop the product and was in a position to launch it by the summer of 2014. AMCo again mothballed the development process in June and July of 2014 when it secured ongoing discounted supply of 10mg tablets from Auden.
- 6.282. In February 2015, AMCo was again concerned that the 10mg Agreement might come to an end following Allergan's acquisition of Auden. This concern again prompted AMCo to step up its development of its own 10mg tablet. Again, the advanced nature of AMCo's development process was reflected by the fact that it received saleable product from Aesica in October 2015 (despite Aesica having previously been told to discontinue the project completely). Since a sufficiently short period to exert competitive pressure may well significantly exceed a year (see paragraphs 6.76 to 6.78, above), the speed with which AMCo was able to get market ready 10mg hydrocortisone tablets when it re-engaged in the development process in

²¹⁹⁹ Document 204967, Cinven's RSSO, paragraph 6.48(d).

²²⁰⁰ C-307/18 *Generics (UK) and others v CMA* EU:C:2020:52, paragraph 43.

²²⁰¹ C-591/16P *Lundbeck v Commission* EU:C:2021:241, paragraph 57.

both 2014 and 2015 indicates that it was in a position to exert competitive pressure on Auden from 31 October 2012 onwards.

- 6.283. AMCo did not prioritise the Aesica 10mg development during 2013 as it continued to receive supplies from Auden under the 10mg Agreement. The Aesica 10mg development only became a priority in January 2014 in light of the increasing uncertainty around the continuity of supply from Auden as set out below and as set out in Annex C AMCo only engaged with the remaining development work at that stage.
- 6.284. During 2013, AMCo only considered the Aesica 10mg Development to be a '*[p]rotective project to ensure continuity of supply*'²²⁰² and a '*back up plan*' '*in the event that other supply sources fail us, for whatever reason*'.²²⁰³ Although Aesica manufactured a batch of 10mg hydrocortisone tablets for AMCo in October 2013, AMCo did not take a decision as to how to pack these tablets. Later in December 2013, AMCo identified that the assay results of the July 2010 10mg Validation Batches²²⁰⁴ were 'Out of Specification' which prompted AMCo to engage with the optimisation of the assay method with Aesica.
- 6.285. In January 2014, AMCo was negotiating with Auden in relation to a formal supply agreement (see sections 3.F.III.f and 3.F.III.g) but proved unsuccessful in securing higher supply volumes and ultimately rescinded its offer to contract with Auden after the end of the existing arrangement at the end of March 2014. Until then, the Aesica 10mg development had been described within AMCo as '*a bit of a ham-fisted effort to date*',²²⁰⁵ but in January 2014 it became '*an unusual project and really urgent*'.²²⁰⁶ From then onwards, AMCo decided to pack the tablets manufactured in October 2013 in blisters and resolved the assay issues by submitting a variation to the MHRA in early April 2014, which was approved by the MHRA within a month (see section 3.F.III.f.ii).
- 6.286. In March 2014, AMCo was aiming to enter the market in May 2014. Despite some delays in May and June 2014, the contemporaneous documentary evidence confirms that at the date of entering into the Second Written

²²⁰² Document 202593, Hydrocortisone 10mg Tablets, slide 1, attached to Document 202592, email from [AMCo Employee] to [AMCo Employee] dated 18 December 2013.

²²⁰³ Document 202599, email from [AMCo Senior Employee 2] to [AMCo Employee], [REDACTED], [AMCo Employee] and [REDACTED] dated 2 January 2014.

²²⁰⁴ Document 202591, email from [Aesica Employee] to [AMCo Employee] dated 2 December 2013; Document 201733, Stability Data – Hydrocortisone 10mg tablets dated 2 December 2013; and Document 201734, Stability Data – Hydrocortisone 10mg tablets dated 2 December 2013.

²²⁰⁵ Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014.

²²⁰⁶ Document 202609, email from [AMCo Employee] to [REDACTED] dated 17 January 2014.

Agreement on 25 June 2014 AMCo understood it had market ready stock which was due to be delivered by Aesica imminently.

- 6.287. Instead of launching the Aesica-manufactured 10mg tablet, AMCo used the threat of its imminent potential entry as leverage in its negotiations with Auden and declared its potential to enter the market during these negotiations.²²⁰⁷ For example, [AMCo Senior Employee 1] reported internally that he had used AMCo's competitive threat to Auden to negotiate for an increased volume (supply of 12,000 packs) of 10mg hydrocortisone tablets, stating that he had told Auden's chief executive: *'I told him that if not we will launch our own'*.²²⁰⁸ In interview, [AMCo Senior Employee 1] confirmed this interpretation of the email, explaining that *'I wanted him [Auden Senior Employee 1] to understand that we were able to launch'* because he thought *'that it [AMCo's ability to enter] was more likely to help him [Auden Senior Employee 1] give me some better terms'*.²²⁰⁹
- 6.288. Further contemporaneous evidence confirms that AMCo understood it had or was about to have market ready stock. For example, on 28 June 2014 (three days after entering into the Second Written Agreement) [AMCo Senior Employee 1] (AMCo's [X]) and primary negotiator with Auden) thanked AMCo staff for *'bringing the Aesica Hydrocortisone product to a position where we are able to launch'* and for providing *'certainty of launch of our product'*.²²¹⁰ Further, [AMCo Senior Employee 7] (AMCo's [X]) referred to the Aesica-manufactured 10mg stock as being *'available for sale'* on 10 July 2014.²²¹¹
- 6.289. Accordingly, from the point AMCo started prioritising the Aesica 10mg Development (ie January 2014), it only took it around 7-8 months to obtain a market-ready product from Aesica (by early August). There is nothing to suggest that AMCo's position would be any different had it decided to prioritise the Aesica 10mg Development immediately after 31 October 2012.
- 6.290. However, despite having what it understood to be market ready 10mg hydrocortisone tablets, AMCo did not enter the market due to the Second Written Agreement: AMCo reported internally in June 2014 that *'Hydrocortisone 10mg batches manufactured and ready for sale ... however,*

²²⁰⁷ As set out above, the CAT has considered that an undertaking which holds a MA and *'with a declared intention of entering the market in the near future'* should be regarded as a potential competitor (see *Lexon (UK) Limited v Competition and Markets Authority* [2021] CAT 5, paragraph 234).

²²⁰⁸ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 15 June 2014.

²²⁰⁹ Document 201997, [AMCo Senior Employee 1] interview transcript dated 7 June 2018, page 25 lines 1 and 10 to 11. See also pages 2-3.

²²¹⁰ Document 200126, email from [AMCo Senior Employee 1] to [AMCo Employee], [AMCo Senior Employee 7], [AMCo Employee] and others dated 28 June 2014 (emphasis added).

²²¹¹ Document 202705, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 10 July 2014.

these won't be sold due to a deal extension being signed with Auden McKenzie'.²²¹²

- 6.291. Following and because of the Second Written Agreement, AMCo paused its activities with Aesica: it was decided to '*advise Aesica that the project is now parked*' and '*cancel the order for the 4th batch and any other subsequent orders that have been placed with Aesica*'.²²¹³ Further to this decision, [AMCo Senior Employee 5] ([X]) emailed Aesica on 27 June 2014 to inform them that AMCo's '*Hydrocortisone tablet project will be suspended for the UK territory*'.²²¹⁴ Nevertheless, AMCo decided to '*continue with the packing of the three available batches at Aesica*' and store them '*as a contingency against failure to supply from Auden*'.²²¹⁵ Those were delivered to AMCo in August 2014 (the August 2014 Batches).
- 6.292. The parties have made various representations to the effect that AMCo could not have been a potential competitor to Auden/Actavis prior to November 2015, due to certain development issues experienced with Aesica subsequent to the initial entry into the 10mg Agreement. As a matter of principle, the existence of potential competition is to be assessed at the point of conclusion of the agreement concerned, and the fact that actual entry may ultimately have taken longer than anticipated does not demonstrate that the relevant contracting parties were not potential competitors at the time of their agreement.²²¹⁶ Without prejudice to that point of principle, the parties' detailed representations on the development issues are addressed in Annex C to this Decision. The short point is that these representations do not establish that there was no relationship of potential competition between Auden/Actavis and AMCo prior to November 2015 when AMCo had a saleable product.

Entry continued to be economically viable

- 6.293. The CMA concludes that AMCo's entry was economically viable.
- 6.294. At the time when AMCo succeeded Waymade as a counterparty to the 10mg Agreement with Auden, the NHS Reimbursement Price of 10mg hydrocortisone tablets in October/November 2012 was over £46 and increasing, and AMCo's cost of producing its own 10mg hydrocortisone tablets (via Aesica) would have been significantly lower than that: in August

²²¹² Document 200192, the June 2014 Strategic Development – Monthly Report, page 8 (emphasis added).

²²¹³ Document 200124, email of [AMCo Senior Employee 5] to [AMCo Senior Employee 2], [AMCo Senior Employee 7], [AMCo Employee] and others dated 25 June 2014.

²²¹⁴ Document 200275, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 27 June 2014.

²²¹⁵ Document 200124, email of [AMCo Senior Employee 5] to [AMCo Senior Employee 2], [AMCo Senior Employee 7], [AMCo Employee] and others dated 25 June 2014.

²²¹⁶ See paragraphs 6.71 and 6.78 above.

2013, Aesica's proposal to AMCo specified cost of goods of [£1-£4] per bottle of 10mg hydrocortisone tablets.^{2217,2218} Indeed, Cinven had recognised the importance of AMCo's 10mg hydrocortisone tablets MA in mid-2012 in the run-up to its acquisition of Amdipharm UK: according to Waymade Cinven was '*very insistent on acquiring it*'.²²¹⁹ This is indicative of the considerable value a professional investor like Cinven attached to the MA and supports that entry on the basis of that MA was considered to be economically viable.

6.295. The economic viability of independent entry is further supported by the subsequent evidence contemporaneous with the period when AMCo rescinded its offer to contract with Auden after the end of the existing arrangement at the end of March 2014 and started prioritising the Aesica 10mg Development:

- a. AMCo's internal profit projections in January 2014 estimated that AMCo would be able to enter the market with its 10mg hydrocortisone tablets at a price of £38 per pack and achieve sales of 12,000 packs per month with a cost of goods of [£1-£4] per pack. This equated to annual revenues of upwards of £5.47m for the period of 2015 to 2018 with gross profit of 94%.²²²⁰
- b. AMCo dedicated considerable resources to developing a product which would be ready for launch: AMCo's senior management and Board approved the development of the Aesica-manufactured product on a number of occasions throughout the duration of the 10mg Agreement.²²²¹ AMCo would not have done this if it did not believe that its skinny label product was economically viable: AMCo's conduct in pursuing the project shows it believed that entry was economically viable.

6.296. AMCo's 10mg MA post-dated the orphan designation protection afforded to Plenadren and therefore did not include the '*adrenal insufficiency in adults*'

²²¹⁷ Document 202578, letter from [Aesica Employee] to [AMCo Employee] dated 13 August 2013.

²²¹⁸ Although in January 2014 it was ultimately decided to pack the October 2013 bulk batch in blisters (see Document 200076, letter from [Aesica Employee] to [AMCo Employee] dated 9 January 2014), the price of manufacture including packing in blisters was approximately [£1-£4] per blister pack and therefore significantly lower than the NHS Reimbursement Price.

²²¹⁹ Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016, paragraph 6.1.

²²²⁰ Document 200090, Product Development: Hydrocortisone 10mg tablets, 22nd Jan 2014, PPRM, slide 10.

²²²¹ For example, AMCo informed the CMA that on 20 January 2014, the Amdipharm Board approved '*pushing ahead with the development and manufacture of the reduced indication 10mg hydrocortisone tablets to be packaged in blister packs of 30*' (Document 200288, Chronology of 'Amdipharm's Development of Reduced Indication 10mg Hydrocortisone', submitted on a voluntary basis by AMCo on 14 October 2016, page 5). Further, the CMA notes that the progress of the Aesica 10mg Development was regularly reported to the AMCo Board (see, for example, Document 200167, minutes of a meeting of the Board of Directors of Amdipharm Mercury Limited dated 29 January 2014).

indication. Nevertheless as further described at sections 3.E.III and 3.E.IV and Annex D:

- a. the orphan designation did not preclude market demand for the skinny label product: not only did the orphan designation not cover the whole market, there was also the possibility of off-label dispensing, which was appreciated by key market players at the time. It is notable that the MHRA took no steps that would have prevented off-label dispensing prior to skinny label tablets being launched (for example by requiring a brand name to be used), as it was not concerned about patients switching from full to skinny label tablets;²²²²
- b. various contemporaneous internal email exchanges between key AMCo staff indicate that they did not consider the lack of an indication for adrenal insufficiency in adults would affect the economic viability of its skinny label tablet throughout the term of the 10mg Agreement;
- c. Auden's conduct throughout the period that AMCo was party to the 10mg Agreement clearly indicates that it perceived that AMCo could have successfully entered the market; and
- d. the economic viability of skinny label 10mg tablets is supported by the evidence of subsequent successful market entry by skinny label suppliers including AMCo itself.

There were no insurmountable barriers to entry

- 6.297. The CMA concludes that there were no '*insurmountable barriers*' to AMCo's entry with 10mg hydrocortisone tablets, as AMCo understood at the time (otherwise it would not have developed the product to the brink of entry) and as corroborated by its subsequent independent entry into the market in May 2016.
- 6.298. The orphan designation afforded to Plenadren did not constitute an '*insurmountable barrier*' to AMCo entering the market and therefore being considered a potential competitor. As described at sections 3.E.III and 3.E.IV, Annex D and paragraph 6.296 above, at the time, the orphan designation did not preclude market demand for the skinny label product;

²²²² See paragraphs 3.220 and 3.240-3.241

AMCo submitted that the evidence cited in the Letter of Facts relating to market demand (discussed in sections 3.E.III and 3.E.IV and Annex D) is relevant only to whether the Orphan Designation was an insurmountable barrier to entry, and not the CMA's case that AMCo was a potential competitor to Auden/Actavis (Document 206670, AMCo's RLOF, paragraph 5.3). This submission must be dismissed: the market demand for the product that is demonstrated by this evidence (and the contemporaneous evidence it corroborates) clearly also shows that entry would have been economically viable and supports the CMA's entire case that AMCo had taken '*sufficient preparatory steps to enter the market to show it had a firm intention and an inherent ability to do so*'.

AMCo and Auden did not consider that it did so, and nor did they consider that it would prevent AMCo's entry into the market; and despite lacking the '*adrenal insufficiency in adults*' indication, suppliers of the skinny label product have subsequently successfully entered the market.

Relevance of legal advice received by AMCo concerning potential competition

6.299. AMCo, Cinven and Auden/Actavis submitted that AMCo received legal advice that it could not be considered a potential competitor while the orphan designation is in place. The parties contend that:

- a. AMCo obtained advice from a Pinsent Masons regulatory specialist that '*the OD [orphan designation] cannot be challenged*' and AMCo refers to the '*insurmountable OD issue*' throughout its representations. It therefore looked to source full label 10mg hydrocortisone tablets from Auden.²²²³
- b. Both the First and Second Written Agreements were cleared for competition law compliance by Pinsent Masons. In particular, Pinsent Masons reviewed the draft Second Written Agreement, after AMCo sought advice as to whether it was '*appropriate and legally compliant*' for AMCo to enter into this agreement. Pinsent Masons advised AMCo that Auden and AMCo '*would not be considered competitors whilst the orphan designation was in place*'. AMCo states that it received '*unambiguous legal advice*' to the effect it was not a potential competitor to Auden for 10mg hydrocortisone tablets.²²²⁴

6.300. In section 10.B.II.e.iv, the CMA addresses the relevance of the legal advice to the question of penalties. As explained there, the advice does not take into account essential facts of which AMCo was aware but of which it did not inform its external legal advisers. In any case, the legal advice was obtained after AMCo was already a party to the 10mg Agreement (from 31 October 2012).

6.301. It must also be noted that the legal advice provided in June 2014 cannot affect the objective analysis of whether at the crucial points assessed by the CMA (the start of the 10mg Agreement in October 2012, its transfer to AMCo at the end of that month, and its renewal in June 2014), AMCo had real

²²²³ Document 204922, AMCo's RSSO, paragraphs 3.24, 3.37.2, 3.52, 3.223, 3.617-3.621, 3.679, 3.686-3.687; Document 204967, Cinven's RSSO, paragraphs 3.47, 3.54, 4.18, 9.18, 10.11 – 10.10.13; Document 205217, Auden/Actavis's RSSO, paragraph 7.7, paragraph 11.25.1; Document 204903, Waymade's RSSO, paragraph 8.127.

²²²⁴ Document 204922, AMCo's RSSO, paragraphs 3.376, 3.384-5, 3.625-3.631 (2013 advice on the unwritten supply arrangements), 3.693 – 3.703 4.96. AMCo refers throughout to Document 201971, email from external adviser to [AMCo Senior Employee 8] dated 6 June 2014.

concrete possibilities to enter the relevant market within a sufficiently short period of time. This is particularly so where that advice does not consider whether AMCo could compete for the indications that were not covered by the orphan designation or the possibility that pharmacists might dispense the product off-label. Both possibilities were actively considered by AMCo's commercial staff, particularly in the period leading up to the June 2014 advice and the renewal of the 10mg Agreement in the same month. Both possibilities later turned out to be successful routes to market for a considerable number of entrants.

- 6.302. Further, AMCo's assertion that it relied on the legal advice as indicating that it could not enter the 10mg market is inconsistent with the contemporary evidence showing AMCo's perception of the impact of the orphan designation at the time. It is clear that AMCo understood that there would have been some market demand for its skinny label tablets, both from the indications that are not covered by the orphan designation and by the potential of pharmacists dispensing off-label to patients falling within the protected indication (see further sections 3.E.III and 3.E.IV and Annex D). It is also inconsistent with the fact that AMCo used its skinny label tablets to exert leverage over Auden/Actavis, including [AMCo Senior Employee 1]'s threat to [Auden Senior Employee 1] that if [Auden Senior Employee 1] did not continue to supply AMCo, '*we will launch our own*'.²²²⁵

Additional factors which indicate the existence of potential competition: the 10mg Agreement and the value transfer

- 6.303. The very fact that Auden sought to conclude agreements with AMCo and made value transfers to AMCo when it was not yet on that market provides a strong indication that a competitive relationship existed between Auden and AMCo.²²²⁶
- 6.304. The CMA concludes that Auden perceived AMCo to be a competitive threat at the time it acquired Waymade's MA and this resulted in it continuing the 10mg Agreement. When Cinven acquired Amdipharm and merged it with Mercury to form AMCo, it acquired Waymade's 10mg hydrocortisone business (including the 10mg MA). From that point, Auden perceived AMCo rather than Waymade as a competitive threat.
- 6.305. AMCo benefitted from a very low price for the 10mg hydrocortisone tablets it purchased from Auden. By contrast Auden stopped selling 10mg

²²²⁵ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 15 June 2014.

²²²⁶ See section 6.C.I.c.

hydrocortisone tablets to Waymade at a heavily discounted price, and instead Waymade sourced its requirements from AMCo at the standard market rate.²²²⁷

6.306. Auden's perception of the competitive threat AMCo posed is further evidenced by the increased payments (in a form of increased supply volumes from 6,000 to 12,000 packs per month) Auden made to AMCo under the Second Written Agreement after the latter had threatened to launch its own 10mg hydrocortisone tablets.²²²⁸

6.307. These additional factors are a strong indication of a competitive relationship.

Auden perceived AMCo to be a competitive threat

6.308. In addition to the evidence of the existence of the agreement and the value transfer, the CMA has further contemporaneous documentary evidence and witness evidence to show that Auden perceived AMCo to be a competitive threat. As explained in section 6.D.II.c.ii²²²⁹ below, the competitive relationship between AMCo and Auden was the rationale given for the 10mg Agreement by both [Auden Senior Employee 1] and [Amdipharm Senior Employee] of AMCo. [Auden Senior Employee 1] stated that the 10mg Agreement protected its volume commitments to its CMO.²²³⁰

6.309. As discussed in section 3.F.III.h, Auden launched Project Guardian in early 2014²²³¹ in response to the competitive threat AMCo posed because it believed AMCo's 10mg hydrocortisone tablet '*threaten[ed] to weaken Auden Mckenzie's market share*',²²³² given that it '*may be adopted as a cheaper alternative*'.²²³³

6.310. Contrary to a representation made by AMCo to the effect that Project Guardian does not constitute evidence of potential competition,²²³⁴ the contemporaneous evidence is clear that Project Guardian was a response to the threat of market entry by AMCo, with a clear motivation being Auden's

²²²⁷ Document 200003, paragraph 11.13, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

²²²⁸ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 15 June 2014.

²²²⁹ See also section 6.D.III.c.ii (in response to the representations on '*The supply deals 'sought to maintain Auden/Actavis's CMO volumes*')

²²³⁰ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.16.

²²³¹ For a detailed account of the steps that Auden took to defend its position in the market against the potential launch of skinny label product by AMCo, and later, Orion, see sections 3.F.III.h, 3.F.III.i and 3.F.III.m.

²²³² Document 00062F, Professional Advice (Hydrocortisone) Proposal Prepared for Auden Mckenzie (Pharma Division) Ltd by [Auden's External Consultant], dated 6 February 2014, page 2.

²²³³ Document 00137, 'A communications proposal to support Project Guardian', submitted by Salix Consulting dated 16 April 2014, slide 3.

²²³⁴ Document 204922, AMCo's RSSO, paragraph 4.72.

desire to maintain its market share. Auden/Actavis has made no representations on the CMA's findings with respect to Project Guardian.

6.311. Subsequently, during the operation of the Second Written Agreement and in the lead-up to Actavis plc's (subsequently renamed Allergan plc) acquisition of Auden, Actavis plc also considered skinny label products to be such a competitive threat that it affected the outcome of its negotiations with Auden and, ultimately, significantly reduced the purchase price by over £200m:

- a. An internal Auden email from [Auden Senior Employee 1] stated that in November 2014 (ie around the time Orion was granted a 10mg MA), *'Actavis were seriously concerned about the new Orion license [sic] been [sic] used "Off label" and the impact this would have on their investment if they acquired Auden.'*²²³⁵
- b. In a financial model Actavis plc prepared in the run-up to its acquisition of Auden in December 2014, entry by competitors without the adrenal insufficiency indication was envisaged, with their hydrocortisone tablets being *'dispensed off label'*. Actavis plc projected competition from skinny label suppliers leading to a *'share erosion of 60% and price erosion of 90%'*.²²³⁶
- c. This led to a reduction in the purchase price for the Auden business. When Actavis plc acquired Auden, the purchase price for the shares was significantly reduced: from £520 million to £300 million plus royalty payments.²²³⁷ The purpose of this concession was to offer Actavis plc *'a total and complete de risking of Hydrocortisone for Actavis'*.²²³⁸

6.312. The CMA therefore concludes that Auden considered AMCo to be a competitive threat.

v. The orphan designation was not an insurmountable barrier to entry to the holder of the MA for 10mg hydrocortisone tablets

6.313. As set out in sections 3.E.III and 3.E.IV, Annex D and paragraphs 6.251 and 6.296, the orphan designation did not preclude market demand for the skinny label 10mg product, and AMCo, Waymade and Auden/Actavis clearly

²²³⁵ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015, but this indicates that the issue was raised in meetings about Actavis UK's interest in acquiring Auden on 20 November 2014.

²²³⁶ Document 00679, Auden presentation dated December 2014, slide 4. While this evidence is from a later date than the start date of the Agreements, the CMA has not seen any evidence to indicate that the orphan designation would have had a materially different impact on entry at an earlier stage.

²²³⁷ See section 3.D.VI.g.

²²³⁸ Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

expected there to be demand for skinny label 10mg hydrocortisone tablets throughout the relevant period notwithstanding it, as borne out by the receptivity of customers to the skinny label product upon Alissa's market entry in October 2015. Based on this evidence the CMA concludes that the orphan designation afforded to Plenadren did not constitute an '*insurmountable barrier*' to market entry by the holder of the MA for skinny label 10mg hydrocortisone tablets (i.e. first Waymade, and then AMCo), and the parties did not believe it was at the time. It may at most have acted as a barrier to expansion following entry. In any event, as set out above, market entry with a skinny label tablet was clearly an economically viable strategy, and Auden perceived Waymade (and later AMCo) to be a competitive threat. In any case, the orphan designation only protected the '*adrenal insufficiency in adults*' indication, not the other indications for which 10mg hydrocortisone tablets could be used, and therefore the market was clearly not closed off in its entirety to skinny label suppliers. Alissa entered the market on the basis of its expectation of taking market share in that segment only.²²³⁹

Representations on the relevance of the orphan designation in relation to the existence of potential competition

- 6.314. The parties have made a range of representations in which the consistent theme is that there was no demand or uncertainty of demand for skinny label tablets at the relevant time, especially as a result of the orphan designation, and that there was therefore no relationship of potential competition between the parties to the 10mg Agreement.²²⁴⁰
- 6.315. The issue of off-label dispensing and customer demand in the context of the orphan designation is addressed in sections 3.E.III and 3.E.IV and Annex D. In summary, contrary to this submission, the evidence considered in that section shows that throughout the period prior to Alissa's entry in October 2015, the orphan designation did not preclude demand for skinny label products, and that there was an expectation in the market that there would be demand for skinny label tablets once they were launched, even if the extent of such potential demand was uncertain. Insofar as these submissions are said to be relevant to the question of potential competition, the CMA therefore rejects these representations.

²²³⁹ Document 206413, note of call between the CMA and Alissa, paragraph 2.4.

²²⁴⁰ Document 204922, AMCo's RSSO, paragraphs 3.802-3.807, 3.680, 4.93-4.97, 6.52; Document 204903, Waymade's RSSO, paragraphs 8.118-8.129; Document 204967, Cinven's RSSO, paragraphs 6.12-6.13, 6.31-6.38, 6.38, 6.52(d), 6.61-6.70; Document 205217, Auden/Actavis' RSSO, paragraphs 2.8, 7.38-7.42; Document 206670, AMCo's RLOF, paragraphs 4.1-4.13, 5.11, 5.15-5.142, 6.31-6.42; Document 206665, Cinven's RLOF, paragraphs 1.11-1.12, 3.4-3.8 and 3.10-3.32; Document 206667, Auden/Actavis' RLOF, paragraphs 3.13-3.15.

6.316. There is a substantial overlap between these points and aspects of the parties' representations on market definition, which the CMA addresses within section 4.B above).²²⁴¹

D. Agreements restricting competition by object

I. Legal framework

6.317. The Chapter I prohibition prohibits agreements between undertakings which have as their object or effect the prevention, restriction or distortion of competition and which may affect trade within the UK.

6.318. Such agreements are illegal, unless exempt under section 9 of the Act.

a. Agreement

6.319. An agreement is '*a concurrence of wills between at least two parties, the form in which it is manifested being unimportant, so long as it constitutes the faithful expression of the parties' intention*'.²²⁴²

6.320. The European General Court has held that in order to establish a concurrence of wills '*it is sufficient that the undertakings in question should have expressed their joint intention to conduct themselves on the market in a specific way*'.²²⁴³

6.321. Courts have also described the concept of an agreement as a '*common understanding*' between the parties – which has the same meaning as '*concurrence of wills*'. For example, in its judgment in *Hitachi*, the European General Court held that: '*the Commission was right to find that the common understanding constituted an agreement between undertakings within the meaning of Article [101](1)*'.²²⁴⁴

6.322. That a party may have played only a limited part in setting up an agreement, may not be fully committed to its implementation, or may have participated only under pressure from another party, does not mean that it is not party to

²²⁴¹ AMCo, Cinven and Auden/Actavis's representations on the relevance of AMCo's legal advice to its understanding of AMCo's position as a potential competitor is addressed at section 10.B.II.e.iv.

²²⁴² T-41/96 *Bayer AG v Commission*, EU:T:2000:242, paragraph 69 (upheld on appeal in Joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure eV and Commission v Bayer AG*, EU:C:2004:2, paragraphs 96 to 97).

²²⁴³ T-7/89 *SA Hercules Chemicals NV v Commission*, EU:T:1991:75, paragraph 256.

²²⁴⁴ T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 272.

the agreement.²²⁴⁵ That a party ‘cheats’ on the agreement also does not absolve it.²²⁴⁶ *The CAT has confirmed that:*

‘An agreement, in our view, can be constituted by an “understanding” even if there is nothing to prevent either party from going back on, or disregarding, the understanding in question.’²²⁴⁷

6.323. The form of an agreement is unimportant, and in particular it is not necessary that an agreement is formal or legally binding: agreements may include written contracts, oral agreements and ‘morally’ binding ‘gentlemen’s agreements’.²²⁴⁸

6.324. The European General Court has held that:

‘the commitment of a group of producers not to enter a market reserved to the other group ... is based on a simple concept which may be implemented easily. Similarly, its implementation does not require, in principle, interaction between the undertakings concerned. Consequently, such a commitment is perfectly capable of existing as an unwritten understanding, which also reduces the likelihood of its discovery’.²²⁴⁹

6.325. An agreement therefore need not be articulated by the parties explicitly. It may not be necessary for the parties to refer in their discussions to their common understanding, which may ‘go without saying’ *‘since the content of that understanding was understood, accepted and implemented by all the participants in the cartel without the need for any specific discussion on it.’²²⁵⁰* This may be particularly likely where the common understanding consists of *‘a mere commitment not to act’* – for example, not to enter a market.²²⁵¹

²²⁴⁵ *Agreements and Concerted Practices (OFT401)*, December 2004 (adopted by the CMA Board), paragraph 2.8. See also *T-25/95 Cimenteries CBR and Others v Commission*, EU:T:2000:77, paragraphs 1389 and 2557 (this judgment was upheld on liability by the European Court of Justice in Joined Cases C-204/00 P etc. *Aalborg Portland A/S and Others v Commission*, EU:C:2004:6, although the fine was reduced); and *C-49/92 P Commission v Anic Participazioni SpA*, EU:C:1999:356, paragraphs 79 to 80.

²²⁴⁶ *T-141/89 Trefileurope v Commission*, EU:T:1995:62, paragraphs 53 to 60.

²²⁴⁷ *Argos and Littlewoods v OFT* [2004] CAT 24, paragraph 658.

²²⁴⁸ *C-41/69 ACF Chemiefarma NV v Commission*, EU:C:1970:71, in particular paragraphs 106 to 114. Compare *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2004] CAT 24 at paragraph 658. See also Commission Decision 2003/675/EC *Video Games, Nintendo Distribution and Omega-Nintendo* [2003] OJ L255/33, paragraph 247.

²²⁴⁹ *T-112/07 Hitachi v Commission*, EU:T:2011:342, paragraph 91. See also *T-133/07 Mitsubishi v Commission* EU:T:2011:345, paragraph 186. Upheld on further appeal in *C-239/11*, *C-489/11* and *C-498/11 Siemens and Others v Commission*, EU:C:2013:866.

²²⁵⁰ *T-112/07 Hitachi v Commission*, EU:T:2011:342, paragraphs 141 and 269.

²²⁵¹ *T-112/07 Hitachi v Commission*, EU:T:2011:342, paragraph 141.

6.326. The conduct of the parties may amount to an expression of their joint intention to conduct themselves on the market in a specific way. The European Court of Justice held in the *Bayer* case that:

*‘the existence of an agreement within the meaning of that provision [Article 101(1) TFEU] can be deduced from the conduct of the parties concerned’.*²²⁵²

b. Restriction of competition by object

6.327. To come within the Chapter I prohibition, an agreement must have ‘as [its] object or effect’ the prevention, restriction or distortion of competition within the UK. It is settled case law that certain types of coordination between undertakings reveal a sufficient degree of harm to competition, such that there is no need to examine their effects.²²⁵³ That case law arises from the fact that certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition.²²⁵⁴

6.328. The term ‘object’ in the Chapter I prohibition refers to the sense of ‘aim’, ‘purpose’, or ‘objective’ of the coordination between undertakings in question.²²⁵⁵ This is assessed objectively. It is not necessary to establish that the parties jointly intended, subjectively, to pursue an anti-competitive aim – only that they had a common understanding whose terms, assessed objectively, pursue or result in such an aim.²²⁵⁶

6.329. An agreement may be regarded as having an anti-competitive object even if it does not have a restriction of competition as its sole aim but also pursues other, legitimate, objectives. The European Court of Justice has held that:

‘even supposing it to be established that the parties to an agreement acted without any subjective intention of restricting competition ... such

²²⁵² C-2&3/01 P *BAI and Commission v Bayer* [2004] ECR I-23, paragraph 100. See also T-168/1 *GlaxoSmithKline Services Unlimited v Commission*, ECLI:EU:T:2006:265, paragraphs 82-83: the existence of an agreement may be established by ‘indirect evidence, for example in the form of conduct’.

²²⁵³ C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 26; and C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 49.

²²⁵⁴ C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 26; and C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 50.

²²⁵⁵ See, for example, respectively: 56/64 *Consten & Grundig v Commission*, EU:C:1966:41, paragraph 343; 96/82 *IAZ and Others v Commission*, EU:C:1983:310, paragraph 25; C-209/07 *Competition Authority v Beef Industry Development Society*, EU:C:2008:643, paragraphs 32 to 33.

²²⁵⁶ T-168/01 *GlaxoSmithKline Services Unlimited v Commission*, EU:T:2006:265, paragraph 77 (upheld on appeal in Joined cases C-501/06P etc *GlaxoSmithKline Services Unlimited v Commission*, EU:C:2009:610). See also C-614/16 P *Merck v Commission*, paragraph 92: ‘characterisation as a ‘restriction by object’ does not require that parties to those agreements pursue an anticompetitive objective, even though such an objective may nevertheless be taken into consideration’.

*considerations are irrelevant for the purposes of applying that provision [Article 101].*²²⁵⁷

- 6.330. In order to determine whether an agreement objectively reveals a sufficient degree of harm such as to constitute a restriction of competition by object, regard must be had to:
- a. the economic and legal context of which it forms a part;
 - b. its content; and
 - c. its objectives.²²⁵⁸
- 6.331. It is well-established that an agreement need not be implemented to infringe the prohibition on anti-competitive agreements, including to amount to a restriction of competition by object.²²⁵⁹ However, evidence of the parties' conduct showing that the agreement was implemented may corroborate the assessment of its content and objectives.²²⁶⁰ The European Commission's *Guidance on the Application of Article 101(3)* states: '*The way in which an agreement is actually implemented may reveal a restriction of competition by object even where the formal agreement does not contain an express provision to that effect*'.²²⁶¹
- 6.332. Although the parties' subjective intentions are not a necessary factor in determining whether an agreement is restrictive of competition, those intentions may be taken into account as corroboration of the objective assessment.²²⁶²

i. Market sharing and market exclusion

- 6.333. The Chapter I prohibition expressly applies in particular to agreements or practices which:
- a. share markets or sources of supply; or

²²⁵⁷ C-209/07 *Competition Authority v Beef Industry Development Society*, EU:C:2008:643, paragraph 21.

²²⁵⁸ C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 53, citing C-32/11 *Allianz Hungaria v Commission*, EU:C:2013:160, paragraph 36 and the case law cited. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 27.

²²⁵⁹ C-277/87 *Sandoz v Commission*; *WANO Schwarpulver*, OJ 1978 L232/26, [1979] 1 CMLR 403; Case 19/77 *Miller v Commission*, paragraphs 7 to 10. See also COMP/37750 *French Beer*, [2006] 4 CMLR 577, paragraph 68.

²²⁶⁰ C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraphs 81 to 88.

²²⁶¹ *European Commission Guidance on the Application of Article 101(3)*, recital 22.

²²⁶² C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 54; and C-286/13 P *Dole v Commission*, EU:C:2015:184, paragraph 118. See also C-32/11 *Allianz Hungaria v Commission*, EU:C:2013:160, paragraph 37 and the case law cited.

- b. limit or control production, markets, technical development or investment.

6.334. The European Court of Justice has consistently held that market sharing constitutes a particularly serious breach of the competition rules.²²⁶³ It has also consistently held that agreements that aim to share markets have, in themselves, an object restrictive of competition, and that such an object cannot be justified by an analysis of the economic context of the anti-competitive conduct concerned.²²⁶⁴

6.335. The European General Court has held that ‘*The exclusion of competitors from the market constitutes an extreme form of market sharing and of limitation of production*’.²²⁶⁵

6.336. In the *Irish Beef* case, the Irish Competition Authority challenged a mechanism (the so-called BIDS arrangements) to reduce perceived overcapacity in the Irish beef sector. As part of the BIDS arrangements, the undertakings that stayed in the market paid financial compensation to those who agreed to leave. The European Court of Justice held:

‘The BIDS arrangements are intended therefore, essentially, to enable several undertakings to implement a common policy which has as its object the encouragement of some of them to withdraw from the market and the reduction, as a consequence, of the overcapacity which affects their profitability by preventing them from achieving economies of scale.

That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article 81(1) EC [now 101(1)] is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between undertakings for the risks of competition.

In the context of competition, the undertakings which signed the BIDS arrangements would have, without such arrangements, no means of improving their profitability other than by intensifying their commercial rivalry or resorting to concentrations. With the BIDS arrangements it would be possible for them to avoid such a process and to share a

²²⁶³ C-373/14 *Toshiba Corporation v Commission*, EU:C:2016:26, paragraph 28; C-449/11 *Solvay Solaxis v Commission*, EU:C:2013:802, paragraph 82; and C-408/12 *YKK and Others v Commission*, EU:C:2014:2153, paragraph 26.

²²⁶⁴ C-373/14 *Toshiba Corporation v Commission*, EU:C:2016:26, paragraph 28; and C-239/11, C-489/11 and C-498/11 *Siemens and Others v Commission*, EU:C:2013:866, paragraph 218.

²²⁶⁵ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 435 (emphasis added).

large part of the costs involved in increasing the degree of market concentration...'.²²⁶⁶

- 6.337. The European Court of Justice concluded that the arrangements in question were a restriction of competition by object. Advocate General Trstenjak, whose Opinion the Court followed, characterised the arrangements as ‘*the “buying off” of competition*’.²²⁶⁷
- 6.338. In *Cartes Bancaires*, the European Court of Justice explained that ‘*The object of the BIDS arrangements was ... to change, appreciably, the structure of the market through a mechanism intended to encourage the withdrawal of competitors*’.²²⁶⁸
- 6.339. In the pharmaceutical industry, the European Commission and the CMA have issued a number of decisions finding that agreements involving incumbent pharmaceutical companies making payments to potential generic entrants to delay or abandon their efforts to enter the market independently are comparable to market exclusion and constitute restrictions of competition by object: *Lundbeck*,²²⁶⁹ *Perindopril (Servier)*²²⁷⁰ and *Fentanyl*²²⁷¹ in the EU and *Paroxetine*²²⁷² in the UK. These types of agreements are commonly known as ‘pay for delay’ agreements. They are essentially variations on ‘classic’ market exclusion agreements such as those in *Irish Beef* and *Toshiba*, with (in most cases) the additional complexity of a patent context.
- 6.340. Specifically, in its *Lundbeck* judgment, the European General Court upheld a decision by the European Commission that so-called ‘pay for delay’ agreements entered into between a patent holder and potential generic entrants were ‘*comparable to market exclusion agreements, which are among the most serious restrictions of competition*’.²²⁷³ In its *Servier* judgment, the European General Court held with respect to such agreements that ‘*Where there is an inducement, the agreements in question must be regarded as being market exclusion agreements, in which the stayers are to compensate the goers*’.²²⁷⁴ In both the *Lundbeck* and *Servier*

²²⁶⁶ C-209/07 *BIDS*, EU:C:2008:643, paragraphs 33 to 35.

²²⁶⁷ Opinion of AG Trstenjak in C-209/07 *BIDS*, EU:C:2008:467, paragraph 77. Compare T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 352. See also the European Commission’s *International Removal Services* decision (Commission decision of 11 March 2008 in Case 38.543 *International Removal Services*): in its *Lundbeck* decision the Commission explained that the competitors in *International Removal Services* paid each other not to compete, and as a result all undertakings fared better, at the expense of higher consumer prices (Commission decision of 19 June 2013 in Case 39.227 *Lundbeck*, footnote 1178).

²²⁶⁸ C-67/13 P *Groupeement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 84.

²²⁶⁹ Commission decision of 19 June 2013 in Case 39.227 *Lundbeck*.

²²⁷⁰ Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*.

²²⁷¹ Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.

²²⁷² *GSK v CMA* [2018] CAT 4 (*Paroxetine*).

²²⁷³ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 435.

²²⁷⁴ T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 233.

judgments, the General Court characterised these agreements as ‘*a buying-off of competition*’.²²⁷⁵ In both cases, the General Court held that these agreements were restrictions by object.²²⁷⁶

- 6.341. Unlike the present case, *Lundbeck*, *Servier* and *Paroxetine* all concerned patent litigation. All three cases concerned originator companies with patented drugs, facing the threat of entry by generics and in some cases seeking to end patent litigation with those generics through settlement agreements. The Commission’s analysis of the agreements in *Lundbeck* and *Servier* was substantively upheld on appeal by the European General Court and (in the case of *Lundbeck*) the European Court of Justice,²²⁷⁷ with the exception of the agreement between Servier and Krka, in respect of which the General Court annulled the Commission’s decision because the agreements at issue (settlement agreements combined with ancillary licence and assignment agreements) could not be shown to contain value transfers to Krka.²²⁷⁸
- 6.342. The patent context was a key factor in the CAT’s decision to refer the *Paroxetine* case to the European Court of Justice: although the CAT found that the agreements in question ‘*amounted to a monopoly supplier ... agreeing to share a significant but limited part of the market with independent distributors of its own product*’,²²⁷⁹ it referred to the Court specific questions on whether the agreements amounted to infringements of competition law in circumstances where there were pending court proceedings relating to the validity and/or infringement of the relevant patent. In its judgment, the CAT noted that:

*‘the patent position cannot be ignored, and this situation cannot be equated to a simple agreement for exclusion of a potential competitor from the market or for market sharing’.*²²⁸⁰

²²⁷⁵ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 352; and T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 233.

²²⁷⁶ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 476; and T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 233.

²²⁷⁷ C-591/16 P *Lundbeck v Commission*; C-588/16 P *Generics (UK) v Commission*; C-586/16 P *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*; C-601/16 P *Arrow Group v Commission*; C-611/16 P *Xellia Pharmaceuticals and Alpharma v Commission*; C-614/16 P *Merck v Commission*. The Court of Justice found that the General Court had relied on the wrong case law in relation to one procedural argument in the Xellia/Alpharma appeal; however the appeal on this point did not succeed because the General Court’s findings could be upheld on the basis of other factors (paragraphs 144-157).

²²⁷⁸ T-684/14 *Krka Tovarna v Commission*, EU:T:2018:918.

²²⁷⁹ GSK v CMA [2018] CAT 4 (*Paroxetine*), paragraph 303.

²²⁸⁰ GSK v CMA [2018] CAT 4 (*Paroxetine*), paragraphs 244 and 303 (emphasis added).

- 6.343. Following the Court of Justice's judgment, the CAT upheld the CMA's findings that the agreements amounted to restrictions of competition by object.²²⁸¹
- 6.344. For the purposes of assessing whether the agreements at issue in each of *Lundbeck*, *Perindopril (Servier)* and *Fentanyl* revealed in themselves a sufficient degree of harm to competition to amount to restrictions 'by object', the European Commission took into account the following factors relating to the content, the context and the objectives of those agreements:²²⁸²
- a. the potential entrant and the incumbent were at least potential competitors;
 - b. the agreements involved a payment (or 'value transfer') from the incumbent to the potential entrant; and
 - c. in return, '*the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter into one or more ... markets with a generic product*'.²²⁸³
- 6.345. The CMA took those factors into account in its *Paroxetine* decision, in which it found that GSK and two generic companies had entered into anti-competitive agreements by object. GSK made cash payments and other value transfers to the generic companies in return for which the generic companies accepted restrictions on their ability to enter the market independently.²²⁸⁴
- 6.346. These factors are relevant to establishing a market exclusion agreement, whether or not in a patent context. However, in the absence of a patent context (such as in the present case, which involves unbranded, generic drugs long off-patent and in the third phase of the drug lifecycle, when exclusivity is lost), establishing a restriction of competition by object where a potential competitor agrees not to enter the market is more straightforward since it is not necessary to consider whether that agreement not to enter reflects potentially legitimate recognition of the strength of a patent.

²²⁸¹ *GSK v CMA* [2021] CAT 9, paragraphs 33-58.

²²⁸² Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1154; Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 661; and Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 219.

²²⁸³ Or, in the *Fentanyl* case: '*due to the Agreement, the generic undertaking limited, for the duration of the Agreement, its independent efforts to enter the market with its generic product*' (Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, paragraph 219).

²²⁸⁴ CMA decision in case CE-9531/11 *Paroxetine*, sections 6.E and 6.G.

Potential competition

6.347. The legal framework for potential competition is set out in paragraphs 6.62 to 6.86 above.

Payment (or 'value transfer')

6.348. A relevant question is whether the incumbent made a payment, also known as value transfer, to the potential entrant.

6.349. A payment may, for example, be in cash. In some cases, cash payments have been given spurious labels, attributing them to fictitious or negligible services provided by the potential entrant. In *Fentanyl*, the payments were expressed to relate to promotional activities, though their value far exceeded that of the minimal activities carried out.²²⁸⁵ In *Paroxetine*, the CAT noted that the parties' descriptions of payments as 'marketing payments' or 'promotional allowances' were '*simply convenient labels selected for what was part of the overall financial consideration ... We find it remarkable, and somewhat revealing, that the parties chose in the formal agreements to designate these payments in a manner that we find was misleading.*'²²⁸⁶

6.350. A payment may also be '*through a more covert transfer of value*' than cash.²²⁸⁷

6.351. For example, in *Paroxetine* the agreements involved the supply of specified volumes of product for the potential entrants to sell on their own account. The CAT held that '*the CMA was correct to regard the margin which the generic company was likely to earn on the specified volumes supplied as part of the consideration*'.²²⁸⁸ The CAT found that:

'So long as no other generic company was able to enter the market with an independent product, the generic companies could expect to sell the paroxetine supplied by IVAX for at least the PI price'.²²⁸⁹

6.352. The European Court of Justice confirmed the CAT's (and the CMA's) analysis of the properties of these supply agreements, holding that they amounted to value transfers or payments.²²⁹⁰

²²⁸⁵ The limited promotional activities are summarised at paragraph 274 of Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.

²²⁸⁶ *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 179 to 180. See also *GSK v CMA* [2021] CAT 9, paragraph 47. Compare T-208/08 *Gosselin v Commission*, in which cartelists issued each other with invoices for common payments on rejected offers, or offers not made, '*referring to fictitious services*' (paragraph 12).

²²⁸⁷ Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 660.

²²⁸⁸ *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 184.

²²⁸⁹ *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 184.

²²⁹⁰ C-307/18 *GSK v Commission*, paragraphs 90-91 and 109.

- 6.353. Similarly, in *Servier*, one of the agreements provided, in addition to cash payments, for Servier to supply Teva with a defined quantity of product to be distributed in Teva livery (or pay damages for non-supply).²²⁹¹ In *Lundbeck*, part of the consideration for non-entry in some of the relevant agreements was the supply by Lundbeck of a specified volume of the drug citalopram at a substantial discount for GUK and Ranbaxy to sell in their territories.²²⁹² In its judgment on Sun Pharmaceutical Industries and Ranbaxy's appeal, the European General Court agreed with the Commission that these supplies were part of the consideration granted to Ranbaxy, and pointed out that the discount involved Lundbeck giving up the profits it would have made in selling the product itself.²²⁹³ The European Court of Justice upheld the General Court.²²⁹⁴
- 6.354. An incumbent may therefore pay a potential entrant in the form of a transfer of its margin on specified quantities of product: it pays by supplying product to the potential entrant at an artificially low supply price, allowing the potential entrant to make a profit margin on resale.

In return for non-entry (or delayed entry)

- 6.355. The key factor is whether, in return for the payment, the potential entrant gave a commitment not to enter the market.
- 6.356. As is the case for any agreement (see paragraphs 6.319 to 6.326 above), such a commitment need not be explicit, but can be a common understanding between the parties. In *Paroxetine*, for example, the CAT stated:

*'Although under the IVAX Agreement there was no contractual restriction on IVAX entering the UK market independently (by contrast with the position under the GUK and Alparma Agreements), we have no doubt that this was the intention and understanding of the parties.'*²²⁹⁵

²²⁹¹ Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1578.

²²⁹² T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* EU:T:2016:453, paragraphs 246-251.

²²⁹³ T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* EU:T:2016:453, paragraph 249.

²²⁹⁴ C-586/16 P *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*.

²²⁹⁵ *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 422.

II. Agreements for the purpose of the Chapter I prohibition

a. Conclusions

i. The 20mg Agreement

6.357. As explained in paragraph 6.3 above, the CMA concludes that from 11 July 2011 to 30 April 2015 Auden and Waymade shared a common understanding that:

- a. Auden would supply Waymade with 20mg hydrocortisone tablets on terms that amounted to monthly payments (or 'value transfers') to Waymade; and
- b. In exchange for these payments, Waymade would not enter the market independently with its own 20mg hydrocortisone tablets.

6.358. The CMA refers to this common understanding as the 20mg Agreement. The CMA concludes that the 20mg Agreement amounts to an 'agreement' for the purposes of the Chapter I prohibition.

ii. The 10mg Agreement

6.359. As explained in paragraph 6.17 above, the CMA concludes that between 23 October 2012 and 24 June 2016, Auden/Actavis shared a common understanding first with Waymade, and then with AMCo, that:

- a. Auden/Actavis would supply first Waymade, and then AMCo, with 10mg hydrocortisone tablets on terms that amounted to monthly payments (or 'value transfers') to them; and
- b. In exchange for these payments, each of Waymade and AMCo would not enter the market independently with its own 10mg hydrocortisone tablets.

6.360. The CMA refers to this common understanding as the 10mg Agreement. The CMA concludes that the 10mg Agreement amounts to an 'agreement' for the purposes of the Chapter I prohibition:

- a. From 23 to 30 October 2012, between Auden and Waymade; and
- b. From 31 October 2012 to 24 June 2016, between Auden/Actavis and AMCo.²²⁹⁶

²²⁹⁶ AMCo succeeded Waymade as counterparty to the 10mg Agreement from 31 October 2012 onwards. Actavis continued the 10mg Agreement from 1 September 2015 onwards.

b. Auden/Actavis agreed to supply Waymade and AMCo with hydrocortisone tablets on terms that amounted to monthly payments (or ‘value transfers’) to them

6.361. The terms on which Auden/Actavis supplied Waymade and AMCo with hydrocortisone tablets amounted to significant monthly payments to them.

6.362. The monthly payments in the **20mg Agreement** comprised the following:

- a. 800 packs (later 928 and 982) were ‘supplied’ (on paper only) at a ‘*special price*’:²²⁹⁷ £4.50 per pack (an 87% discount to the rest of the market). These packs were to be immediately ‘sold back’ to Auden at approximately market rate (initially²²⁹⁸ £34.50 per pack) so that in practice Auden simply made a substantial monthly cash payment to Waymade (the **Buyback**); and
- b. 200 packs were supplied to Waymade every month, also at a ‘*special price*’²²⁹⁹ (initially²³⁰⁰ £4.50 per pack), for Waymade to sell to its own customers for a profit.

6.363. In relation to 20mg tablets, the majority of the monthly payments were therefore in cash, under the Buyback.

6.364. The Buyback was a ‘supply’ on paper only: these packs never left Auden’s warehouse.

6.365. As explained in section 3.F.III.b above, the parties agreed that Auden would ‘*invoice us [Waymade] the stock at the special price [£4.50] and we immediately sell back 800 of them to you at £34.50*’.²³⁰¹ The Buyback therefore involved direct cash payments to Waymade, initially of £24,000 per month. The ‘*special price*’ was an 87% discount to market rate. The quantity of packs subject to the Buyback remained 800 per month until April 2013, when it increased to 928. In December 2013 there was one further increase, to 982 packs per month.²³⁰²

²²⁹⁷ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

²²⁹⁸ The price at which these packs were ‘bought back’ by Auden increased during the term of the 20mg Agreement (see table 3.26 above).

²²⁹⁹ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

²³⁰⁰ The price at which the 200 packs were supplied to Waymade increased during the term of the 20mg Agreement, though this was more than compensated for by the overall increasing value of the payments to Waymade (see table 3.26 above).

²³⁰¹ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

²³⁰² Document 200003, paragraph 11.10, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016.

- 6.366. The remainder of the monthly payments to Waymade were by way of the transfer of Auden's margin on the 200 packs given to Waymade each month for resale.²³⁰³ These packs were also supplied at a '*special price*' (initially £4.50 per pack),²³⁰⁴ allowing Waymade to make a profit when selling them to its customers.
- 6.367. The monthly payments in the **10mg Agreement** were entirely by way of the transfer of Auden/Actavis's margin on the packs given to Waymade and AMCo each month for resale. These packs were supplied at a 97% discount to market rate throughout the 10mg Agreement, allowing Waymade and AMCo to make a profit when selling them to their customers. They comprised the following:
- a. in October 2012, Waymade received 2,000 packs at £1 per pack;
 - b. between 31 October 2012 and 31 December 2012, AMCo received 2,000 packs per month at £1 per pack;
 - c. between 1 January 2013 and 24 June 2014, AMCo received 6,000 packs per month at £1 per pack; and
 - d. between 25 June 2014 and 24 June 2016, AMCo received 12,000 packs per month at £1.78 per pack.
- 6.368. The volume of 10mg hydrocortisone tablets supplied to Waymade at £1 per pack – 2,000 packs per month – is shown by data supplied by Waymade: Waymade purchased a total of 3,500 packs of 10mg hydrocortisone tablets from Auden in October 2012, but the price of £1 per pack (a 97% discount to market rate) only applied to 2,000 of them, with the remaining 1,500 packs costing the regular price of £34.50.²³⁰⁵
- 6.369. The volumes supplied to AMCo are shown by data supplied by Auden/Actavis, AMCo and Waymade (which acted as agent for AMCo in relation to 10mg hydrocortisone tablets after the sale of the Amdipharm

²³⁰³ Waymade was supplied with 200 packs during most months of the 20mg Agreement's term. In other months it received between 0 and 650 packs. This reflected variations in individual monthly orders corrected in subsequent months to ensure an average of 200 packs per month across the whole term of the 20mg Agreement. See table 3.26 above. The agreement between the parties was that Waymade would receive 200 packs per month. See Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011 and response from [Auden Senior Employee 2]: '*we are ok with the idea to Invoice us the stock at the special price and we immediately sell back 800 of them to you at £34.50. The problem we have as I suspected is the other 200, where we are not willing to compromise on the agreed terms of these coming to us also at the special price.*' [Auden Senior Employee 2] replied, '*agree that we will go with the terms below*' and asked Waymade to submit the first order '*and we will despatch the 200 for you*'.

²³⁰⁴ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

²³⁰⁵ Document 200010, data supplied by Waymade on its purchases of hydrocortisone tablets from Auden.

group), and by contemporaneous evidence.²³⁰⁶ See sections 3.F.III.g.i and 3.F.III.j.i above.

6.370. In addition to the cash payments to Waymade under the Buyback, Auden/Actavis therefore made value transfers to each of Waymade and AMCo by supplying them with specified volumes at a very substantial discount, which allowed them to make a significant profit margin on resale. Such value transfers are a means of payment. It is well-established that a payment may consist of the transfer of the incumbent's margin on specified volumes of product.²³⁰⁷

i. The value of the payments under the 20mg Agreement

6.371. At the start of the 20mg Agreement in July 2011, the total value of the payments from Auden to Waymade was around £30,000 per month comprising:

- a. A cash payment from Auden to Waymade, initially of £24,000 per month (the Buyback);²³⁰⁸ and
- b. 200 packs per month at an 87% discount compared to prices charged to all other customers, which Waymade could expect to sell at a substantial profit (around £30 per pack, or £6,000 per month) if it sold all 200 packs at the prevailing rate of £34.50.

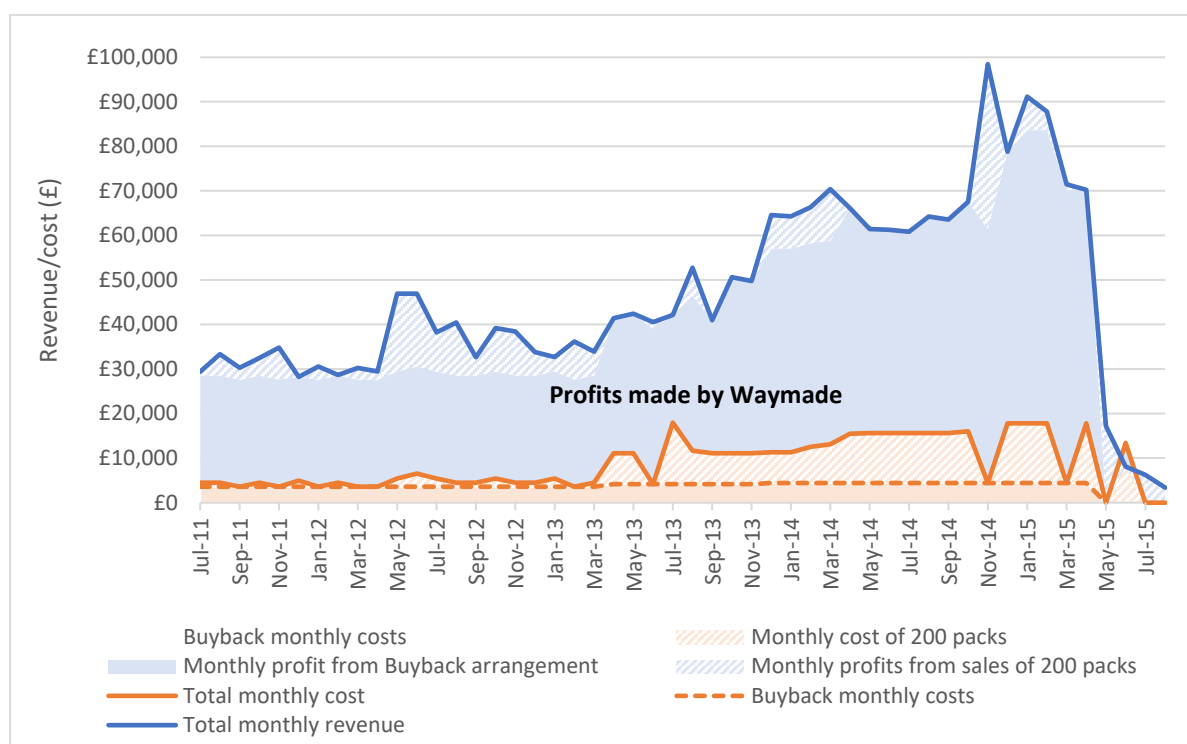
6.372. The value of the 20mg Agreement to Waymade is shown in figure 6.1 below.

²³⁰⁶ Documents 00674, 00448 and 200010 (data provided by Auden/Actavis, AMCo and Waymade, respectively). See also Document 202008, AMCo purchase orders and invoices relating to 10mg tablets. The data indicate that AMCo received 7,000 packs at the £1 price in January 2013, and 6,000 packs thereafter until June 2014 (in some months 0 packs, corrected in the subsequent month to 12,000 to ensure 6,000 on average until the volumes increased in the Second Written Agreement). However, the First Written Agreement, which was backdated to 1 January 2013, specified 6,000 packs per month. When he prepared to negotiate that agreement, [Amdipharm Senior Employee] stated: *'We have been receiving 6,000 packs per month since January [2013] although initially this was via Waymade'* (Document 202526, email from [Amdipharm Senior Employee] to [X] dated 1 August 2013). AMCo received 12,200 packs in December 2014; however, only the 12,000 packs were supplied at the £1.78 price.

²³⁰⁷ See, for example, Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 660; *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 184 and 293; C-307/18 *GSK v CMA*, paragraphs 90-91 and 109. See also Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1578; and T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* EU:T:2016:453, paragraph 249, upheld in C-586/16 P *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*.

²³⁰⁸ The resale price to Auden of the 800 packs Waymade 'received' for £4.50 per pack under the Buyback was to be £34.50. The Buyback therefore equated to a cash payment of £24,000 per month initially.

Figure 6.1: Waymade's 'profit'* from the 20mg Agreement



Source: CMA analysis based on data submitted by relevant parties.

* Waymade provided no services in exchange for the 20mg Agreement

Note: this figure shows the same data as presented in table 3.26, with the exception that in months where the value of the margin transfer from the sale of packs supplied to Waymade for sale to its own customers was negative, this has been subtracted from the value of the cash transfer from the Buyback packs for presentational ease (without affecting the total value transferred to Waymade).

- 6.373. As figure 6.1 shows, the monthly payments to Waymade increased during the term of the 20mg Agreement.
- 6.374. The value transferred to Waymade under the 20mg Agreement increased from around £30,000 per month initially to more than £55,000 per month in 2014, to more than £65,000 per month in 2015.²³⁰⁹
- 6.375. As the figure shows, the majority of the increase in value to Waymade is accounted for by the cash payments under the Buyback, which Auden continued to pay until the 20mg Agreement ended. As Waymade itself has confirmed: *'The money transferred by Auden Mckenzie to Waymade per pack pursuant to this arrangement continued to increase from October 2013, in line with increase in prices in the market'*.²³¹⁰ As explained above, Auden would 'buy back' at market rate the 800 packs it had 'supplied' to Waymade. Because prices in the market increased substantially through Auden's own conduct (Auden's price to customers that did not hold a 20mg MA and

²³⁰⁹ See also table 3.26 above.

²³¹⁰ Document 200003, paragraph 11.10, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

therefore did not pose a competitive threat to Auden increased from around £33 per pack to a peak of around £70 per pack during the 20mg Agreement), while the price at which Auden ‘supplied’ Waymade remained £4.50, the amount of the Buyback grew month over month.

- 6.376. The Buyback was given a label for accounting purposes, however it was not reflective of any work carried out by Waymade on behalf of Auden.²³¹¹ Within Waymade, the Buyback was referred to as a ‘*Fee re Hydrocortisone*’, ‘*Promotional Fee*’, or ‘*Marketing Fee*’, and was added to net profit calculations.²³¹² Waymade issued regular invoices to Auden for payment of the Buyback, attributing those fees (amounting to at least £24,000 per month) to ‘*PROMO. SERVICES IN RES. OF HYD 20MG*’.²³¹³
- 6.377. This was, however, purely an accounting mechanism to implement the Buyback arrangement. As a monopoly supplier of an important drug, Auden did not need to procure such services. Indeed, no services corresponding to the invoices ever took place and there is no evidence that Waymade provided services of any description to Auden:
- a. [Auden Senior Employee 2] – who was Auden’s customer relationship manager for Waymade and who was named on Waymade’s invoices as the relevant customer contact at Auden – was unable to explain why Waymade was invoicing Auden for ‘*promotional services*’ in interview. When asked whether he knew what promotional work Waymade was doing to justify those sums, he said: ‘*Didn’t need to know really*’. He stated: ‘*that’s something [Auden Senior Employee 1]] agreed*’.²³¹⁴
 - b. [Auden Senior Employee 1], when asked in interview why these monthly payments were attributed to promotional services, said ‘*I have no idea ... it’s not me that came up with that*’. He stated that he could not recall Waymade ever providing any promotional services to Auden on hydrocortisone tablets.²³¹⁵

²³¹¹ Compare *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 179 to 180; *GSK v CMA* [2021] CAT 9, paragraph 47.

²³¹² For example, Waymade included a £24,000 ‘*Fee re Hydrocortisone*’ in its sales figures when preparing divisional financial statements: Document 300760, spreadsheet attached to Document 300758, email from [Waymade Employee] to [X] dated 16 December 2011. Document 300275, email from [X] to [Waymade Senior Employee 1] dated 24 July 2012, refers to a £24,000 per month ‘*Promotional Fee*’. Document 300785, Excel spreadsheet attached to email from [Waymade Senior Employee 2] to [Waymade Senior Employee 1] dated 27 March 2013, referred to a ‘*Marketing Fee*’.

²³¹³ For example, Document 300594 and Document 300572, Waymade purchase orders for 20mg hydrocortisone tablets dated 25 October 2012 and 25 February 2013.

²³¹⁴ Document 301352, transcript of interview with [Auden Senior Employee 2] dated 23 May 2018, CD2 page 15 line 3 to page 16 line 26.

²³¹⁵ Document 301380, transcript of interview with [Auden Senior Employee 1] dated 23 May 2018, page 56 lines 18-27 and page 57 lines 1-12.

- c. [Amdipharm Senior Employee] also confirmed that the invoices did not relate to promotional services and stated: *'I can't explain why it's attributed in that way.'*²³¹⁶
- d. [Waymade Employee] of Waymade stated that he had *'not a clue'* why these sums were attributed to promotional services.²³¹⁷
- e. [Waymade Senior Employee 1] stated that Waymade provided promotional services to Auden in exchange for the monthly payments under the Buyback. He stated that these monthly payments reflected that *'We are promoting their products, their product here, to our customers. He [[Auden Senior Employee 1]] did not have access to these customers.'*²³¹⁸ However, Waymade never sold the 800 packs subject to the Buyback to its customers. It 'sold them back' to Auden immediately and they never left Auden's warehouse.
- f. [Waymade Senior Employee 4] of Waymade stated that because the invoices under the Buyback related to *'a non-stock item ... You can't sell what you haven't got'*, Waymade's invoicing system required it to assign a code, and that Waymade had used the pre-existing code 'Promotional Services' *'for general use just for invoicing out': 'it's just a way of getting it into the system and getting it recorded so you can use the system to do your invoicing'*.²³¹⁹

6.378. Accordingly, Waymade reported *'PROMO. SERVICES IN RES. OF HYDTA 20MG'* in its product sales reports as pure profit, with a cost of £0.00.²³²⁰

6.379. In addition to the Buyback, Waymade continued to benefit from the transfer of margin on the 200 packs it received for resale:

- a. Waymade continued to receive the 200 packs per month at the *'special'* £4.50 price until April 2013, when the price for the 200 packs increased to £34.50.²³²¹ This was still a *'special'* price: Waymade recognised internally that *'This price is exclusive nobody else gets that from*

²³¹⁶ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 14 lines 25-26 and page 15 lines 1-6.

²³¹⁷ Document 302543, transcript of [Waymade Employee] interview dated 13 December 2018, page 59 line 15.

²³¹⁸ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 25 lines 1-15.

²³¹⁹ Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, page 38 lines 5-22, page 39 lines 1-22 and page 40 lines 1-3.

²³²⁰ For example, Document 300826, file attached to Document 300825, email from <notification.message@waymade.co.uk> to <sales-3@waymade.co.uk> dated 1 March 2014; Document 300852, file attached to Document 300851, email from <notification.message@waymade.co.uk> to <sales-3@waymade.co.uk> dated 1 August 2014.

²³²¹ Document 200010, Annex 12 to Waymade's response to the CMA's section 26 notice dated 5 May 2016.

*Auden.*²³²² It still allowed Waymade to make a substantial (20%) profit on this generic product: Waymade's ASP in April 2013 was £41.70.²³²³

- b. The price for the 200 packs per month remained £34.50 per pack until February 2014,²³²⁴ when it began to increase gradually. However, the market price for 20mg hydrocortisone tablets also continued to increase, so that Waymade continued to make a profit on the 200 packs.²³²⁵ [Waymade Senior Employee 4] of Waymade explained in interview: *'the price was changing to us ... and he [[Auden Senior Employee 1]] was putting the price up in the market as well'*, so that Waymade continued to get a price that enabled it to make a substantial profit – *'£37.50 is better than the £46.50...'*²³²⁶

6.380. In total, using these mechanisms Auden paid Waymade **at least £1.8 million** during the term of the 20mg Agreement, comprising at least £1,751,192 in cash payments under the Buyback and at least £143,194 through the transfer of margin.²³²⁷ These were substantial payments both in themselves and in relative terms. For example, at the time the parties entered into the 20mg Agreement, Auden estimated that the total available sales of 20mg hydrocortisone tablets were worth £100,000 per month.²³²⁸ At the start of the 20mg Agreement, Auden agreed to pay Waymade sums equivalent to around a third of that total value. The amount paid to Waymade over the term of the 20mg Agreement was in itself more than 3.5 times the NHS's total expenditure on both strengths of hydrocortisone tablets in 2007, the last year prior to Auden taking over sales of the drugs.

ii. The value of the payments under the 10mg Agreement

The payments to Waymade

6.381. By September 2012 Waymade was a long-term customer of Auden in respect of 10mg hydrocortisone tablets. The price it was paying Auden in

²³²² Document 300357, email from [Waymade Senior Employee 4] to [X] dated 17 April 2013.

²³²³ Based on monthly sales and volume data supplied to the CMA on a rolling basis.

²³²⁴ In a single month (August 2013) the price was £37.50.

²³²⁵ Waymade adjusted its selling prices upwards to achieve this. For example, Document 300448, email from [Waymade Senior Employee 4] to [X] dated 7 April 2014. Waymade charged a higher price than Auden for the 200 packs in some months. It did not succeed in selling all the 200 packs in every month. This meant that in certain months it made a loss on the 200 packs. However, when this happened its allowance was adjusted in subsequent months so that it made a total profit of at least £143,194 from selling the 200 packs: CMA calculations based on Document 200010, Annex 12 to Waymade's response to the CMA's section 26 notice dated 5 May 2016.

²³²⁶ Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 2, page 25 lines 24-25, page 26, line 3. Further, these increases in the price Waymade paid for the 200 packs per month were more than offset by the fact that the cash payments it received under the Buyback – which accounted for the majority of the 20mg Agreement's value to Waymade – also increased, as explained above.

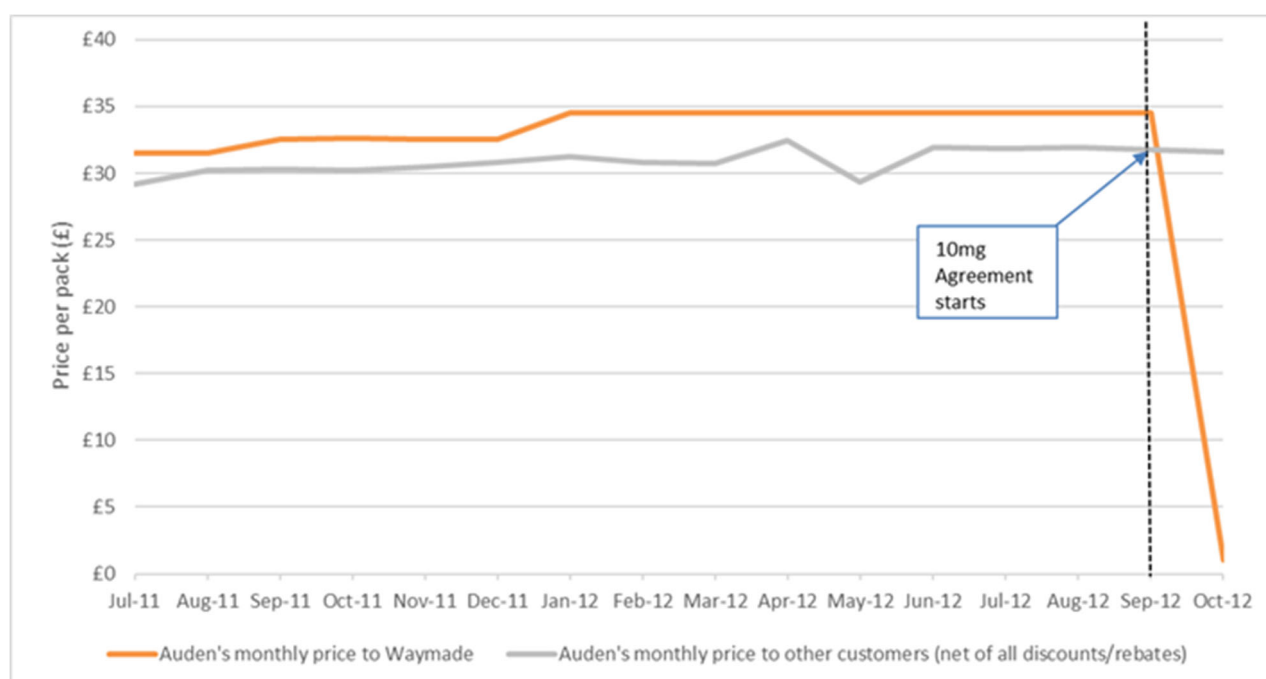
²³²⁷ These calculations are based on table 3.26 above.

²³²⁸ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

September 2012 was £34.50. In the same month it was granted a 10mg MA and after that it paid Auden a substantially lower amount.

- 6.382. Following the grant of its 10mg MA Waymade paid Auden just £1 per pack for 2,000 packs of 10mg hydrocortisone tablets in October 2012. This was a 97% discount on the price it had previously been paying and on Auden's ASP to its other customers (£31.80). This change is shown in figure 6.2 below.

Figure 6.2: change to Waymade's 10mg supply price in October 2012, compared to its supply price to date and to Auden's price to other customers

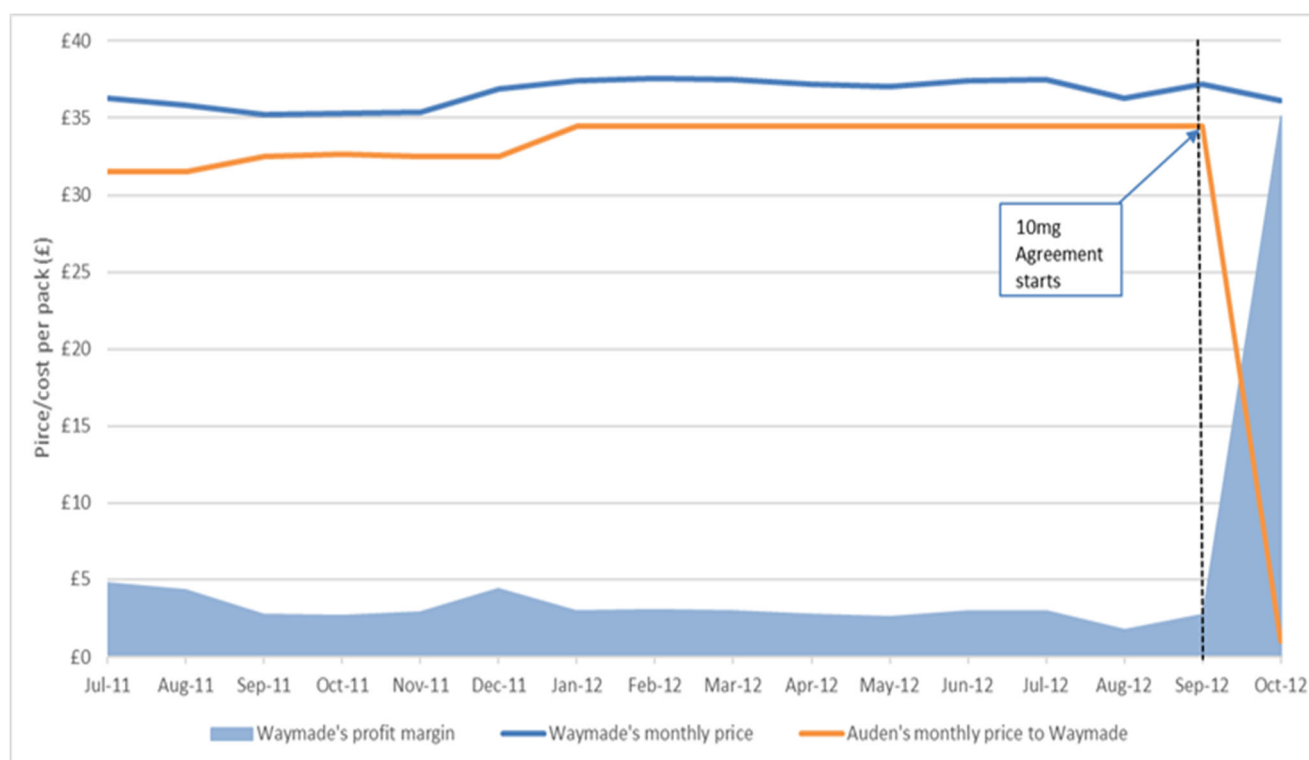


Source: CMA analysis based on data submitted by relevant parties.

- 6.383. The price reduction was implemented by a rebate: Auden supplied the 2,000 10mg packs to Waymade at £38 per pack, then issued a rebate to Waymade of £37 per pack.²³²⁹
- 6.384. The value of the 10mg Agreement to Waymade, and how this compared to Waymade's profit margin on 10mg tablets prior to the 10mg Agreement, are shown in figure 6.3 below.

²³²⁹ Document 200003, paragraphs 11.6 and 13.2, Waymade's response to the CMA's section 26 notice dated 5 May 2016.

Figure 6.3: Changes to Waymade's profit margin on 10mg tablets as a result of the 10mg Agreement



Source: CMA analysis based on data submitted by relevant parties.

- 6.385. Figure 6.3 shows the increase in Waymade's profit margin on 10mg tablets under the 10mg Agreement:²³³⁰ its margin increased from £2.70 per pack in September 2012 to £35.14 in October 2012, a 1,200% increase.²³³¹
- 6.386. The arrangement had therefore changed overnight from Waymade paying Auden around £52,000 per month,²³³² to Auden paying Waymade around £70,000 per month.²³³³ The only change that occurred (as recognised and accepted by key staff on both sides: see paragraphs 6.563 to 6.566, 6.578 and 6.590 to 6.591 below) was that Waymade was granted a 10mg MA and as such posed a competitive threat to Auden. Auden's price to its other customers remained £31.55 per pack in October 2012, compared to Waymade's £1.

²³³⁰ Calculated as the difference between Waymade's monthly price and Auden's monthly price to Waymade.

²³³¹ Waymade purchased the packs from Auden at £1 per pack and sold the packs at £36.14, giving it a profit of £35.14.

²³³² On average 1,500 packs per month at a price of £34.50.

²³³³ Calculated as Waymade's price of £36.14 (minus the £1 cost per pack) multiplied by 2,000 packs.

6.387. In total, Auden therefore paid Waymade around **£70,000** through the transfer of its margin on these packs during Waymade's term as counterparty to the 10mg Agreement.²³³⁴

The payments to AMCo

6.388. As with the 10mg Agreement between Auden and Waymade, Auden/Actavis also supplied AMCo with specified volumes of 10mg hydrocortisone tablets at a heavily discounted price:

- a. Between 31 October 2012 (when AMCo started to receive the benefit of the 10mg Agreement) and 24 June 2014, the supply price was £1 per pack (for 2,000 packs per month until the end of 2012, 6,000 packs thereafter).²³³⁵ The price reduction continued to be implemented by the rebate until around September 2013, after which Auden simply invoiced AMCo at £1 per pack.²³³⁶
- b. From 25 June 2014 (when the Second Written Agreement began), the supply price increased to £1.78 per pack (for 12,000 packs per month) without a rebate.²³³⁷

6.389. The arrangement therefore entailed AMCo paying Auden/Actavis first £2,000 per month, then £6,000, and finally £21,360. However, these were minimal sums compared to the profits available to AMCo on resale of those packs at much higher prices. The supply price to AMCo represented a 97% discount to the price Auden/Actavis charged the rest of the market throughout AMCo's term as counterparty to the 10mg Agreement.²³³⁸ This is shown in figure 6.4 below.

²³³⁴ Compare Document 300646, hand-annotated list of Waymade's 10mg hydrocortisone tablets orders from Auden, showing that Waymade assigned the October 2012 order a 'Stock value' of £69,000.

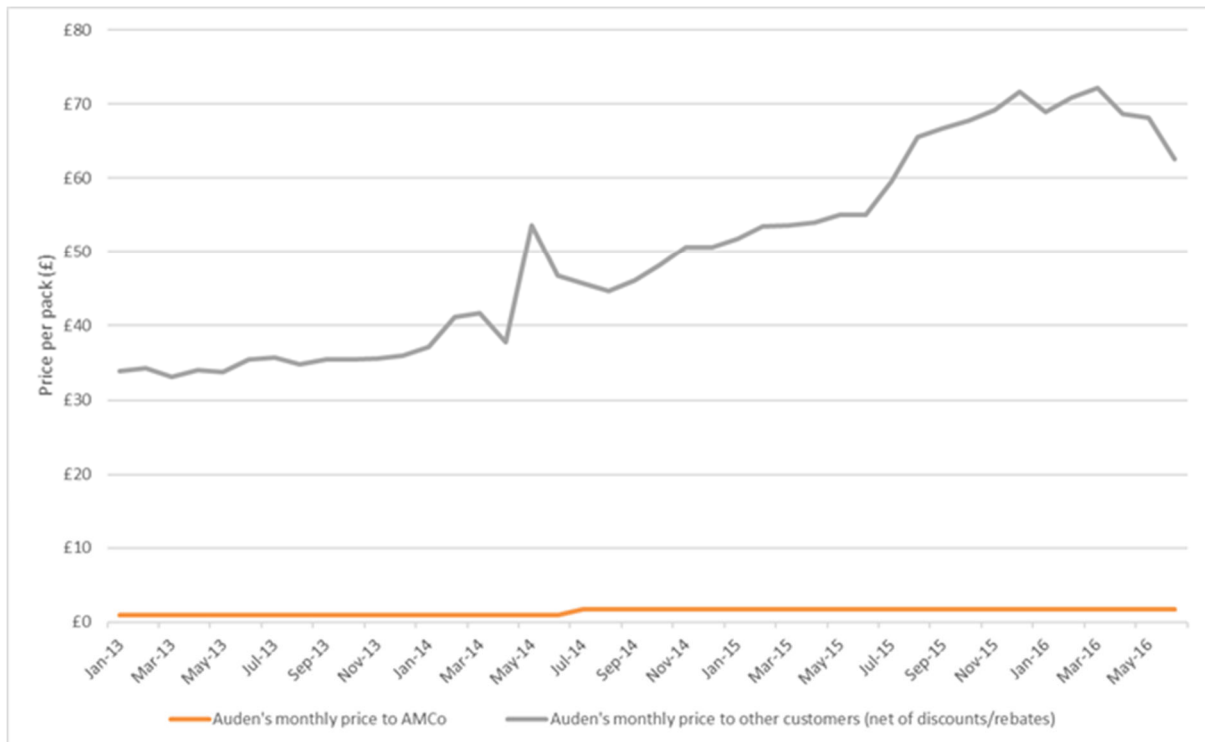
²³³⁵ 7,000 packs in January 2013, as explained above.

²³³⁶ Document 00674, Annex 4 to AM Pharma's response to the CMA's section 26 notice dated 23 June 2016. Document 200010, Waymade's hydrocortisone tablet purchase data provided to the CMA as Annex 12 of Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016. Document 00444, AMCo's response to the CMA's section 26 notice dated 15 April 2016, paragraph 1.14: '*the rebate arrangement was removed shortly afterwards in around September 2013 ... Following the removal of the rebate arrangement in September 2013, there was a straight price of £1 per pack, which was then reflected in the First Hydrocortisone Agreement [the First Written Agreement]*'.

²³³⁷ Document 00446, Second Written Agreement, Schedule A. Document 00674, Annex 4 to AM Pharma's response to the CMA's section 26 notice dated 23 June 2016.

²³³⁸ For example, in November 2012 Auden's ASP for 10mg tablets was around £32. In June 2014 Auden's ASP for 10mg tablets was around £47. In June 2016 Actavis's ASP for 10mg tablets was around £63.

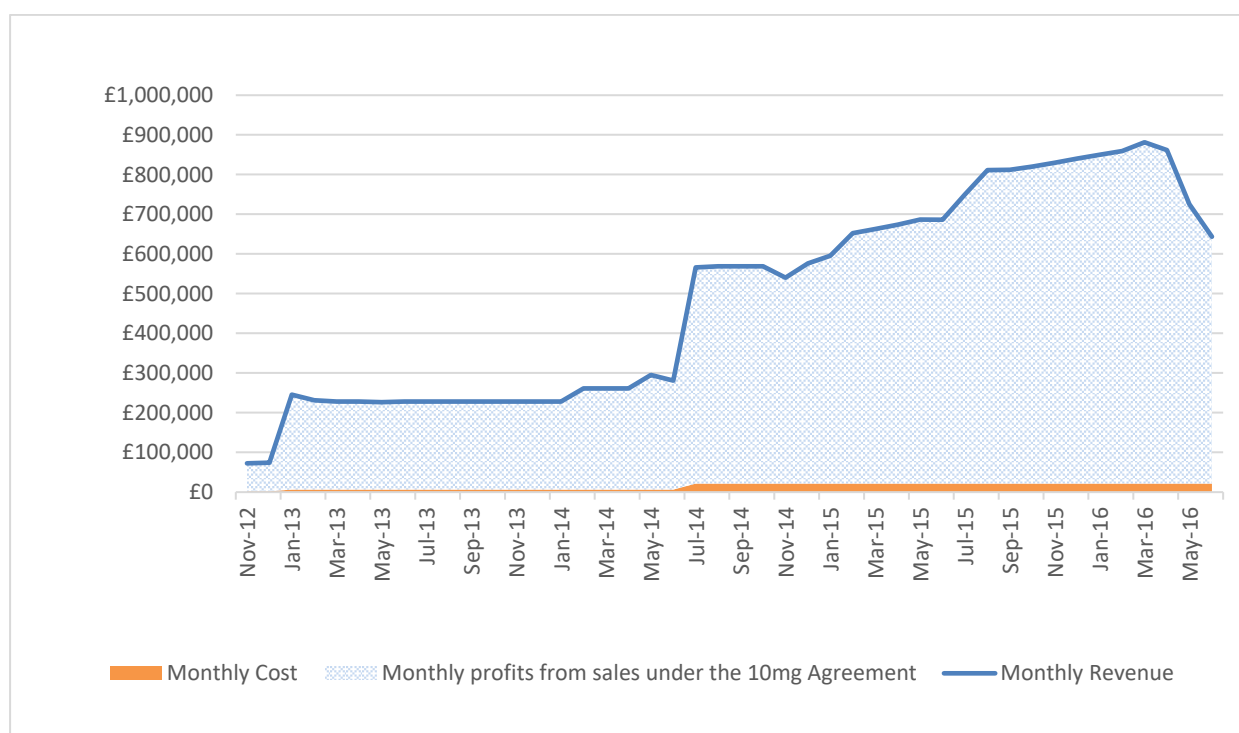
Figure 6.4: Auden's price to AMCo compared to its price to other customers throughout the 10mg Agreement



Source: CMA analysis based on data submitted by relevant parties.

6.390. AMCo was therefore able to make a significant profit margin when it sold those volumes in the market. The value of the 10mg Agreement to AMCo is shown in figure 6.5 below.

Figure 6.5: AMCo's profit as a result of the 10mg Agreement



Source: CMA calculations based on submitted by relevant parties.

Note: AMCo's monthly profits from sales under the 10mg Agreement have been calculated as AMCo's monthly selling price less the monthly cost that AMCo paid Auden in each month, multiplied by the volumes AMCo purchased from Auden in each month.

6.391. As figure 6.5 shows, the payments to AMCo increased significantly over time – first because the volumes supplied to it under the 10mg Agreement increased, from 2,000 packs a month to 6,000 packs and then to 12,000, and secondly because as time went on AMCo was able to sell its increasing volumes for increasing prices: Auden remained the monopoly supplier and could increase its prices without effective constraint, and AMCo could follow suit and share its monopoly profits.

6.392. For example:²³³⁹

- a. In February 2014, AMCo sold the 6,000 packs of 10mg hydrocortisone tablets it purchased from Auden for £1 per pack into the market at £43.50 per pack (the same as Auden's ASP to customers other than AMCo). Consequently, AMCo achieved a gross profit of more than £250,000 from its sales of the 10mg hydrocortisone tablets it obtained for £1 per pack in this month alone.

²³³⁹ CMA analysis of AMCo and Auden monthly sales and volume data (Document 00447, data submitted by AMCo on its sales of hydrocortisone tablets; and Document 00676, data submitted by Auden on its sales of hydrocortisone tablets).

- b. In March 2015, AMCo sold the 12,000 packs of 10mg hydrocortisone tablets it purchased from Auden for £1.78 per pack on the market for £55.21 per pack (compared to Auden's ASP to customers other than AMCo of £56). Consequently, AMCo achieved a profit of more than £640,000 from its sales of the 10mg hydrocortisone tablets it obtained for £1.78 per pack in this month alone.
- 6.393. In total, Auden/Actavis paid AMCo around **£20.6 million** through the transfer of its margin on these packs during AMCo's term as counterparty to the 10mg Agreement.²³⁴⁰
- c. In exchange, each of Waymade and AMCo agreed not to enter the market independently with their own hydrocortisone tablets**
- 6.394. No party or individual has provided a credible legitimate explanation for the payments Auden/Actavis made to Waymade and AMCo. The CMA finds that the reason Auden/Actavis made these substantial payments to Waymade and AMCo is clear: they bought off the competitive threat each of Waymade and AMCo posed to Auden/Actavis. Indeed, this rationale (expressed in terms of protecting Auden's CMO volumes) was put forward by interviewees from each of Waymade, AMCo and Auden: see paragraphs 6.442 to 6.451, 6.578, 6.585 to 6.586, and 6.590 to 6.591 below.
- 6.395. The counter-performance that each of Waymade and AMCo gave in exchange for the payments it received was therefore its agreement not to enter the market independently with its own hydrocortisone tablets.
- i. The 20mg Agreement**
- 6.396. The terms of the 20mg Agreement were not recorded in a formal written contract.
- 6.397. There is contemporaneous documentary evidence demonstrating the negotiations leading up to the 20mg Agreement and confirming its existence, although this evidence only represents a small proportion of the negotiations that took place – with the majority being in un-minuted meetings.²³⁴¹ Despite

²³⁴⁰ CMA calculations based on data supplied by Auden/Actavis (Document 00675 and Document 00676), AMCo (Document 00447 and Document 200271) and Waymade (Document 200010 and Document 200345). This is calculated as: £0.1 million between 1 November and 31 December 2012, based on volumes of 2,000 packs per month; £4.0 million between 1 January 2013 and 30 June 2014, based on volumes of 6,000 packs per month (with the exception of January 2013 when AMCo received 7,000 packs); and £16.5 million between 1 July 2014 and 30 June 2016, based on volumes of 12,000 packs per month. The overall figure is based on Auden/Actavis's ASPs, although AMCo charged very similar ASPs. The overall figure represents the total gross profit generated under the 10mg Agreement by AMCo.

²³⁴¹ For example, contacts occurred between Auden and Waymade prior to Auden offering its supply terms on 21 June 2011. Additionally, [Amdipharm Senior Employee] and [Auden Senior Employee 2] acknowledged that there

this, the terms of the 20mg Agreement – and in particular, the parties’ common understanding that in exchange for payments, Waymade would not enter the market independently with its own 20mg hydrocortisone tablets – can be established from contemporaneous documentary evidence and statements made by witnesses during interviews with CMA officials during the course of the Investigations.

6.398. That Waymade agreed with Auden that it would not enter the market independently with its own 20mg hydrocortisone tablets is, in particular, demonstrated by the contemporaneous evidence of Waymade’s negotiating strategy and the evidence of the negotiations leading to the 20mg Agreement, which show that:

- a. Waymade planned to develop its own product and negotiate a supply deal with Auden at the same time;
- b. Waymade believed that its product provided it with ‘leverage’²³⁴² in its negotiations with Auden, via the threat of competitive entry; and
- c. Waymade was correct in believing that the threat of competitive entry provided it with substantial leverage in negotiations with Auden. Waymade successfully used that leverage to secure the 20mg Agreement.

6.399. As explained further below, the contemporaneous evidence is corroborated by *ex post* interview evidence.²³⁴³

6.400. The parties’ conduct after entering into the 20mg Agreement provides further evidence of their common understanding that Waymade would not enter independently with its own 20mg hydrocortisone tablets in exchange for the substantial payments it received from Auden. The parties’ common understanding was reaffirmed each month. Each month, Auden made a substantial payment to Waymade, communicating its desire to continue buying off Waymade’s entry; and in exchange, Waymade communicated its continued commitment not to enter through its consistent pattern of behaviour: accepting that payment; selling Auden’s product into the market; and not launching its own 20mg tablets.

were further discussions between the two sides between 21 June 2011 and 28 June 2011 and there was a further meeting between the two sides on 4 July 2011. Also see Document 302543, transcript of [Waymade Employee] interview dated 13 December 2018, pages 19 to 22; and page 47, lines 7 to 8.

²³⁴² Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 12, line 27, and page 13, lines 1 to 7.

²³⁴³ See in particular paragraphs 6.442 to 6.451 below.

Waymade planned to develop its own product and negotiate a supply deal with Auden at the same time

6.401. As set out in section 6.C.II.b.ii above, Waymade was a potential competitor to Auden. It had treated the development of its own 20mg hydrocortisone tablets as a high priority²³⁴⁴ and in May 2011 it took delivery of the tablets packed from the Third Batch from Aesica. This batch had cleared all regulatory requirements and was available for commercial sale. At this stage, Waymade could have entered the market and competed with Auden. However, Waymade never sold these tablets – instead they were warehoused and ultimately destroyed when they passed their expiry date in November 2013.

6.402. At first sight, investing in and developing a product and then not launching it does not seem to be commercially rational behaviour. Waymade had incurred costs in getting its 20mg hydrocortisone tablets to a point where they were ready for commercial sale and it is reasonable to infer that it would have sought to recover its costs by selling the tablets packed from the Third Batch and conducting the ‘*very straight forward*’²³⁴⁵ reformulation work recommended to ensure sustained supply. This is not least because the very high prices in the market were favourable to profitable entry.

6.403. Indeed, [Waymade Senior Employee 3] [REDACTED] acknowledged in interview that:

*‘it is very unusual for a product to be developed, manufactured and received into stock and then not launched.’*²³⁴⁶

6.404. However, while it was ‘*very unusual*’ for Waymade not to market a product it had developed to manufacture, the possibility of not launching its own 20mg hydrocortisone tablets and instead taking supply of Auden’s 20mg hydrocortisone tablets had in fact been part of Waymade’s strategy from at least the end of 2010.

6.405. In December 2010, [Waymade Senior Employee 3] sent an email to [Waymade Senior Employee 1] [REDACTED] in which [Waymade Senior Employee 3] provided an update on the progress of Waymade’s 20mg hydrocortisone tablets:

‘the earliest launch of our Hydrocortisone product in glass bottles is May or June 2011. This is tracking with the project plan. Approval for

²³⁴⁴ See section 3.E.II.a above.

²³⁴⁵ Document 300453, email from [Waymade Senior Employee 2] to [REDACTED] and [Waymade Senior Employee 1] dated 6 May 2014.

²³⁴⁶ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 34, lines 3 to 5.

*blister packaging is anticipated in Sep or Oct 2011. With regards to a negotiation with Auden Mckenzie, I suggest that opening a discussion in January would be about right. IMS suggests that the UK market for Hydrocortisone 20mg tablets x 30 is valued at 38,000 packs and £1.6m a year.*²³⁴⁷

- 6.406. After accurately projecting that Waymade's product would be ready in mid-2011, [Waymade Senior Employee 3] proposed opening negotiations with Auden in January of that year (*'With regards to a negotiation with Auden Mckenzie, I suggest that opening a discussion in January would be about right'*²³⁴⁸). This statement shows that Waymade was contemplating negotiating with Auden alongside developing its own product.
- 6.407. It is clear from the surrounding context (in particular, the fact that Waymade and Auden negotiated and agreed the 20mg Agreement in the first half of 2011) that the '*discussion*' that [Waymade Senior Employee 3] referred to related to entering into a supply agreement under which Auden would supply Waymade with 20mg hydrocortisone tablets. The absence of further clarification on the '*negotiation with Auden Mckenzie*' indicates that the idea of negotiating with Auden alongside developing Waymade's product was well-understood within Waymade. The phrase '*opening a discussion in January would be about right*' implies that the aim was for the negotiations to reach an outcome around the same time as Waymade anticipated being ready to launch its own 20mg product, ie in mid-2011.
- 6.408. The implications of [Waymade Senior Employee 3]'s 23 December 2010 email are clear. Waymade would simultaneously pursue bringing its 20mg hydrocortisone tablets to launch-readiness while negotiating with Auden, with a view to bringing both workstreams to an outcome at the same time, in mid-2011. When its product was ready to launch and the negotiations with Auden had produced a clear offer, it would make a choice, considering the total value of the supply of 20mg hydrocortisone tablets. It would choose either to launch its own 20mg hydrocortisone tablets, or instead to take supply of Auden's tablets on terms that gave it acceptable value.
- 6.409. The status of Waymade's own product, and the credibility of its threat to Auden's market position as the incumbent sole supplier of hydrocortisone tablets, would naturally bear on the minds of those conducting these

²³⁴⁷ Document 300138, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] dated 23 December 2010 (emphasis added).

²³⁴⁸ Document 300138, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] dated 23 December 2010.

negotiations. By putting those things together, [Waymade Senior Employee 3]'s email acknowledges that they are related.

6.410. As the following contemporaneous documents show, Waymade pursued the development of its own 20mg hydrocortisone tablets in a manner consistent with the strategy outlined in [Waymade Senior Employee 3]'s email. There was a close relationship between the decisions Waymade took in relation to the development and commercialisation of its own 20mg tablets and the negotiation of a supply agreement with Auden.

6.411. On 9 May 2011, [Waymade Senior Employee 3] explained in an email to [Amdipharm Senior Employee] [§] and others that the tablets packed from the Third Batch were not being released for sale because of '*commercial negotiations with a third party*':

*'Finished packs of 20mg tablets in glass will be delivered into Basildon this week. Stock will not be released for sale pending the outcome of commercial negotiations with a third party. The outcome of these discussions will inform the decision as to whether the 20mg tablet is reformulated in line with the 10mg tablet.'*²³⁴⁹

6.412. A Sovereign Generics monthly report of April 2011 also stated that Waymade would not be launching its product '*pending the outcome of negotiations*' and identified the third party Waymade was negotiating with as Auden: '*The product will be released into stock and then frozen pending the outcome of the negotiations with Auden McKenzie.*'²³⁵⁰

6.413. [Waymade Senior Employee 3] explained in interview that '*frozen*' meant '*it was blocked on the system, so that an operative telephone sales person couldn't inadvertently take an order and despatch product ... It's disabled if you like.*'²³⁵¹ [Waymade Senior Employee 3] also stated:

*'The explicit meaning is that the product could be launched but it was decided that they would ..., the product would not be launched.'*²³⁵²

²³⁴⁹ Document 300178, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] and others dated 9 May 2011 (emphasis added).

²³⁵⁰ Document 300180, attachment to Document 300179, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] and others dated 11 May 2011 (emphasis added).

²³⁵¹ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 32, lines 18 to 20 and page 33, lines 6 to 7.

²³⁵² Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 32, lines 15 to 16 (emphasis added).

6.414. On 6 June 2011, Waymade's regular hydrocortisone tablets meeting²³⁵³ considered *'whether we want to reformulate 20mg strength tablet (i.e. inclusion of 'pre-gelatinised starch' in line with the fix for the 10mg formulation)'*. Consistently with the Sovereign Generics monthly report of April 2011 and [Waymade Senior Employee 3]'s email of 9 May 2011, it was decided that the *'status of negotiations with third party [ie Auden] ... will inform decision as whether we undertake reformulation.'* At this stage, *'no further regular Monday meetings are necessary. This might change if we pick up the 20mg reformulation project.'*²³⁵⁴

6.415. On 23 June 2011, [Waymade Senior Employee 3] emailed Waymade's principal negotiator [Amdipharm Senior Employee] to propose that Waymade put reformulation on hold if the *'trading relationship'* with Auden was *'going to stick'*, again tying the development of Waymade's 20mg hydrocortisone tablets to its negotiations with Auden:

*'If you and [Waymade Senior Employee 1] are confident that the Auden Mckenzie trading relationship is going to stick then I would suggest that we do not need to reformulate at the current time...[w]e can come back to the reformulation at a later date if we want to...'*²³⁵⁵

6.416. [Waymade Senior Employee 3]'s emails of 9 May 2011 and 23 June 2011, the Sovereign Generics monthly report of April 2011, and the outcome of the 6 June 2011 hydrocortisone tablets meeting demonstrate:

- a. First, a clear link between Waymade's development of its own 20mg hydrocortisone tablets and its negotiations with Auden. This is consistent with [Waymade Senior Employee 3]'s email of 23 December 2010;²³⁵⁶
- b. Second, that Waymade would not sell its own 20mg hydrocortisone tablets while the negotiations with Auden were ongoing; and
- c. Third, that the outcome of those negotiations would determine both whether the tablets packed from the Third Batch would be released for

²³⁵³ The CMA infers that this meeting was attended by, in addition to [Waymade Senior Employee 3], those individuals who were asked to review the minutes and inform [Waymade Senior Employee 3] of any misinterpretations or omissions, including [Waymade Senior Employee 2], [Waymade Employee] and [Waymade Employee] (the addressees of Document 300184, email from [Waymade Senior Employee 3] to [X], [Waymade Senior Employee 2] and others dated 6 June 2011). The email was copied to [Amdipharm Senior Employee], who was carrying out the negotiations with Auden.

²³⁵⁴ Document 300184, email from [Waymade Senior Employee 3] to [X], [Waymade Senior Employee 2] and others dated 6 June 2011.

²³⁵⁵ Document 200017, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] dated 23 June 2011.

²³⁵⁶ Document 300138, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] dated 23 December 2010.

sale and whether Waymade would reformulate its own 20mg hydrocortisone tablets, with the implication being that Waymade would not enter the market independently or undertake reformulation if the negotiations with Auden were successful.

Waymade believed that its product provided it with 'leverage' in its negotiations with Auden via the threat of competitive entry

6.417. Waymade believed developing its own 20mg hydrocortisone tablets provided it with 'leverage' in its negotiations with Auden via the threat of competitive entry. Auden would have understood that Waymade could have entered the market and competed with it. In his interview with the CMA [Waymade Senior Employee 3], [REDACTED] at the time, explained:

'the fact that the product is there in the warehouse in Basildon, is the leverage in that Waymade could have placed that product on the market ... so, the leverage is it's in the warehouse in, in Basildon, it could be released for sale'.²³⁵⁷

6.418. The form this 'leverage' took is clear. At this time, Auden was the monopoly supplier of 20mg hydrocortisone tablets in the UK and had been able to set prices without being effectively constrained. This had resulted in its wholesale price being over £34 per pack in June 2011 (from a starting point of just £5.14 per pack in April 2008). As hydrocortisone tablets are a prescription only product, the level of demand is fixed by the number of prescriptions written. Accordingly, if Waymade had successfully entered the market with its own product, it would have likely constrained Auden by reducing Auden's sales volumes²³⁵⁸ and consequently its revenues. Waymade may have also initiated price competition, which would have further reduced the value of Auden's sales. Therefore, Waymade believed that Auden may have been prepared to strike a deal which removed the risk of its competitive entry and preserved Auden's monopoly position and high profit margins.

6.419. In interview with the CMA, [Waymade Senior Employee 1] explained Waymade's 'leverage': *'If we [Waymade]..., when we came to the market, they could have actually lost a lot of the market share to us, therefore they would have said ... "Look, we'll supply you or we will come to an agreement"*

²³⁵⁷ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 12, line 27, and page 13, lines 1 to 7 (emphasis added).

²³⁵⁸ In relation to a prescription medicine such as hydrocortisone tablets, there is a finite number of overall prescriptions which limits the overall demand. See section 6.C.II.b.i above.

... the fact that there's not a second player is always in their [Auden's] interest'.²³⁵⁹

- 6.420. Waymade's Chairman and co-owner therefore clearly understood that if Waymade had entered, Auden stood to lose '*a lot of market share*' to it. Therefore, Auden would be willing to '*come to an agreement*' with Waymade that would avoid having a competitor ('*a second player*') in the market, which [Waymade Senior Employee 1] understood was '*always in their interest*'.
- 6.421. [Waymade Senior Employee 1]'s comments also show that he understood Waymade's options were mutually exclusive: Auden would only have been prepared to do a deal to avoid '*a second player*' and losing '*market share*', which was incompatible with Waymade also entering independently with its own product.
- 6.422. When asked why Auden entered into the 20mg supply deal with Waymade, [Waymade Senior Employee 1] went on to say that Auden was only prepared to supply Waymade at £4.50 a pack because Waymade had an MA and therefore posed a competitive threat to Auden: '*Simply because, you know, we had agreed that we had a licence and we could produce the product at £4.50, and by buying it from him [Auden Senior Employee 1]], then we wouldn't produce it, even though we were paying him more than it would cost us.*'²³⁶⁰
- 6.423. He further explained: '*The only reason why they would give this product to us is because we had a supply, because of our licence, that's all.*'²³⁶¹
- 6.424. Again, [Waymade Senior Employee 1]'s comments show that Waymade understood that its options were mutually exclusive: '*by buying it [20mg hydrocortisone tablets] from him [Auden Senior Employee 1], then we [Waymade] wouldn't produce it [ie independently enter with its own 20mg tablets].*'
- 6.425. [Amdipharm Senior Employee] also explained how Waymade's potential to compete with Auden motivated Auden to enter into a preferential supply deal with Waymade:
- a. '*The marketing authorisation changed Waymade's position towards*

²³⁵⁹ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 15 to 20 and page 14, lines 16 to 17 (emphasis added).

²³⁶⁰ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 37, lines 10 to 13 (emphasis added).

²³⁶¹ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 13, lines 4 to 5.

Auden Mckenzie';²³⁶² and

- b. *'If they [Auden] choose to supply us [Waymade], then they're making a lower margin on that product, but they are retaining the manufacturing volume, and that – depending on the product, depending on the batch size, depending on a number of things – that can be important, to keep up your manufacturing volumes'.*²³⁶³

6.426. The implication of [Amdipharm Senior Employee]'s explanation is clear: Waymade's options were mutually exclusive – either it entered into an agreement with Auden which protected Auden's '*manufacturing volumes*', or it entered independently with its own 20mg hydrocortisone tablets. Auden's '*manufacturing volumes*' would have been reduced if Waymade had entered independently with its own 20mg hydrocortisone tablets.

6.427. [Amdipharm Senior Employee] added: *'they [Auden] know that we can get product made at our own CMO, or they can supply us at a price which we feel is competitive'*.²³⁶⁴ [Amdipharm Senior Employee] subsequently explained that he was aiming to secure *'the price that [Waymade] would hope to achieve from an alternative CMO'*.²³⁶⁵ In another interview, he explained that *'Auden was supplying the 20-milligram to Waymade on the basis of it being a contract manufacturer as opposed to Waymade buying from Aesica, or whoever.'*²³⁶⁶

6.428. When asked what would have happened if Auden had declined to supply Waymade at a substantially reduced price, [Amdipharm Senior Employee] responded: *'If they had declined, we would have carried on with our own 20mg.'*²³⁶⁷ In other words, [Amdipharm Senior Employee] negotiated the 20mg Agreement with Auden with the understanding that if Auden agreed to charge Waymade a substantially reduced supply price, Waymade would not enter the market independently with its own product.

6.429. [Waymade Senior Employee 2], provided the following rationale for the 20mg supply deal: *'maintaining your volumes with your contract manufacturer is significant ... I assume there would have been penalties for not having*

²³⁶² Document 200354, Witness Statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraph 1.15.

²³⁶³ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 32, lines 6 to 10.

²³⁶⁴ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 26, lines 26 and page 27, lines 1 to 2 (emphasis added).

²³⁶⁵ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 32, lines 18 to 19 (emphasis added).

²³⁶⁶ Document 200349, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 9, lines 19 to 20.

²³⁶⁷ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 30, lines 9 to 16.

maintaining [sic] your volumes or selling less or procuring less from the CMO'.²³⁶⁸ He therefore also understood that Auden's motivation for entering into the 20mg Agreement was the need to avoid '*selling less or procuring less from the CMO*' – to avoid the reduction in volumes that would follow independent entry.

6.430. The explanations Messrs [Waymade Senior Employee 1], [Waymade Senior Employee 2], and [Amdipharm Senior Employee] gave, together with the contemporaneous documents, demonstrate that:

- a. Waymade understood that developing its own 20mg hydrocortisone tablets meant that it posed a competitive threat to Auden which provided it with negotiating '*leverage*' with Auden;²³⁶⁹
- b. Waymade understood that Auden would want to avoid competitive entry and retain its position as the sole supplier of 20mg hydrocortisone tablets (it is only in this way that Auden would '*retain... the manufacturing volume*'²³⁷⁰) by entering into a supply agreement;
- c. Waymade understood that it could not independently enter the market as part of any such agreement ('*then we wouldn't produce it*'²³⁷¹ and '*there's not a second player*'²³⁷²);
- d. but Waymade expected a substantially lower supply price in return – equivalent to the price of an '*alternative CMO*'²³⁷³ ('*they're making a lower margin on that product*'²³⁷⁴).

Negotiating the 20mg Agreement 21 June to 11 July 2011

6.431. Contemporaneous documents, corroborated by witness evidence obtained from key Auden staff, demonstrate that Waymade was correct in believing its ability to enter the market provided it with substantial '*leverage*' in negotiations with Auden.

²³⁶⁸ Document 301312, transcript of [Waymade Senior Employee 2], part 2, page 19, lines 21 to 24.

²³⁶⁹ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 12, line 27, and page 13, lines 1 to 7.

²³⁷⁰ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 32, lines 6 to 10.

²³⁷¹ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 37, lines 10 to 13.

²³⁷² Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 15 to 20 and page 14, lines 16 to 17.

²³⁷³ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 32, lines 18 to 19.

²³⁷⁴ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 32, lines 6 to 10.

21 June 2011: email from [Auden Senior Employee 2] (Auden) to [Amdipharm Senior Employee] (Waymade)

6.432. On 21 June 2011, [Auden Senior Employee 2] of Auden had a telephone call with [Amdipharm Senior Employee] and [Waymade Employee] of Waymade. [Auden Senior Employee 2]'s handwritten notes of the call indicate that its purpose was to introduce Waymade to Auden: Waymade gave a summary of its business. [Auden Senior Employee 2] then wrote:

'Send list products.

- New molecules would look at exclusivity.

- 10mg Hydro.

20mg Hydro.

[✂].

...

£33 2,400

£34.50 240'²³⁷⁵

6.433. These notes indicate that on the call, [Auden Senior Employee 2] had agreed to send Waymade – in particular, [Amdipharm Senior Employee] – its list of products with a view potentially to agreeing an exclusive supply deal. Auden and Waymade had discussed the quantities and prices that might apply in that deal.

6.434. Later that same day, [Auden Senior Employee 2] emailed [Amdipharm Senior Employee] of Waymade to propose that Auden would initially supply Waymade with 240 packs of 20mg hydrocortisone tablets at a price of £34.50 a pack:

'Good to speak with you earlier, as discussed attached is a list of all our lines that have retail usage.

With regards an initial order suggest you look at taking the following quantities;

²³⁷⁵ Document 00752, [Auden Senior Employee 2]'s handwritten note of telephone call on 21 June 2011.

Hydrocortisone 10mg – 2,400 @ £33.00 Hydrocortisone 20mg – 240 @ £34.50

*Look forward to meeting you both, would you be available on the 4th July’.*²³⁷⁶

- 6.435. [Auden Senior Employee 2] therefore proposed supplying Waymade with both 10mg and 20mg hydrocortisone tablets at market rate,²³⁷⁷ and suggested a meeting with [Amdipharm Senior Employee] and [Waymade Employee] on 4 July 2011.

28 June 2011: email exchange between [Auden Senior Employee 2] (Auden) and [Auden Senior Employee 1]

- 6.436. Between 21 and 28 June 2011, there was at least one, un-minuted, discussion between [Waymade Employee] of Waymade and [Auden Senior Employee 2] of Auden. Following this discussion, [Auden Senior Employee 2] emailed [Auden Senior Employee 1] on 28 June 2011. [Auden Senior Employee 2] started by updating [Auden Senior Employee 1] on what [Waymade Employee] had requested from Auden in respect of the supply of 20mg hydrocortisone tablets:

*‘Finally spoken with [Waymade Employee], not agreed any pricing as I’m going to see them at 12.30 on the 4th July and suggested we discuss then ... Initial feedback is that they are looking for 1,000 x 20mg per month at cogs and the 10mg at 20% off our £33.00 giving them £26.40.’*²³⁷⁸

- 6.437. Accordingly, [Waymade Employee] had asked that Auden supply Waymade on substantially different and more beneficial terms than those [Auden Senior Employee 2] had proposed to [Amdipharm Senior Employee] on 21 June 2011. Waymade was ‘looking for’ 1,000 packs per month at ‘cogs’ (cost of goods). This counterproposal was starkly different from [Auden Senior Employee 2]’s initial proposal of £34.50 per pack of 21 June 2011, just a week earlier.

²³⁷⁶ Document 300186, email from [Auden Senior Employee 2] to [Amdipharm Senior Employee] dated 21 June 2011.

²³⁷⁷ [Auden Senior Employee 2] confirmed to the CMA that the prices initially offered by Auden were the prevailing wholesale prices for 10mg and 20mg hydrocortisone tablets at the time (Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, part 1, page 9, lines 1 to 10).

²³⁷⁸ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011 (emphasis added).

6.438. [Auden Senior Employee 2] then went on to set out his '*thoughts*' in response to Waymade's counterproposal. The result is substantially different from the terms he had initially proposed on 21 June 2011:

'My thoughts are:

- 1. 20mg Mkt size 3,500 giving monthly market value of £100K*
- 2. If Waymade had their own licence and achieved 50% mkt share at current pricing then they would net £50K per mth.*
- 3. Selling them 1K packs per month to enable them just under a third mkt share at £4.50 per pack would net them £30K per mth.*
- 4. Giving them 10mg at 15% off would be £28.00. Allowing them 5% mkt share, 3.5K packs per mth would net them another £17.5K per mth.*
- 5. Therefore in total £47.5K per mth across both lines.*
- 6. Would be happier allowing a lower price on the 20mg because it would be in their interest to maintain high resale price rather than giving them too low a price on the 10mg.*
- 7. This should be the maximum we allow as there are other cost savings for them in not bringing the product to market.'²³⁷⁹*

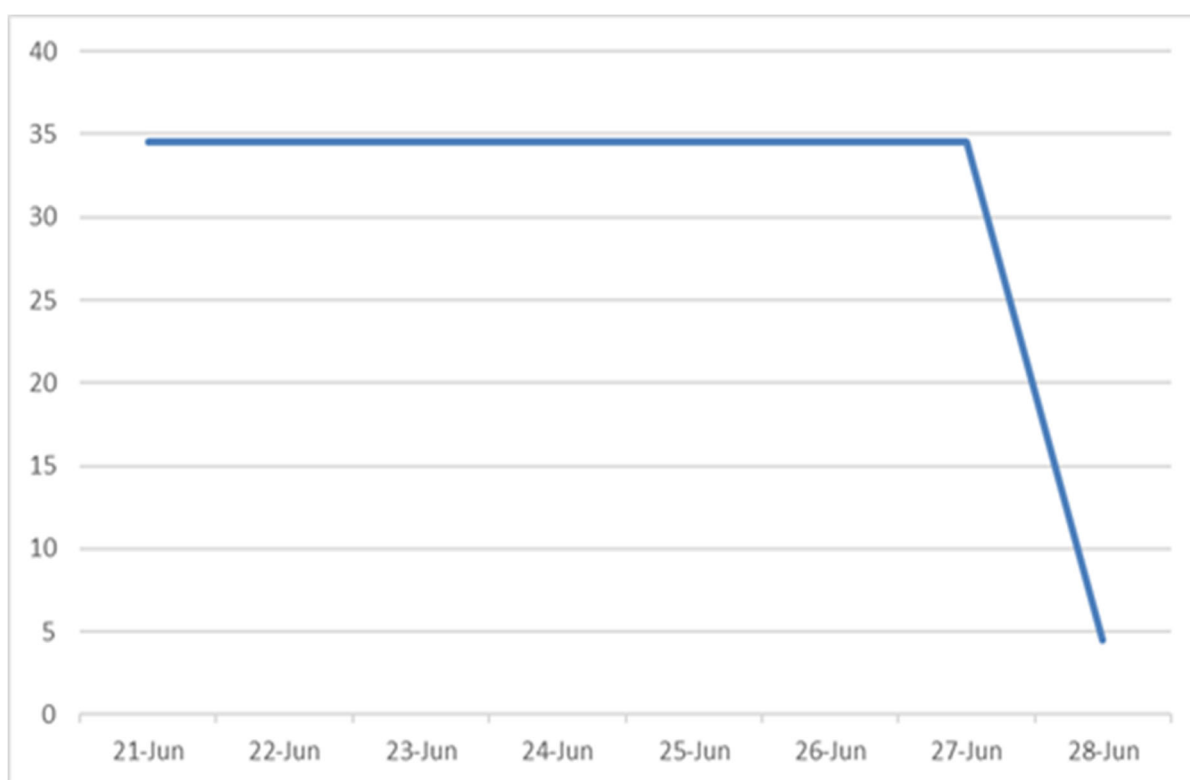
6.439. [Auden Senior Employee 1] replied: '*[Auden Senior Employee 1] I totally agree we should not give away to [sic] much*'.²³⁸⁰

6.440. Accordingly, [Auden Senior Employee 2] now proposed that Auden supply Waymade with 1,000 packs of 20mg hydrocortisone tablets at £4.50 a pack (this was an 87% reduction on both the price [Auden Senior Employee 2] had originally offered to supply Waymade at and the price Auden charged its other customers). He estimated that this would '*net*' Waymade £30,000 per month if it sold the packs at £34.50 per pack. The change in Auden's proposed supply price to Waymade is illustrated in figure 6.6 below.

²³⁷⁹ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011 (emphasis added).

²³⁸⁰ Document 00031C, email from [Auden Senior Employee 1] to [Auden Senior Employee 2] dated 28 June 2011 (emphasis added).

Figure 6.6: change to Waymade's offered supply price between 21 and 28 June 2011



6.441. [Auden Senior Employee 2]'s email does not explain what prompted him to recommend these substantially revised terms. However, witness evidence and the surrounding context show that Waymade had, by this point, exercised its '*leverage*' by informing Auden that it was preparing to enter the market.²³⁸¹ In response [Auden Senior Employee 2] and [Auden Senior Employee 1] had decided to buy off Auden's potential competitor by offering Waymade a substantially lower supply price when compared to that offered on 21 June 2011 and to its other customers.

6.442. In his first interview with CMA officials, [Auden Senior Employee 1] explained why Auden offered the revised terms:

²³⁸¹ In witness interviews with the CMA, both [Amdipharm Senior Employee] and [Auden Senior Employee 2] explained that the very significant change in the proposed terms of supply was likely to have been the result of [Amdipharm Senior Employee] disclosing to [Auden Senior Employee 2] that Waymade had an MA to produce 20mg tablets. [Amdipharm Senior Employee] of Waymade stated in interview: '*at some point in our discussions, I may have made clear that Waymade had a marketing authorisation*' (Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 31, lines 6 to 7). [Auden Senior Employee 2] of Auden said that '*I think it must have been on one of the phone calls when they'd said that we have our own marketing authorisation*' (Document 00716, [Auden Senior Employee 2] interview transcript, page 18, lines 6 to 7). In any event, this information would have been available to Auden from industry databases: as explained below, RAMA includes information on all MAs granted, enabling market participants to identify potential competitors. [Amdipharm Senior Employee] of Waymade stated in interview: '*It's in the public domain that the marketing authorisation is there, so Auden and others can see that*' (Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 30, lines 9 to 10).

'It was important for us to maintain our volumes with Tiofarma, our CMO, for 20mg hydrocortisone tablets, especially for a low volume steroid product which was difficult to manufacture. We had a commitment to increase business at our CMO every year, or at least to maintain it, and if we lost volumes on one product, then we would try and replace it with something else, so it was always in our interest to try to keep the volumes reasonably level at the CMO. This is why we entered into the arrangement with Waymade for a low supply price ... This supply was something we did with our CMO volumes in mind.'²³⁸²

6.443. It is clear that [Auden Senior Employee 1] saw Waymade as a competitive threat. In his witness statement he stated: *'I recall having an internal discussion which acknowledged Waymade was our competitor and that we could supply it with hydrocortisone tablets...'*²³⁸³

6.444. In a subsequent interview, [Auden Senior Employee 1] emphasised that it was the fact Waymade could have entered the market with its own 20mg hydrocortisone tablets and taken volume (market share) from Auden that prompted Auden to offer Waymade a £30 discount on the supply terms it had proposed on 21 June 2011:

*'they [Waymade] had come, come and asked us for supply, they had a 20 milligram [MA] and it was either for us to do nothing, which we could have, or to supply them, which would maintain our volume and still make us money, so that's what we did.'*²³⁸⁴

*'they had their own product which they came to us and said look we have our product but we'd like to take supply from you'*²³⁸⁵

6.445. [Auden Senior Employee 1] continued:

'if they had their own product, they could either source supply somewhere else or they could source it from us; and sourcing from us allowed us to keep our volume.

[Interviewer]: Whereas if they sourced it from elsewhere the consequence would have been...

²³⁸² Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.16 and 1.17 (emphasis added).

²³⁸³ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.16 and 1.17.

²³⁸⁴ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 31, line 27 and page 32, lines 1 to 3.

²³⁸⁵ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 32 line 27 and page 33 line 1.

[Auden Senior Employee 1]: Our, our volumes could have dropped.

[Interviewer]: And that was the reason why they got a...

[Auden Senior Employee 1]: Correct.

[Interviewer]: ... A £30 discount?

[Auden Senior Employee 1]: That's right.²³⁸⁶

- 6.446. [Amdipharm Senior Employee] of Waymade confirmed in interview that the key change in the negotiations that led to this £30 discount was that Waymade posed a competitive threat to Auden as a result of its MA:

*'Waymade moves from a position of being just another wholesaler customer to Auden McKenzie ... to Waymade being in a position where it can, in theory, bring its product to the market'*²³⁸⁷

- 6.447. [Auden Senior Employee 2] of Auden also confirmed that it was Waymade's competitive threat that prompted him to offer the substantial discount: *'it was key that we maintain our volumes on this line so we'd be happy to supply at a lower price, they could go elsewhere and source this product if they wanted to, there is certainly the savings for them by not doing that'*.²³⁸⁸ When asked in a subsequent interview *'What was special about Waymade?'*, [Auden Senior Employee 2] stated: *'Because we know Waymade had their own marketing authorisation ... Because Waymade had the facility to manufacture their product. Or they could buy it from us'*.²³⁸⁹

- 6.448. [Auden Senior Employee 2] further explained that if Waymade did independently enter the market with its own 20mg tablets, Auden's volumes would inevitably be reduced:

'It was all about maintaining the volumes with Tiofarma ... I suppose there's a finite number of prescriptions there, so if [Waymade] had their

²³⁸⁶ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 35, lines 21 to 26 and page 36, lines 1 to 9.

²³⁸⁷ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10 (emphasis added).

²³⁸⁸ Document 00716, transcript of [Auden Senior Employee 2] interview, page 16, lines 3 to 10. He confirmed this in a subsequent interview, in which he said that Auden McKenzie was *'keen to make sure that we maintain our volumes of this product for the purposes of the contract manufacturer'* (Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, part 1, page 17, lines 18 to 20).

²³⁸⁹ Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, page 19, lines 8-14.

*own manufacture and brought product into the market we would then naturally reduce our volumes.'*²³⁹⁰

- 6.449. Both [Auden Senior Employee 1] and [Auden Senior Employee 2] of Auden therefore understood that Waymade's entry to the market under its own MA would '*naturally reduce*' Auden's volumes, given the '*finite number of prescriptions*'.
- 6.450. [Auden Senior Employee 1] and [Auden Senior Employee 2]'s statements confirm that Auden would only have supplied Waymade '*at a lower price*'²³⁹¹ if Waymade did not independently enter the market with its own 20mg hydrocortisone tablets. The aim of the '*lower price*' was to '*maintain our [Auden's] volumes*'²³⁹² and '*keep our [Auden's] volume*'.²³⁹³ This would only have been achieved if Waymade did not independently enter the market with its own 20mg tablets.
- 6.451. On the Waymade side, [Amdipharm Senior Employee] gave the same explanation in interview, consistently with the evidence discussed in paragraphs 6.417 to 6.430 above showing that Waymade understood its competitive threat provided it with leverage over Auden:

*'If they don't supply us then other things being equal, and you can make the product acceptably, and we come to the market, then they will have lost that manufacturing volume. If they choose to supply us, then they're making a lower margin on that product, but they are retaining the manufacturing volume'*²³⁹⁴

- 6.452. The conditionality of Auden's proposal is further illustrated by [Auden Senior Employee 2]'s email of 28 June 2011. He informed [Auden Senior Employee 1] that, given the total market size of 3,500 packs per month, selling 1,000 packs per month to Waymade would '*enable them [Waymade] just under a third market share*'. In other words, [Auden Senior Employee 2] was proposing that Auden share the market with its potential competitor Waymade on an approximate 70:30 basis in terms of volume. This is not only a clear indication of a plan to share the market between the two parties but is also premised on Waymade not independently entering the market

²³⁹⁰ Document 00717, transcript of [Auden Senior Employee 2] interview dated 21 September 2016, part 2, page 4, lines 6 and 14 to 16.

²³⁹¹ Document 00716, transcript of [Auden Senior Employee 2] interview, page 16, lines 3 to 10.

²³⁹² Document 00716, transcript of [Auden Senior Employee 2] interview, page 16, lines 3 to 10. See also Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, part 1, page 17, lines 18 to 20.

²³⁹³ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 35, lines 21 to 26 and page 36, lines 1 to 9.

²³⁹⁴ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 32 lines 3-10.

with its own product alongside that supply agreement. If Waymade had independently entered, it would have disrupted [Auden Senior Employee 2]'s proposed market sharing ratio.

- 6.453. The fact that [Auden Senior Employee 2] devised Auden's proposal on the basis that Waymade would not be independently entering the market is further demonstrated by his reference to not offering better terms than those he had devised because there would be '*cost savings for [Waymade] in not bringing the product to market*'.²³⁹⁵ This is significant: it demonstrates that [Auden Senior Employee 2] understood that Waymade could have independently entered the market (he understood they were a potential competitor) and that he had prepared an offer that involved Auden allocating Waymade approximately 30% of the market's volume ('*just under a third mkt share*') and a substantial reduction in Auden's supply price on the basis that Waymade would '*not [be] bringing its product to market*.'
- 6.454. Further evidence that [Auden Senior Employee 2] was working on the basis that Waymade would not be independently entering the market in exchange for the payments it would receive from Auden is provided by his attempt to calibrate Waymade's profit from the supply deal overall to what it may have achieved through successful entry. [Auden Senior Employee 2] calculated that the supply deal (across both strengths of hydrocortisone tablets) would yield a net profit for Waymade of £47,500 per month against the £50,000 per month profit [Auden Senior Employee 2] estimated Waymade could earn if it entered (taking into account Waymade's '*cost savings in not bringing the product to market*').²³⁹⁶
- 6.455. Putting the contents of [Auden Senior Employee 2]'s 28 June 2011 email and [Auden Senior Employee 2]'s and [Auden Senior Employee 1]'s witness evidence alongside Waymade's contemporaneous internal correspondence and [Waymade Senior Employee 1]'s, [Waymade Senior Employee 2]'s and [Amdipharm Senior Employee]'s witness evidence, it is clear that Auden considered Waymade to be a threat to its market position. Waymade understood that it was this threat that gave it '*leverage*' in the negotiations. Waymade used this leverage to ensure Auden's proposed supply price to it dropped from £34.50 to £4.50 within a week. Auden's rationale for this was that, in exchange, Waymade would '*not [be] bringing its product to market*.'

²³⁹⁵ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011 (emphasis added).

²³⁹⁶ Noting that '*If Waymade had their own licence and achieved 50% mkt share at current pricing then they would net £50K per mth*', [Auden Senior Employee 2] proposed a deal that would give Waymade '*in total £47.5K per mth across both lines*.' Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

6.456. By 28 June 2011, therefore, the key terms of what would become the 20mg Agreement, once concluded, were becoming clear:

- a. Auden would make payments to Waymade. Rather than supplying Waymade at the prevailing wholesale rate (£34.50) as Auden had proposed a week earlier, Auden would instead supply Waymade with 1,000 packs per month at an 87% discount (£4.50 per pack). Auden acknowledged that this amounted to paying Waymade: [Auden Senior Employee 2] proposed to give Waymade a deal that would generate total value for Waymade of '*£47.5K per mth across both lines*'.
- b. In exchange, Waymade would not enter independently with its own 20mg hydrocortisone tablets:
 - i. Auden was willing to revise its proposed supply terms in this way because it meant Waymade would be '*not bringing the product to market*' and '*by buying it from him [[Auden Senior Employee 1]] then we wouldn't produce it*'.²³⁹⁷
 - ii. Waymade understood that it was able to obtain these much more favourable terms because by disclosing to Auden that it held a 20mg MA it had moved '*from a position of being just another wholesaler customer to Auden Mckenzie ... to Waymade being in a position where it can, in theory, bring its product to the market*'.²³⁹⁸ The competitive threat Waymade posed was key: '*they would have actually lost a lot of the market share to us [Waymade], therefore they would have said ... "Look, we'll supply you or we will come to an agreement"*'.²³⁹⁹

4 July 2011: meeting between [Auden Senior Employee 2] and [Amdipharm Senior Employee]

6.457. On 4 July 2011, [Auden Senior Employee 2] of Auden met with [Amdipharm Senior Employee] and [Waymade Employee] of Waymade. At this meeting, they agreed that Auden would supply Waymade with 20mg hydrocortisone tablets at a price of £4.50 per pack.

²³⁹⁷ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011. Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 37, lines 10 to 13.

²³⁹⁸ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10.

²³⁹⁹ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 15 to 20 and page 14, lines 16 to 17.

- 6.458. [Auden Senior Employee 2]'s handwritten notes of the meeting record that [Amdipharm Senior Employee], [Waymade Senior Employee 4] and [Waymade Employee] attended for Waymade. They state:

'Hydrocortisone 10mg & 20 mg – Favourable terms

...

Hydro 10mg – 20%

4.50 – Invoice higher and quarterly to send buying price. Check [Auden Senior Employee 1]'.²⁴⁰⁰

- 6.459. These notes indicate that the parties had discussed Auden supplying Waymade with hydrocortisone tablets on '*Favourable terms*': in relation to 20mg tablets, at a price of £4.50 achieved via a rebate ('*Invoice higher*'). [Auden Senior Employee 2] was to obtain approval of this deal from [Auden Senior Employee 1] ('*Check [Auden Senior Employee 1]*').

- 6.460. The following day [Auden Senior Employee 2] emailed [Amdipharm Senior Employee] and [Waymade Senior Employee 4] of Waymade, stating: '*The hydrocortisone 20mg will be at the pricing we agreed in the meeting*'.²⁴⁰¹ [Waymade Senior Employee 4] of Waymade confirmed in interview that the price agreed at the meeting was £4.50 per pack: '*The price that... I was to put on the purchase order ...was £4.50. That was the price that was agreed on the 20 milligram ... By [Amdipharm Senior Employee]*'.²⁴⁰²

11 July 2011: exchange of emails between [Auden Senior Employee 2] and [Waymade Senior Employee 4]

- 6.461. The 20mg Agreement was concluded on 11 July 2011 by an exchange of emails between [Auden Senior Employee 2] and [Waymade Senior Employee 4] which demonstrate a common understanding between the parties in respect of: (i) the volume of packs Auden would supply to Waymade; (ii) the price Waymade would pay for those packs; and (iii) the existence of the Buyback and how it would work. Considered in their full context, the emails further demonstrate that there was a common understanding between the parties that Waymade would not independently enter the market with its own 20mg tablets in exchange for the substantial

²⁴⁰⁰ Document 00751, [Auden Senior Employee 2]'s handwritten notes of meeting on 4 July 2011.

²⁴⁰¹ Document 300190, email from [Auden Senior Employee 2] to [Waymade Senior Employee 4] and [Amdipharm Senior Employee] dated 5 July 2011; Document 300191, Auden McKenzie – Waymade List, July 2011.

²⁴⁰² Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, page 13, lines 5 to 10. Document 200010, data submitted by Waymade on its purchases of hydrocortisone tablets from Auden, also confirms that the price was £4.50.

payments it received from Auden through the 'special price' and the Buyback.

6.462. [Waymade Senior Employee 4] stated:

*'Managed to get to both [Amdipharm Senior Employee] and [Waymade Employee] Friday evening to discuss the amended offer and yes we are ok with the idea to Invoice us the stock at the special price and we immediately sell back 800 of them to you at £34.50. The problem we have as I suspected is the other 200, where we are not willing to compromise on the agreed terms of these coming to us also at the special price. Basically yes if and when we see another 20mg licence granted on RAMA²⁴⁰³ ([Auden Senior Employee 1]'s terms to us) then we will have to come to discuss, but until that happens the deal is sound.'*²⁴⁰⁴

6.463. [Auden Senior Employee 2] replied: *'understand your situation and agree that we will go with the terms below [ie those that [Waymade Senior Employee 4] had set out] and reassess the situation as and when there are any licensing updates.'*²⁴⁰⁵

6.464. The emails exchanged on 11 July 2011 show that Auden further improved its supply terms to Waymade from those it was internally considering on 28 June 2011, to include the unusual Buyback, under which Auden would 'sell' 800 packs to Waymade at £4.50 and then immediately 'buy them back' at £34.50. The remaining 200 packs would be sold to Waymade at the 'special price', which remained £4.50, consistent with [Auden Senior Employee 2]'s email of 28 June 2011.

6.465. The emails also confirm that the total volume covered by the 20mg Agreement remained 1,000 packs per month comprised of 800 packs under the Buyback and an additional 200 packs which would be supplied to Waymade. This is consistent with [Waymade Employee]'s proposal to [Auden Senior Employee 2] and [Auden Senior Employee 2]'s email of 28 June 2011 to [Auden Senior Employee 1], and also achieved the approximate 70:30 split in volume terms that [Auden Senior Employee 2] had suggested.

²⁴⁰³ See below for an explanation of 'RAMA' and its relevance to the Agreements.

²⁴⁰⁴ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011 (emphasis added)

²⁴⁰⁵ Document 300619, email from [Auden Senior Employee 2] to [Waymade Senior Employee 4] dated 11 July 2011.

- 6.466. The scale of the changes to the deal are such that, under the terms [Auden Senior Employee 2] initially offered on 21 June 2011, Waymade would have paid Auden £8,280 per month. Under those eventually agreed on 11 July 2011, it was Auden that paid Waymade £30,000 per month: £24,000 in cash through the Buyback and £6,000 in margin transfer on the 200 packs sold to Waymade at £4.50 that it could sell to its customers at market rate (ie around £34.50).
- 6.467. These monthly payments from Auden would have been terminated had Waymade entered the market independently with its own 20mg product.²⁴⁰⁶
- 6.468. Auden was free to terminate the 20mg Agreement (which was never formalised in a written supply agreement) at any time if Waymade had in fact entered the market independently. There would have been no commercially rational reason for Auden to continue making the payments if Waymade entered the market with its own product: the reason that it made the payments was to protect its volumes from Waymade's entry, something both parties understood. That rationale would be undermined if Waymade entered independently.
- 6.469. This is illustrated by the fact that the 11 July 2011 emails also included a provision that the parties would revisit the 20mg Agreement's terms if a third party was granted an MA (*'if and when we see another 20mg licence granted on RAMA ... then we will have to come to discuss, but until that happens the deal is sound'* and [Auden Senior Employee 2]'s response that the parties would *'reassess the situation as and when there are any licensing updates'*).
- 6.470. 'RAMA' refers to RAMA XL – an external resource provided by the UK Government that would allow the parties to know when a third party obtained a 20mg MA.²⁴⁰⁷

²⁴⁰⁶ For example, [Waymade Senior Employee 4] of Waymade explained in interview that once Waymade entered with its own 20mg product, *'you would naturally end that supplier agreement.'* When asked why Waymade could not have entered with its own product and continued the 20mg Agreement, [Waymade Senior Employee 4] said: *'to me it's natural [that the 20mg Agreement would end], I don't understand why you're questioning that'*. Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 2, pages 36 to 39.

²⁴⁰⁷ RAMA XL is a subscription service offered by the MHRA with direct access to real-time information on all medicinal products authorised in the UK (www.gov.uk/government/publications/how-to-use-ramaxl/ramaxl). Its features include access to information on all UK MAs. In response to a due diligence question, *'Does [AM Pharma] expect any increased competition on any of its products in the near future?'* AM Pharma explained to its prospective buyers that it *'becomes aware of new license grants when it enters the public domain through the MHRA RAMA Portal which we monitor on a regular basis'*. Document 00208, responses to Project Apple due diligence questions dated 11 November 2014, response to question 5(a). [Waymade Senior Employee 4] explained in interview: *'you can see all the licences in the country for products'*. Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 1, page 22, line 15. [Waymade Employee], [REDACTED], explained that she was *'asked to run regular RAMA reports ... which is really monitoring who has a licence for what products and you would get ... a list of new licences that were granted within a period.'* She clarified that

6.471. '[Auden Senior Employee 1] *terms*' to Waymade, which Waymade accepted, were therefore that the 20mg Agreement would be '*sound*' until the parties became aware of another licence being granted for 20mg hydrocortisone tablets.²⁴⁰⁸ In other words, the 20mg Agreement would only serve its purpose for as long as there was no other potential entrant to the market.

6.472. When asked in interview with the CMA what he had meant by these terms ('[Auden Senior Employee 1]s *terms to us*'), [Auden Senior Employee 1] confirmed that the 20mg supply arrangement might need to be revisited if another competitor emerged (ie in addition to Waymade):

*'they were taking supply from us ... All this is saying if there was another competitor, then that scenario may change.'*²⁴⁰⁹

6.473. By '*that scenario*', [Auden Senior Employee 1] referred to the 20mg supply arrangement ('*they were taking supply from us...*'): a scenario in which Waymade, Auden's potential competitor, took supplies from Auden at a '*special*' supply price because that would protect Auden's volumes.

6.474. The emergence of another competitor would destabilise that scenario: it would mean that the 20mg Agreement no longer sufficed to preserve Auden's position as the monopoly supplier of 20mg hydrocortisone tablets and the value both parties could extract from it. As [Waymade Senior Employee 4] explained:

*'The more licence holders you have in the market the more the price and the stability of your product ... gets disrupted ... the agreement won't stand ... if there was another licence holder come to the market then ...we start again, we re-negotiate or whatever we have to do at that point, because the dynamics change.'*²⁴¹⁰

6.475. The 'RAMA clause' was entirely consistent with Auden's strategy. The 20mg Agreement was designed to protect Auden's position as the monopoly supplier of 20mg tablets. If another company was granted an MA, the 20mg

RAMA could be used to identify companies that were '*potentially coming to the market*': Document 302405, transcript of [Waymade Employee] interview dated 23 November 2018, page 38 lines 15 to 24.

²⁴⁰⁸ Compare the IVAX and Alpharma (Actavis) agreements in *GSK v CMA* [2018] CAT 4 (*Paroxetine*), which '*could be terminated if or when generic supplies of paroxetine from other companies entered the UK market*' (paragraph 55). Compare also the agreement in Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, which provided for renegotiation if any party had a rival product registered on the Dutch pharmacy TAXE list.

²⁴⁰⁹ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018 page 40, lines 21 to 23 (emphasis added).

²⁴¹⁰ Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018, part 1, page 22, lines 25 to 27; page 23, lines 1 to 2 and lines 26 to 27; page 26, line 27 and page 27 lines 1 to 3.

Agreement might no longer serve its purpose of protecting Auden's monopoly position and would require renegotiation.

- 6.476. Further, taking account of the rationale for the 'RAMA clause' and the wider context (in particular [Auden Senior Employee 2]'s costing of the 20mg Agreement on the basis that Waymade would not independently enter; Auden's desire to protect its market position as the monopoly supplier of 20mg hydrocortisone tablets and the fact that Waymade understood it could not benefit from the 20mg Agreement and enter the market independently at the same time), the 'RAMA clause' provides evidence that Auden would have terminated the 20mg Agreement if Waymade had independently entered the market and that the parties had a common understanding in this regard.
- 6.477. This is because there is no reason why Auden would have treated entry by Waymade into the market with 20mg tablets differently from any other third party. The effect of independent entry (whether by Waymade or a third party) would be the same: a reduction in Auden's sales volumes and revenues; and it was this risk that the RAMA clause was guarding against. Auden was also clear: its rationale for entering into the 20mg Agreement was to protect its sales volumes from Waymade's potential entry, demonstrating that it would not have seen Waymade's entry differently from others'. Moreover, Waymade understood that Auden wished to protect its market position.
- 6.478. The evidence discussed throughout the sections above therefore shows that there was a common understanding between the parties as to what the 20mg Agreement entailed: that Waymade, Auden's potential competitor, received a substantial (87%) reduction in the price it paid for Auden's 20mg hydrocortisone tablets and that in exchange Waymade would not enter the market independently with its own 20mg hydrocortisone tablets. In particular:
- a. It is clear from [Auden Senior Employee 1] and [Auden Senior Employee 2]'s witness interviews that Auden offered Waymade a substantially reduced price to maintain its volumes – which also meant Waymade would not be independently entering the market if the negotiations were successful. [Auden Senior Employee 2] prepared Auden's proposed supply terms on the basis of Waymade '*not bringing*' its '*product to market*'. [Auden Senior Employee 1] stated that Waymade '*came to us [Auden] and said look we have our product but we'd like to take supply from you*'²⁴¹¹ (emphasis added) – suggesting that Waymade told Auden expressly that it considered supply from

²⁴¹¹ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 32 line 27 and page 33 line 1.

Auden an alternative (in fact, a preferred alternative) to launching its own product.

- b. Waymade understood that its competitive threat provided it with '*leverage*' in negotiations with Auden and this meant that Auden may have been prepared to offer it a substantially lower supply price to protect its volumes. It also understood (in common with Auden) that the low price would be in exchange for it not independently entering the market with its own 20mg tablets. For example, [Waymade Senior Employee 1] understood that Auden offered Waymade a low supply price to protect its market share by avoiding Waymade being '*a second player*' in the market.²⁴¹² [Amdipharm Senior Employee] [§] also understood that Auden offered its low price to protect its market share, explaining that Waymade could either '*get product made at our own CMO, or they [Auden] can supply us at a price which we feel is competitive*'²⁴¹³ and that, if Auden had not agreed to supply Waymade at a significantly reduced price, Waymade '*would have carried on with our own 20mg*.'²⁴¹⁴
- c. The parties included the additional 'RAMA clause' recognising that independent third-party entry would undermine the rationale for their arrangement and require it to be revisited.

The parties' conduct after entering into the 20mg Agreement

- 6.479. The parties' conduct after entering into the 20mg Agreement provides further evidence of their common understanding that Waymade would not enter independently with its own 20mg product in exchange for the substantial payments it received from Auden.
- 6.480. On Auden's side, implementation of the 20mg Agreement would require it to make monthly payments to Waymade, so long as Waymade did not enter with its own 20mg hydrocortisone tablets. Auden made these regular payments to Waymade until April 2015.
- 6.481. On Waymade's side, implementation of the 20mg Agreement would require that it did not enter the market independently with its own 20mg tablets, so long as it was receiving the payments from Auden. Any delays in the

²⁴¹² Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 12 to 20 and page 14, lines 16 to 17.

²⁴¹³ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 26, lines 26 and page 27, lines 1 to 2 (emphasis added).

²⁴¹⁴ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 30, lines 9 to 16.

(re)development of its own 20mg product, when considered in their context, are further evidence of implementation of the 20mg Agreement.

6.482. Waymade did not enter the market until July 2015 (after the 20mg Agreement had finished), despite having saleable product years before then, in the form of the tablets packed from the Third Batch. That product was warehoused and stringent steps were taken to ensure it was not inadvertently sold.

6.483. As explained in paragraphs 6.401 to 6.416 above, Waymade took delivery of a saleable batch of 20mg hydrocortisone tablets in May 2011. However, by that point Waymade had already decided to ‘freeze’ this product *‘pending the outcome of negotiations with Auden McKenzie’*.²⁴¹⁵

6.484. [Waymade Senior Employee 3] [REDACTED] explained:

*‘it [the stock packed from the Third Batch] was blocked on the system, so that an operative telephone sales person couldn’t inadvertently take an order and despatch product ... It’s disabled if you like.’*²⁴¹⁶

6.485. [Waymade Senior Employee 3] further stated:

‘The explicit meaning is that the product could be launched but it was decided that they would..., the product would not be launched’.²⁴¹⁷

6.486. This decision meant that Waymade’s staff had to review the accounting of the development costs leading to the tablets from the Third Batch being packaged. On 21 November 2011 [Waymade Employee], [REDACTED] at Waymade, emailed [Amdipharm Senior Employee] with the subject: ‘Sovereign Medical – Hydrocortisone 20mg tabs’:

*‘I understand that the fee arrangement has now come into effect to defer marketing of our product. As this represents revenue attributable to the development costs, I will need to review the accounting of the costs.’*²⁴¹⁸

6.487. [Waymade Employee] asked [Amdipharm Senior Employee] to clarify whether all Waymade’s costs *‘relate to the 20mg strength, ie necessary*

²⁴¹⁵ Document 300180, Monthly Report Sovereign Generics April 2011, page 2.

²⁴¹⁶ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, page 32, lines 18 to 20.

²⁴¹⁷ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, page 32, lines 15 to 16 (emphasis added).

²⁴¹⁸ Document 202157, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 21 November 2011 (emphasis added).

condition for launching this strength' or whether some related to the 10mg development. [Waymade Employee] continued:

*'I understand that stock is currently ready but not being shipped. Does the arrangement lead to any erosion of the current value of stocks (eg loss of shelf life)?'*²⁴¹⁹

6.488. [Waymade Employee]'s email to [Amdipharm Senior Employee] confirms the key terms of the 20mg Agreement. In particular:

- a. Waymade had agreed not to launch its 20mg tablets in exchange for payment (*'the fee arrangement has now come into effect to defer marketing of our product'*);
- b. The payment Waymade received in exchange for not launching was attributable to its investment in developing its own 20mg tablets (*'this represents revenue attributable to the development costs'*). In other words, Waymade's development of its own product had succeeded in extracting this 'fee' (consistently with [Waymade Senior Employee 3]'s assessment of Waymade's 'leverage' discussed at paragraph 6.417 above); and
- c. Waymade's 20mg product was ready for sale but was not to be sold because of this arrangement (*'stock is currently ready but not being shipped'*).

6.489. Rather than selling the packs of tablets from the Third Batch it had received in May 2011, Waymade retained them as an insurance policy in case the 20mg Agreement broke down. For example, an internal exchange of emails in March 2013 stated that the stock was being stored '*just in case*', confirming that '*the decision is that we will be holding the stock and not selling it*'.²⁴²⁰ The expiry date on this batch was 30 November 2013.

6.490. On 13 March 2013, [X] noted that he had seen Waymade's 20mg product in inventory '*and the description line has a dot before the description therefore no one can see this for selling, the expiry date on this is 11/2013, do you know if you want to sell?*' [Waymade Senior Employee 4] responded: '*Please*

²⁴¹⁹ Document 202157, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 21 November 2011 (emphasis added).

²⁴²⁰ Document 300790, emails (i) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; (ii) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; and (iii) from [Waymade Senior Employee 4] to [Waymade Employee] dated 8 April 2013.

*leave the stock where it is, we area ware [sic] it is going out of date but need it available just in case.*²⁴²¹

6.491. As explained in section 3.F.II.a above, Waymade's Fourth Batch failed dissolution tests – meaning that Aesica recommended that Waymade undertake reformulation for future batches. However, Waymade also mothballed the reformulation of its own 20mg hydrocortisone tablets during much of the term of the 20mg Agreement. Waymade deferred for years the routine reformulation work that it understood as early as November 2010²⁴²² and certainly by March 2011²⁴²³ would be necessary to continue production. This decision was clearly linked to Waymade entering into the 20mg Agreement with Auden:

- a. In May 2011 [REDACTED] [Waymade Senior Employee 3] explained to colleagues that Waymade's *'Finished packs of 20mg tablets ... will not be released for sale pending the outcome of commercial negotiations with a third party'*. [Waymade Senior Employee 3] also explained that *'The outcome of these discussions will inform the decision as to whether the 20mg tablet is reformulated in line with the 10mg tablet'*.²⁴²⁴
- b. In June 2011 Waymade's regular hydrocortisone tablets meeting noted that the *'status of negotiations with third party ... will inform decision as whether we undertake reformulation'*, and that *'no further regular Monday meetings are necessary. This might change if we pick up the 20mg reformulation project'*.²⁴²⁵ [Waymade Senior Employee 3] informed [Amdipharm Senior Employee], *'If you and [Waymade Senior Employee 1] are confident that the Auden Mckenzie trading relationship is going to stick then I would suggest that we do not need*

²⁴²¹ Document 300790, emails (i) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; (ii) from [Waymade Employee] to [Waymade Employee] dated 13 March 2013; and (iii) from [Waymade Senior Employee 4] to [Waymade Employee] dated 8 April 2013 (emphasis added).

²⁴²² Document 300125, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 2], [REDACTED], [Waymade Employee] and others dated 29 November 2010.

²⁴²³ Document 300166, Minutes of joint Aesica Sovereign review 31/3/11, pages 1 to 2. See also Document 300736, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee], [Waymade Senior Employee 2] and others dated 28 March 2011; and Document 300176, email from [Aesica Employee] to [REDACTED], [REDACTED], [REDACTED] and others dated 27 April 2011; and attached Document 300177, Minutes update of joint Aesica Sovereign review 31/3/11.

²⁴²⁴ Document 300178, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] and others dated 9 May 2011.

²⁴²⁵ Document 300184, email from [Waymade Senior Employee 3] to [REDACTED], [Waymade Senior Employee 2] and others dated 6 June 2011.

*to reformulate at the current time ... We can come back to the reformulation at a later date if we want to.*²⁴²⁶

- 6.492. There was no formal communication between Waymade and Aesica between May 2011 (when Aesica delivered the tablets packed from the Third Batch to Waymade and submitted a proposal for the 20mg hydrocortisone tablet '*starch replacement project*'²⁴²⁷) and August 2013.
- 6.493. Waymade's decision to put the reformulation of its 20mg tablets on hold is at odds with its previous strategy of treating its development as a high priority and corroborates the CMA's finding that it agreed not to independently enter the market with its own 20mg tablets in exchange for the payments it received from Auden under the 20mg Agreement.
- 6.494. It is reasonable to infer that a commercial organisation such as Waymade, which had invested in developing a product to manufacture, would wish to recoup its costs (or at least minimise its losses) by selling its saleable product and reformulating to obtain a sustainable supply. While Waymade's '*very unusual*'²⁴²⁸ behaviour does not, in itself, demonstrate that it had agreed it would not independently enter the market with its own 20mg tablets, when it is considered in the wider context it corroborates the substantial body of evidence of it having made such a commitment.

Email exchange between Waymade and Ambe Medical Group regarding supply of 20mg hydrocortisone tablets

- 6.495. An email exchange between [Waymade Senior Employee 4] and a contact at Ambe Medical Group on 31 January 2012 further supports the conclusion that Waymade understood it would not independently enter the UK market under the terms of the 20mg Agreement.
- 6.496. Ambe Medical Group enquired whether Waymade would be able to supply it with 5,000 packs of 20mg hydrocortisone tablets, which were destined for Yemen. At the time of the email exchange, Waymade had continued to warehouse the tablets packed from the Third Batch – the 3,560 bottles of Aesica-manufactured tablets it had received in May 2011 and which were available for commercial sale in the UK.
- 6.497. [Waymade Senior Employee 4] responded:

²⁴²⁶ Document 200017, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] dated 23 June 2011.

²⁴²⁷ Document 200017, email from [Aesica] to [Waymade Senior Employee 3] dated 11 May 2011.

²⁴²⁸ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 34, lines 3 to 5.

*'I can get 3550 packs of 20mg 30's that have 11/2013 expiry at a good price but they MUST be exported and guarantee they do not end up back in UK. Interested?'*²⁴²⁹

- 6.498. The 3,550 packs [Waymade Senior Employee 4] referred to were the packs of tablets from the Third Batch and not Auden's tablets.
- 6.499. It is clear from [Waymade Senior Employee 4]'s email that Waymade was only prepared to supply the Aesica-manufactured tablets to Ambe Medical Group on condition that they were not sold in the UK. He emphasised that they *'MUST be exported'* and asked for a *'guarantee they do not end up back in UK.'*
- 6.500. The concern [Waymade Senior Employee 4] showed as to the geographic destination of the product is consistent with Waymade's behaviour in relation to the packs of tablets from the Third Batch – which it had *'blocked'* on its sales system to avoid an *'inadvertent'* sale.²⁴³⁰ It also further corroborates the CMA's conclusion that Waymade had reached a common understanding with Auden that it would not independently enter the market with its 20mg hydrocortisone tablets in exchange for the substantial payments it received from Auden.
- 6.501. This is all the more so when the email is placed in its wider context – in particular, the fact that Waymade understood that Auden was only prepared to offer the payments Waymade received under the 20mg Agreement if Auden's volumes were protected. Significantly, the sender of the email – [Waymade Senior Employee 4] – was an individual who was close to the negotiations with Auden and was also the Waymade employee who exchanged emails with [Auden Senior Employee 2] on 11 July 2011 which confirmed the 20mg Agreement. Therefore, he would have had a clear understanding of Waymade's obligations under the 20mg Agreement.

Internal exchange between [Waymade Employee] and [Waymade Senior Employee 2]

- 6.502. Further evidence of the clear link between the 20mg Agreement and Waymade suspending developing its own 20mg hydrocortisone tablets is provided by a much later exchange of emails between [Waymade Senior Employee 2] and [Waymade Employee] in February 2014. [Waymade Senior Employee 2] had asked [Waymade Employee] to look into the status of its

²⁴²⁹ Document 300216, email from [Waymade Senior Employee 4] to [X] dated 31 January 2012.

²⁴³⁰ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, page 32, lines 18 to 20.

*'frozen'*²⁴³¹ 20mg development project.²⁴³² At the time Waymade was considering selling its 20mg MA to AMCo (see section 3.F.II.c above).

6.503. On 25 February 2014, [Waymade Employee] responded to [Waymade Senior Employee 2]'s request informing him that:

*'There are no regulatory issues preventing us from producing packs of 30 tablets in amber glass bottles ... A decision was made not to proceed with the blister pack and re-formulation due to the commercial arrangement we'd entered into which prevented us marketing our product.'*²⁴³³

6.504. [Waymade Employee] attached a report confirming that three commercial scale batches had been successfully manufactured but were *'not marketed due to agreement with 3rd party'*.²⁴³⁴

6.505. [Waymade Senior Employee 2] replied: *'Very useful. Thanks [Waymade Employee].'*²⁴³⁵

6.506. In his interview [Waymade Employee] explained:

'I knew that we had stock, at the time, we had stock that was suitable for release and that release was put on hold, or delayed, due to the negotiations with the third party.

...

*the stock had been frozen at our warehouse pending the commercial negotiations with the third party. So I assumed that was the only thing that was preventing us from releasing our stock.'*²⁴³⁶

6.507. He added that *'that was what was stated in the project meetings back in 2011 when we did have – after we had received the stock ... By [Waymade Senior Employee 3] [X].'*²⁴³⁷

²⁴³¹ Document 300180, attachment to document 300179, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] and others dated 11 May 2011.

²⁴³² Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, pages 55 to 60.

²⁴³³ Document 301673, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014 (emphasis added).

²⁴³⁴ Document 301674, Hydrocortisone 20mg Tablets – Regulatory Status February 2014, attachment to Document 301673.

²⁴³⁵ Document 301675, email from [Waymade Senior Employee 2] to [Waymade Employee] dated 25 February 2014.

²⁴³⁶ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, (emphasis added) page 57, lines 16-18 and page 58, lines 8-10 (emphasis added).

²⁴³⁷ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, page 57, lines 25-27 and page 58, line 3.

- 6.508. [Waymade Employee]'s evidence is significant because it reflected retrospectively on Waymade's decision to suspend the development of its own 20mg hydrocortisone tablets. It shows that development work had by this time not restarted following Waymade's entry into the 20mg Agreement with Auden.
- 6.509. When asked what '*commercial arrangement*' [Waymade Employee] was referring to in his email, [Waymade Senior Employee2], who had asked [Waymade Employee] to look into the history of Waymade's 20mg product and who received the email, stated: '*I'm not aware of any commercial arrangement which prevented us marketing our product ... I have no idea where [Waymade Employee] got that information from*'.²⁴³⁸ [Waymade Senior Employee2] stated that he was '*surprised to read that*'.²⁴³⁹ He could not explain why [Waymade Employee] would have had this perception or recall whether he had made any further inquiries of [Waymade Employee] or other individuals within Waymade to clarify the statement. At the time, however, he replied to [Waymade Employee]'s email, saying only: '*Very useful. Thanks [Waymade Employee]*'.²⁴⁴⁰ Within an hour of receiving [Waymade Employee]'s email, he forwarded it to his colleague [Waymade Employee], without any further comment.²⁴⁴¹ If he had felt that [Waymade Employee]'s statement was surprising or unfounded, he would presumably have said so at the time or, at a minimum, not forwarded it without further comment.
- 6.510. [Waymade Senior Employee2] stated that rather than clarifying with [Waymade Employee], he had '*gone straight to Aesica and asked them to do the work*'.²⁴⁴² If [Waymade Senior Employee2] was in fact '*surprised to read*' [Waymade Employee]'s account of the 20mg Agreement as a commercial arrangement that '*prevented us marketing our product*', he would surely have made further inquiries as to the nature of this arrangement before risking wasting money on having Aesica do further work.
- 6.511. Further, [Waymade Employee] stated that [Waymade Senior Employee2] was not the only one who had not queried his explanation of the arrangement at the time. Not one of the other recipients of his email queried

²⁴³⁸ Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018, page 34, lines 2 to 6.

²⁴³⁹ Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018, page 35, line 6.

²⁴⁴⁰ Document 301675, email from [Waymade Senior Employee 2] to [Waymade Employee] dated 25 February 2014.

²⁴⁴¹ Document 302310, email from [Waymade Senior Employee 2] to [Waymade Employee] dated 25 February 2014.

²⁴⁴² Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018, pages 35 to 36.

his statement that the '*commercial arrangement*' had prevented Waymade from marketing its product.²⁴⁴³

- 6.512. Moreover, [Waymade Senior Employee2] 's observations are at odds with the contemporaneous documentary evidence which linked Waymade's decision not to carry out the '*very straight forward*'²⁴⁴⁴ reformulation work to its negotiations with Auden: see for example, [Waymade Senior Employee 3]'s email to [Amdipharm Senior Employee] of 23 June 2011, discussed in paragraph 6.415 above.

²⁴⁴³ Document 302466, transcript of [Waymade Employee] interview dated 12 November 2018, pages 55 to 57.

²⁴⁴⁴ Document 300453, email from [Waymade Senior Employee 2] to [X] and [Waymade Senior Employee 1] dated 6 May 2014.

The parties' representations on the 20mg Agreement

- 6.513. Despite making extensive representations on the SSO, neither Waymade nor Auden provided any explanation for the 87% discount Auden gave Waymade under the 20mg Agreement, or for the Buyback, other than that they resulted from Waymade's 20mg MA and Auden's desire to preserve its CMO volumes.²⁴⁴⁵
- 6.514. The parties' representations discussed below should be read in this context. The parties have not explained why Auden agreed to pay Waymade thousands of pounds each month.²⁴⁴⁶

'Waymade did not use its 20mg product as leverage'

- 6.515. Waymade submitted that it did not use its 20mg product as leverage in negotiations with Auden.²⁴⁴⁷ In particular, Waymade stated that its [X] [Waymade Senior Employee 3] was not a party to the negotiations and therefore suggested his observation that *'the fact that the product is there in the warehouse in Basildon is the leverage'* was *'deliberately framed as speculation'* and therefore *'simply not credible ... as an explanation as to how Waymade applied 'leverage' in negotiating with Auden'*.²⁴⁴⁸
- 6.516. First, this representation ignores the significant volume of evidence which corroborates [Waymade Senior Employee 3]'s interview statement with regard to Waymade leveraging its ability to enter the market independently with its own 20mg hydrocortisone tablets to secure better supply terms from Auden. For example:
- a. The fact that Auden initially offered to supply Waymade with 20mg tablets at £34.50 per pack, before revising its proposed price down by 87%, to £4.50 per pack, within the space of a week after Waymade informed Auden that it held a 20mg MA. This proposal was designed on the basis that Waymade would be *'not bringing the product to market'* (see paragraphs 6.432 to 6.440 above).²⁴⁴⁹ Key individuals from both

²⁴⁴⁵ The parties did not dispute that under the Buyback Auden paid Waymade approximately £1.8 million in cash over four years. But neither Waymade nor Auden/Actavis made any attempt to explain this. Waymade stated only that it was agreed *'for what appears to be the sake of convenience'* (Document 204903, Waymade's RSSO, paragraph 7.12). That is no explanation for a potential entrant receiving monthly cash payments from the incumbent supplier. Auden/Actavis stated that it *'secured a constant demand for its [Waymade's] 20mg Hydrocortisone Tablets'* and *'allowed Waymade to obtain an agreed price for 800 packs by accessing Auden's client base'* (Document 205217, Auden/Actavis's RSSO, paragraph 7.80). This misconstrues how the Buyback worked: the Buyback did not relate to Waymade's 20mg tablets or allow Waymade to access Auden's client base.

²⁴⁴⁶ Compare *GSK v CMA* [2021] CAT 9, paragraph 51.

²⁴⁴⁷ Document 204903, Waymade's RSSO, paragraphs 7.38 and 7.42.

²⁴⁴⁸ Document 204903, Waymade's RSSO, paragraphs 7.39-7.41.

²⁴⁴⁹ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

Waymade and AMCo explained that this was because of the competitive threat Waymade posed to Auden. For example, [Waymade Senior Employee 1] stated that *'If we [Waymade]..., when we came to the market, they could have actually lost a lot of the market share to us, therefore they would have said ... "Look, we'll supply you or we will come to an agreement" ... the fact that there's not a second player is always in their [Auden's] interest'*.²⁴⁵⁰ See further paragraphs 6.441 to 6.451 above.

- b. [Waymade Senior Employee 1]'s, [Auden Senior Employee 1]'s and [Amdipharm Senior Employee]'s explanation that the rationale for the 20mg supply deal was to protect Auden's volumes – something that could only be achieved through Waymade agreeing not to independently enter the market with its own hydrocortisone tablets. For example, [Amdipharm Senior Employee] stated in interview that Waymade had moved from being just another customer to *'a position where it can, in theory, bring its product to the market'*.²⁴⁵¹ See paragraphs 6.419 to 6.430 and 6.442 to 6.451 above.
- c. Waymade's conduct, including 'freezing' its 20mg product pending the outcome of its negotiations with Auden and mothballing the product as an insurance policy once those negotiations concluded. See paragraphs 6.411 to 6.416 and 6.483 to 6.491 above.
- d. Waymade's subsequent attempt to sell its product overseas on condition that *'they MUST be exported and guarantee they do not end up back in UK'*.²⁴⁵² See paragraphs 6.495 to 6.501 above.
- e. Waymade staff's subsequent references to *'the fee arrangement ... to defer marketing of our product'* (see paragraph 6.486 above)²⁴⁵³ and *'the commercial arrangement we'd entered into which prevented us marketing our product'* (see paragraph 6.503 above).²⁴⁵⁴

6.517. Secondly, the contemporaneous documentary evidence discussed above demonstrates that, although [Waymade Senior Employee 3] may not have been involved in negotiations with Auden, he did understand that the development of Waymade's 20mg tablets was relevant to those negotiations.

²⁴⁵⁰ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 15 to 20 and page 14, lines 16 to 17 (emphasis added).

²⁴⁵¹ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10.

²⁴⁵² Document 300216, email from [Waymade Senior Employee 4] to [X] dated 31 January 2012.

²⁴⁵³ Document 202157, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 21 November 2011.

²⁴⁵⁴ Document 301673, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014.

For example, [Waymade Senior Employee 3]’s email to [Waymade Senior Employee 1] on 23 December 2010 showed that he knew there was a link between the negotiations with Auden and the development of Waymade’s own product – which is again corroborated by other evidence (including witness evidence provided by [Amdipharm Senior Employee] and [Waymade Senior Employee 1]).²⁴⁵⁵

- 6.518. Accordingly, the CMA finds that [Waymade Senior Employee 3]’s evidence on this point is credible and consistent with (and corroborated by) a wider body of evidence. [Waymade Senior Employee 3] would have understood that the reason that Waymade’s 20mg product was relevant was because of its use as leverage in negotiations, consistently with his explanation in interview. He was, after all, [§].

‘Waymade was negotiating with a wholesaler’

- 6.519. Waymade submitted that *‘There is nothing inherently anti-competitive about seeking to negotiate the best possible supply terms from a wholesaler (this would generally be viewed as pro-competitive)’*.²⁴⁵⁶

- 6.520. This representation completely mischaracterises the CMA’s findings. The CMA has found the existence of a horizontal market sharing agreement between Waymade and Auden in addition to the vertical supply arrangement.

- 6.521. The grounds for finding a horizontal agreement are clear and unambiguous.

- 6.522. Waymade was a potential competitor to Auden, it was at an advanced stage in preparing to independently launch its own 20mg hydrocortisone tablets. Not only did it hold an MA, it had received market ready stock which it could have sold.

- 6.523. However, the common consensus of the witnesses the CMA has interviewed in this case (corroborated by documentary evidence) is that once it was in a position to enter the market, Auden no longer perceived Waymade as a customer – but as a competitive threat. In other words, the wholesaler/customer relationship no longer existed.

- 6.524. The shift from Auden treating Waymade purely as a customer to a competitive threat was reflected in the very significant change in the

²⁴⁵⁵ [Waymade Senior Employee 3] stated: *‘the earliest launch of our Hydrocortisone product in glass bottles is May or June 2011 ... With regards to a negotiation with Auden Mckenzie, I suggest that opening a discussion in January would be about right’* (Document 300138, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] dated 23 December 2010).

²⁴⁵⁶ Document 204903, Waymade’s RSSO, paragraphs 7.139(b) and 2.20.

commercial terms Auden offered to Waymade in order for it to supply 20mg tablets (see paragraphs 6.432 to 6.466 above). This change in terms over the course of a week means that Waymade's characterisation of Auden as a 'wholesaler' does not reflect the reality at the time when the 20mg Agreement was concluded. As explained in paragraphs 6.432 to 6.440 above, Auden initially offered Waymade a wholesale price – £34.50 – before rapidly reducing that price to £4.50 when it became aware of Waymade's 20mg MA and therefore the threat that it would enter the market and compete with it. The price Waymade paid was explicitly not a wholesale price.

6.525. This was acknowledged by the witness evidence of a number of key staff on both sides. For example:

- a. [Auden Senior Employee 1] stated: *'they [Waymade] had come, come and asked us for supply, they had a 20 milligram [MA] and it was either for us to do nothing, which we could have, or to supply them, which would maintain our volume and still make us money, so that's what we did.'*²⁴⁵⁷
- b. [Amdipharm Senior Employee] of Waymade confirmed in interview that the key change in the negotiations that led to Waymade's £30 discount was that: *'Waymade moves from a position of being just another wholesaler customer to Auden Mckenzie ... to Waymade being in a position where it can, in theory, bring its product to the market'*.²⁴⁵⁸
- c. When asked *'What was special about Waymade?'*, [Auden Senior Employee 2] stated: *'Because we know Waymade had their own marketing authorisation ... Because Waymade had the facility to manufacture their product. Or they could buy it from us.'*²⁴⁵⁹

6.526. The CMA has found that in exchange, Waymade agreed not to enter the market independently with its own 20mg hydrocortisone tablets. In addition to the evidence discussed above in paragraphs 6.516 to 6.518, the parties also included in their deal the 'RAMA clause' which stipulated that the arrangement would have to be revisited if independent third-party entry took place. See paragraphs 6.469 to 6.477 above.

²⁴⁵⁷ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 31, line 27 and page 32, lines 1 to 3.

²⁴⁵⁸ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10 (emphasis added).

²⁴⁵⁹ Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, page 19, lines 8-14.

- 6.527. The CMA has therefore found that Waymade took a heavily discounted supply of 20mg hydrocortisone tablets from its potential competitor Auden in exchange for not independently entering the market with its own 20mg tablets. Such an arrangement is inherently anti-competitive as it has the object of restricting and preventing competition between competitors.
- 6.528. For the avoidance of doubt, the characterisation of the 20mg supply deal as a '*wholesale*' arrangement could not provide any explanation for the Buyback, since under that arrangement Waymade received no product to sell. Indeed, if anything Waymade was the '*wholesaler*' under the Buyback, 'selling back' its 800 packs to Auden at what Waymade described as '*approximately a wholesale rate*'.²⁴⁶⁰

'The exhaustive terms of the 20mg Agreement were the terms of the supply deal'

- 6.529. Waymade submitted that the full terms of the 20mg Agreement were those set out in the email exchange between Auden and Waymade on 11 July 2011:²⁴⁶¹ '*1,000 packs sold by Auden to Waymade at £4.50/pack, with 800 being subject to a sell-back at £34.50/pack. These are expressed as the (exhaustive) terms*'²⁴⁶² (emphasis in original). However, Waymade did not attempt to explain the Buyback or 'RAMA clause', which are documented in this exchange (see paragraphs 6.461 to 6.477 above).
- 6.530. Waymade submitted that there was no documentary evidence of any '*term*' prohibiting or delaying Waymade's entry in that exchange, or in the contemporaneous manuscript notes of the discussions between the parties on 21 June and 4 July 2011 (discussed at paragraphs 6.432 and 6.458 above).²⁴⁶³

²⁴⁶⁰ Document 204903, Waymade's RSSO, paragraph 7.45.

²⁴⁶¹ Document 300619, email from [Auden Senior Employee 2] to [Waymade Senior Employee 4] dated 11 July 2011.

²⁴⁶² Document 204903, Waymade's RSSO, paragraph 7.11.

²⁴⁶³ Document 204903, Waymade's RSSO, paragraphs 2.11 and 7.19; Document 00752, [Auden Senior Employee 2]'s handwritten note of telephone call on 21 June 2011; Document 00751, [Auden Senior Employee 2]'s handwritten notes of meeting on 4 July 2011. See also Document 205217, Auden/Actavis's RSSO, paragraph 5.10. Waymade implied that the CMA had deliberately withheld these notes from Waymade, and later '*retrospectively sought to 'fit' the notes to its narrative*' (Document 204903, Waymade's RSSO, paragraph 7.21). This is not the case. As was explained to Waymade in a letter dated 25 September 2020, the notes were initially omitted from disclosure inadvertently and were disclosed as soon as this error became apparent. That their content did not change the CMA's findings reflects the fact that they contain little positive evidence – not any determination to fit evidence to a predetermined narrative.

- 6.531. As a starting point, it has been held that an undertaking's commitment not to enter a market *'is perfectly capable of existing as an unwritten understanding, which also reduces the likelihood of its discovery'*.²⁴⁶⁴
- 6.532. In this case, the parties' common understanding that Waymade would not independently enter the market with its own product is clear from the evidence set out above, considered as a whole.
- 6.533. Waymade's representation is very selective in its focus and ignores this very significant body of evidence.

'Waymade's volumes were not restricted'

- 6.534. Auden/Actavis submitted that the volume supplied to Waymade under the 20mg Agreement was not limited to 200 packs per month, because the true quantity available to Waymade was 1,000 packs (including those subject to the Buyback), and because Waymade's orders in individual months exceeded 200 packs.²⁴⁶⁵
- 6.535. The packs subject to the Buyback were not in any sense 'supplied' to Waymade. They were simply a means of achieving a cash payment from Auden to Waymade. The CMA has found that the packs supplied to Waymade for resale and the Buyback together constituted payments to Waymade. Whether or not Waymade could have accessed some of the packs subject to the Buyback for resale is irrelevant: this would simply have meant a different volume/cash ratio in those payments.
- 6.536. In any event, in relation to the packs that were actually supplied to Waymade, the agreement between the parties was that Waymade would be given 200 packs per month.²⁴⁶⁶ As set out in table 3.26 above, in 30 of the 46 months the 20mg Agreement lasted Waymade received 200 packs of 20mg tablets. In other months the quantity supplied to Waymade varied from 0 to 650 packs. However, this does not mean that the volume actually supplied to Waymade was not capped. These fluctuations reflected variations in individual monthly orders that were then corrected in

²⁴⁶⁴ T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 91. See also T-133/07 *Mitsubishi v Commission* EU:T:2011:345, paragraph 186. Upheld on further appeal in C-239/11, C-489/11 and C-498/11 *Siemens and Others v Commission*, EU:C:2013:866.

²⁴⁶⁵ Document 205217, Auden/Actavis's RSSO, paragraphs 5.16.1.1-5.16.1.3.

²⁴⁶⁶ See Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011 and response from [Auden Senior Employee 2]: *'we are ok with the idea to Invoice us the stock at the special price and we immediately sell back 800 of them to you at £34.50. The problem we have as I suspected is the other 200, where we are not willing to compromise on the agreed terms of these coming to us also at the special price.'* [Auden Senior Employee 2] replied, *'agree that we will go with the terms below'* and asked Waymade to submit the first order *'and we will despatch the 200 for you'*.

subsequent months to ensure an average of 200 packs per month across the term of the 20mg Agreement.

'Waymade's efforts to develop its own 20mg product disprove the CMA's case that it was bought off by Auden'

6.537. Waymade submitted that *'any steps taken by Waymade towards market entry would be very strong evidence that there was no joint intention that Waymade would not enter the market'*. It therefore stated that its periodic efforts to continue developing its 20mg product during the 20mg Agreement were *'overwhelming evidence'* that it had not agreed to refrain from entering with that product.²⁴⁶⁷

6.538. The evidence set out in section 6.D.II.b.i above demonstrates that Waymade received substantial payments from Auden. The evidence set out in section 6.D.II.c.i above demonstrates that both parties understood that those payments were to buy off Waymade's competitive threat. In particular, the key individuals on both sides understood that Waymade had faced two mutually exclusive options in the first half of 2011: continue to work towards launching its 20mg tablets and take volumes from Auden; or enter into an agreement that it would not launch, preserving Auden's volumes. For example, [Auden Senior Employee 1] stated: *'if they had their own product, they could either source supply somewhere else or they could source it from us; and sourcing from us allowed us to keep our volume'*.²⁴⁶⁸ [Auden Senior Employee 2] stated: *'we know Waymade had their own marketing authorisation ... Waymade had the facility to manufacture their own product. Or they could buy it from us'*²⁴⁶⁹ and, *'if they had their own manufacture and brought product into the market we would then naturally reduce our volumes'*.²⁴⁷⁰ [Amdipharm Senior Employee] stated that Waymade was able to obtain its 87% discount because it had moved from a position of being just another customer to Auden to *'a position where it can, in theory, bring its product to the market'*; and that: *'If they don't supply us ... and we come to the market, then they will have lost that manufacturing volume.'*²⁴⁷¹

²⁴⁶⁷ Document 204903, Waymade's RSSO, paragraph 7.89 (emphasis in original). See also paragraphs 2.50, 7.4, 7.89, 7.91, 7.97, 7.102-7.104, 7.114 and 8.98.

²⁴⁶⁸ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 35, lines 21 to 26 and page 36, lines 1 to 9.

²⁴⁶⁹ Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, page 19, lines 8-14.

²⁴⁷⁰ Document 00717, transcript of [Auden Senior Employee 2] interview dated 21 September 2016, part 2, page 4, lines 6 and 14 to 16.

²⁴⁷¹ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10 and page 32 lines 3-10.

- 6.539. Waymade's efforts to develop its own 20mg product are consistent with the evidence that both sides understood that the payments were to buy off Waymade's competitive threat.
- 6.540. As explained in section 6.C.II.b.ii above, on 9 May 2011 Waymade took supply of a market ready batch of its own 20mg hydrocortisone tablets with which it could have independently entered the market. It was also aware by March 2011 that it would need to conduct some routine reformulation work before it would be able to produce further batches for sale. However, rather than carry out that work Waymade froze its development process and its project to reformulate its 20mg tablets for future batches:
- a. In April 2011 Waymade chose to 'freeze' its 20mg tablets '*pending the outcome of negotiations with Auden McKenzie*'.²⁴⁷²
 - b. In May 2011 [X] [Waymade Senior Employee 3] explained to colleagues that Waymade's '*Finished packs of 20mg tablets ... will not be released for sale pending the outcome of commercial negotiations with a third party*'. [Waymade Senior Employee 3] also explained that '*The outcome of these discussions will inform the decision as to whether the 20mg tablet is reformulated in line with the 10mg tablet*'.²⁴⁷³
 - c. In June 2011 Waymade's regular hydrocortisone tablets meeting again noted that the '*status of negotiations with third party ... will inform decision as whether we undertake reformulation*', and that '*no further regular Monday meetings are necessary. This might change if we pick up the 20mg reformulation project*'.²⁴⁷⁴ [Waymade Senior Employee 3] informed [Amdipharm Senior Employee], '*If you and [Waymade Senior Employee 1] are confident that the Auden McKenzie trading relationship is going to stick then I would suggest that we do not need to reformulate at the current time.*'²⁴⁷⁵
- 6.541. As explained in sections 3.F.II.a and c above, once those negotiations succeeded in securing the 20mg Agreement, Waymade had no contact with Aesica on 20mg tablets between May 2011 and August 2013. This meant that it deferred for years the routine reformulation work that it understood as

²⁴⁷² Document 300180, Monthly Report Sovereign Generics April 2011, page 2.

²⁴⁷³ Document 300178, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] and others dated 9 May 2011.

²⁴⁷⁴ Document 300184, email from [Waymade Senior Employee 3] to [X], [Waymade Senior Employee 2] and others dated 6 June 2011.

²⁴⁷⁵ Document 200017, email from [Waymade Senior Employee 3] to [Amdipharm Senior Employee] dated 23 June 2011.

early as November 2010 and certainly by March 2011 would be necessary to continue production.

6.542. Thereafter Waymade periodically re-engaged with the project, in particular when prompted by disruptions to the smooth running of the 20mg Agreement and external stimuli such as its negotiations in February 2014 to sell its 20mg MA to AMCo.²⁴⁷⁶

6.543. The fact Waymade sporadically recommenced the development of its own 20mg tablets during the lifetime of the 20mg Agreement therefore does not undermine the CMA's conclusions regarding the existence of the 20mg Agreement and its terms.

'Delays to Waymade's entry were due to development difficulties, not because it agreed not to enter'

6.544. Waymade submitted that the delays to its entry with its 20mg product were solely attributable to development difficulties.²⁴⁷⁷

6.545. The development issues Waymade faced are explained in detail in sections 3.F.II.a and c and 6.C.II.b.ii above. However, notwithstanding those issues it is clear that Waymade:

- a. Was a potential competitor of Auden throughout the term of the 20mg Agreement (see section 6.C.II.b.ii above); and
- b. Entered into an arrangement under which it sold Auden's product rather than its own and took active steps to 'freeze' the development of its own product. The reason given in contemporaneous documents for Waymade's decision not to launch its own product when it believed it was ready was not development issues but its success in obtaining supply from Auden²⁴⁷⁸ (see paragraphs 6.411 to 6.415, 6.484 to 6.494 and 6.503 to 6.507 above).

6.546. As explained above, Waymade's sporadic re-engagement with its own product is not inconsistent with its common understanding with Auden in the 20mg Agreement. That Waymade faced some delays in product development was at least in part due to its own deprioritisation of its product when confident of receiving continuing payments from Auden.

²⁴⁷⁶ Context that Waymade ignored when asserting that its '*urgent request for supply*' from Aesica in March 2014 was incompatible with the CMA's case (Document 204903, Waymade's RSSO, paragraphs 2.19 and 2.21).

²⁴⁷⁷ Document 204903, Waymade's RSSO, paragraphs 2.50(b) and 7.102-7.104.

²⁴⁷⁸ See, for example, Document 300180, monthly Sovereign Generics report for April 2011: '*The product will be released into stock and then frozen pending the outcome of the negotiations with Auden McKenzie*'.

'Waymade remained incentivised to enter with its own 20mg product'

- 6.547. Waymade submitted that, irrespective of the payments it received, it remained incentivised to enter with its own 20mg product. It pointed to its own economic analysis and purported to demonstrate that it would have made greater profit from independent entry than through the 20mg Agreement.²⁴⁷⁹
- 6.548. This is irrelevant. Market sharing agreements have as their object the prevention, restriction or distortion of competition. The fact that Waymade could feasibly have made more profit from entry is not part of the legal test.²⁴⁸⁰
- 6.549. The facts are that Waymade profited substantially from the 20mg Agreement, sharing in Auden's monopoly profit without taking the risks or incurring the costs of entering with its own product or being exposed to the uncertainty of competition. It substituted the certainty of cooperation for the uncertainty of competition.²⁴⁸¹
- 6.550. Waymade's submission was based on a report prepared by an economics consultancy for the purposes of responding to the CMA's provisional findings in the SSO. The CMA does not propose to engage with the detail of that report, which relies on hindsight and expert economic review of what actually occurred years later in the market to show on an *ex post* basis that Waymade may have undersold the competitive threat it posed to Auden in 2011.
- 6.551. This is completely detached from the evidence that the CMA has adduced in section 6.D.II.c.i above. This evidence has demonstrated, in particular, that:
- a. Auden supplied Waymade with 20mg hydrocortisone tablets in 2011 at an 87% discount to the rest of the market. Waymade has been unable to provide a legitimate reason for this discount, or for the Buyback provision that was included in the 20mg Agreement.
 - b. When Auden designed this deal for Waymade in 2011 [Auden Senior Employee 2] explained that it was on the basis that *'If Waymade had their own licence and achieved 50% mkt share at current pricing then*

²⁴⁷⁹ Document 204903, Waymade's RSSO, paragraphs 2.21 and 7.124-7.130. See also Document 204904, report of RBB Economics dated 26 May 2020.

²⁴⁸⁰ See, for example, *GSK v CMA* [2021] CAT 9, paragraph 49. Waymade's claim that *'The CMA's assessment of the 'incentivising' effect of the 20mg Agreement is predicated upon the 20mg Agreement being more profitable than independent entry'* (Document 204903, Waymade's RSSO, paragraph 7.130) is wrong. The CMA's findings are not predicated on comparing Waymade's profits from the 20mg Agreement with its potential profits from entry.

²⁴⁸¹ Compare C-591/16 P *Lundbeck v Commission*, paragraphs 135-136.

they would net £50K per mth. Selling them 1K packs per month to enable them just under a third mkt share at £4.50 per pack would net them £30K per mth. Auden attempted to calibrate Waymade's profit from the supply deal overall to what it may have achieved through successful entry, taking into account Waymade's '*cost savings in not bringing the product to market*').²⁴⁸²

- c. Waymade used its ability to independently enter the market with its own 20mg hydrocortisone tablets as leverage in its negotiations with Auden. This is a fact acknowledged by both [Amdipharm Senior Employee] of Waymade and [Auden Senior Employee 1] (amongst others).²⁴⁸³
- d. Waymade agreed with its competitor Auden that it would not independently enter the market with its own 20mg hydrocortisone tablets in exchange for the substantially discounted supply that Auden provided.
- e. Waymade suspended commercialising its own 20mg hydrocortisone tablets following its entry into the 20mg Agreement – regardless of the incentives that may have existed.²⁴⁸⁴

²⁴⁸² Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

²⁴⁸³ For example, [Auden Senior Employee 1] stated in interview that the reason for the 87% discount given to Waymade was that '*they could either source supply somewhere else or they could source it from us; and sourcing from us allowed us to keep our volume*' (Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 35, lines 21 to 26 and page 36, lines 1 to 9). [Amdipharm Senior Employee] stated in interview that the key change in the negotiations that led to this discount was that Waymade had moved from being just another customer to '*a position where it can, in theory, bring its product to the market*' (Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10).

²⁴⁸⁴ See, for example, Document 300180, monthly Sovereign Generics report for April 2011: '*The product will be released into stock and then frozen pending the outcome of the negotiations with Auden McKenzie*'. Waymade staff later referred to '*the fee arrangement ... to defer marketing of our product*' (Document 202157, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 21 November 2011) and '*the commercial arrangement we'd entered into which prevented us marketing our product*' (Document 301673, email from [Waymade Employee] to [Waymade Senior Employee 2] dated 25 February 2014).

ii. The 10mg Agreement

Context and summary

- 6.552. As explained in section 6.D.II.b.ii above, in total, Auden/Actavis paid Waymade around **£70,000** during October 2012, and AMCo around **£20.6 million** over the three and a half years between 31 October 2012 and 24 June 2016 by way of heavily discounted supplies of 10mg hydrocortisone tablets.
- 6.553. The counter-performance for these payments was that first Waymade, and then (post-sale of the Amdipharm business) AMCo, agreed with Auden/Actavis that it would not independently enter the market with its own 10mg tablets – just as in relation to the 20mg Agreement – thus preserving Auden/Actavis’s position as the sole supplier of such tablets. The parties agreed to cooperate rather than to compete, substituting the certainties of cooperation for the uncertainties of competition.
- 6.554. The evidence for this common understanding in the 10mg Agreement set out below should be read in the context of the existing 20mg Agreement. This meant the relevant individuals (in particular [Auden Senior Employee 1] and [Amdipharm Senior Employee]) were in regular contact with each other and had cooperated closely in relation to 20mg hydrocortisone tablets for more than a year by the time the 10mg Agreement was concluded in October 2012. These individuals had a template for their cooperation in the 20mg Agreement,²⁴⁸⁵ and they had built up relationships such that correspondence could (and did) take place informally.
- 6.555. The evidence set out in the sections and summarised in the paragraphs below shows that Waymade secured the 10mg Agreement using the same strategy as the 20mg Agreement – of deploying the competitive threat its 10mg MA posed to Auden to secure payments in return for not entering independently with its 10mg product – and that AMCo, which took over the 10mg Agreement from Waymade when it acquired Waymade’s 10mg hydrocortisone tablets development and staff on 31 October 2012, deployed the same strategy in negotiating successive increases in the amount of

²⁴⁸⁵ Indeed, the case law recognises that a commitment not to enter a market ‘*is based on a simple concept which may be implemented easily*’ and ‘*such a commitment is perfectly capable of existing as an unwritten understanding*’ (see T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 91. See also T-133/07 *Mitsubishi v Commission* EU:T:2011:345, paragraph 186. Upheld on further appeal in C-239/11, C-489/11 and C-498/11 *Siemens and Others v Commission*, EU:C:2013:866). In light of their existing cooperation under the 20mg Agreement including the existing relationship between in particular [Amdipharm Senior Employee] (Waymade) and [Auden Senior Employee 1], it would not have been difficult for Auden and Waymade to come to an arrangement similar to the 20mg Agreement for 10mg hydrocortisone tablets.

monthly payments it received from Auden in exchange for continuing that common understanding. In summary:

- a. [Amdipharm Senior Employee] confirmed in interviews and a witness statement that he represented Waymade in negotiations to secure heavily negotiated supplies of 10mg hydrocortisone tablets from Auden once Waymade obtained its 10mg MA on 27 September 2012.²⁴⁸⁶ [Amdipharm Senior Employee] succeeded in securing such an arrangement for Waymade (see paragraphs 6.367 to 6.368 and 6.381 to 6.387 above). The interview evidence of [Amdipharm Senior Employee], [Auden Senior Employee 1] and [Waymade Senior Employee 1] is that Waymade was able to obtain this heavily discounted supply arrangement on the same basis as the 20mg Agreement in July 2011: by using the competitive threat its newly-obtained 10mg MA posed to Auden to secure payments in return for Waymade's agreement not to enter the market independently with its 10mg hydrocortisone tablets. See paragraphs 6.578 to 6.587 and 6.590 to 6.591 below.
- b. Having transferred from Waymade to AMCo with the Amdipharm business on 31 October 2012, [Amdipharm Senior Employee] (at the instigation of [Waymade Senior Employee 1] and alongside [AMCo Senior Employee 1], [X]) negotiated with [Auden Senior Employee 1] a threefold increase in the monthly volume of heavily discounted 10mg hydrocortisone tablets – and therefore a very significant increase in the monthly payments – given to AMCo. No record of those negotiations survives beyond the fact that a meeting between AMCo and Auden took place and AMCo's volumes subsequently tripled.²⁴⁸⁷ In the context of the existing relationship between [Amdipharm Senior Employee], [Waymade Senior Employee 1] and [Auden Senior Employee 1] and of their behaviour over the previous two years (and in the context of the subsequent negotiations between [Auden Senior Employee 1] and [AMCo Senior Employee 1]), the CMA finds that these negotiations involved AMCo using the competitive threat its 10mg MA and product posed to Auden as leverage to secure this increase in its payments. See paragraphs 6.604 to 6.613 below.
- c. During late 2013, AMCo (through [Amdipharm Senior Employee]) attempted to obtain a formal, forward-looking written supply contract

²⁴⁸⁶ Document 200354, Witness Statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraphs 1.19 and 1.22.

²⁴⁸⁷ Document 202425, email from [AMCo Senior Employee 1] to [Waymade Senior Employee 1] dated 21 December 2012.

from Auden. AMCo sought once more to triple its volumes, from 6,000 monthly packs to 18,000 (a volume that corresponded to AMCo's initial estimate of the volume it stood to win from Auden if it launched its own product). However, in December 2013 AMCo noted that Auden was *'being increasingly aggressive'* and beginning to question the extent of the competitive threat AMCo's skinny label 10mg hydrocortisone tablets posed to Auden's full label tablets.²⁴⁸⁸ Concerned that Auden might terminate the 10mg Agreement, AMCo for the first time prioritised its own 10mg development, as a *'Protective project to ensure continuity of supply'*:²⁴⁸⁹ to intensify its negotiating leverage with Auden by presenting a more credible competitive threat, and to provide a *'back-up'* option in case the 10mg Agreement should end.²⁴⁹⁰ See paragraphs 6.623 to 6.658 below.

- d. In January 2014 the arrangement between Auden and AMCo appeared to be on the verge of collapsing. Auden refused to increase AMCo's volumes and instead the parties agreed to document their existing supply arrangement and bring it to an end. AMCo then prepared to enter independently with its own 10mg hydrocortisone tablets, while Auden devised 'Project Guardian', its own protective project designed to discourage off-label dispensing and *'be proactive ahead of Amdipharm's [AMCo's] product entry into the UK market in an attempt to hold Auden Mckenzie share above 50% and close to the existing position as possible'*.²⁴⁹¹ See paragraphs 6.659 to 6.668 below.
- e. However, in April 2014 AMCo and Auden returned to the negotiating table for a renewed 10mg supply deal, with AMCo noting that Auden was *'not keen to get into a battle over the orphan drug status and its validity and so probably would do a better deal on better terms'*.²⁴⁹² [AMCo Senior Employee 1] took over from [Amdipharm Senior Employee] as AMCo's chief negotiator. Each of AMCo and Auden continued to unilaterally assess, and bilaterally discuss, the extent of the competitive threat AMCo's skinny label tablets posed to Auden. In May 2014 [Auden Senior Employee 1] and [AMCo Senior Employee 1] met for lunch.²⁴⁹³ No record of what they discussed has been found.

²⁴⁸⁸ Document 200160, minutes of Mercury Pharma Group Limited management meeting on 19 December 2013.

²⁴⁸⁹ Document 202593, PPRM slides dated 18 December 2013. Document 202632, January 2014 Business Development & Licensing Report PPRM Recommendations for Board Approval, page 3.

²⁴⁹⁰ See, for example, Document 200163, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014.

²⁴⁹¹ Document 00135, *Project Guardian* presentation dated February 2014, page 9.

²⁴⁹² Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.

²⁴⁹³ Document 202953, [AMCo Senior Employee 1] expenses claim for *'Lunch: [AMCo Senior Employee 1] + [Auden Senior Employee 1]'*.

Later in May 2014 [Auden Senior Employee 1] received negative feedback on Project Guardian from the Chief Pharmaceutical Officer of NHS England, who informed him that there were '*no material differences*' between Auden's full label tablets and skinny label tablets and therefore no risks to patient safety from dispensing off label.²⁴⁹⁴ See paragraphs 6.669 to 6.701 below.

- f. Soon after receiving this negative feedback on Project Guardian, Auden approached AMCo to begin the final phase of negotiations. [Auden Senior Employee 1] sent a text message to [AMCo Senior Employee 1] (which has not been recovered) during the following weekend, to which [AMCo Senior Employee 1] responded in an email by setting out AMCo's proposals for a new supply deal, including that AMCo was '*currently forecasting 12k packs per month*' in relation to sales of its own 10mg product.²⁴⁹⁵ [AMCo Senior Employee 1] ultimately made a direct threat to [Auden Senior Employee 1] that if Auden did not come to terms AMCo would '*launch our own*'.²⁴⁹⁶ After [Auden Senior Employee 1] became convinced that AMCo's product posed a significant competitive threat to Auden's (notwithstanding its limited indication) AMCo and Auden agreed a forward-looking, two-year supply agreement (the Second Written Agreement) in June 2014. The Second Written Agreement improved the terms of the 10mg Agreement in AMCo's favour with the payments AMCo received increasing (its volumes of heavily discounted 10mg tablets doubled from 6,000 per month to 12,000). In exchange, AMCo renewed its commitment not to compete with Auden. On the same day, AMCo suspended the development of its own 10mg hydrocortisone tablets, cancelled future orders, and decided to hold the product in 'quarantine' as an insurance policy in case the 10mg Agreement should end. AMCo subsequently considered selling its product overseas but was concerned about '*the product coming back into the UK*', which could '*put us in breach of the contract that we have here with AM*'.²⁴⁹⁷ See paragraphs 6.702 to 6.745 below.
- g. News of the sale of AM Pharma to Allergan in January 2015 prompted AMCo once again to re-engage with its 10mg product, concerned that the new owner might end the 10mg Agreement. However, having taken

²⁴⁹⁴ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to Auden dated 20 May 2014, received 22 May 2014.

²⁴⁹⁵ Document 00149, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 28 May 2014.

²⁴⁹⁶ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014.

²⁴⁹⁷ Document 203640, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 9], [AMCo Senior Employee 8] and others dated 30 June 2014.

over sales of hydrocortisone tablets and supplies to AMCo in September 2015, Actavis continued the arrangement. AMCo now devised a plan to negotiate a further increase in its monthly volume of heavily discounted 10mg tablets (from 12,000 to 24,000 packs), '*leveraging its new competitive position*' derived from its acquisition of Focus Pharmaceuticals, which had its own hydrocortisone tablets portfolio.²⁴⁹⁸ See paragraphs 6.748 to 6.776 below.

- h. However, the extent of independent third-party entry to the market from October 2015 onwards led both Actavis and AMCo to conclude that the 10mg Agreement would not be renewed. The market stability on which the parties' market exclusion agreement depended was disrupted, as customers began to switch between suppliers and prices began to fall. AMCo therefore reached the view that '*We cannot delay any longer*' and launched its 10mg tablets in May 2016.²⁴⁹⁹ It continued to place orders for the heavily discounted supplies it was entitled to from Actavis until 24 June 2016, when the supply arrangement expired. See paragraphs 6.777 to 6.783 below.

The beginning of the 10mg Agreement

6.556. As explained in paragraph 6.17 above, the CMA concludes that during October 2012 – at the latest by 23 October 2012 – Auden and Waymade reached a common understanding that in exchange for substantial payments from Auden, Waymade would not independently enter the market with its own 10mg hydrocortisone tablets. In other words, the parties agreed that in exchange for payment, Waymade would cooperate with and not compete with Auden.

6.557. This conclusion is based, in particular, on the facts that:

- a. When Waymade obtained its 10mg MA on 27 September 2012 and became a potential competitor to Auden, Waymade – principally through [Amdipharm Senior Employee] – negotiated a substantial (97%) reduction to the price it had paid Auden for 10mg hydrocortisone tablets to date. [Amdipharm Senior Employee] deployed the same strategy Waymade had successfully followed to secure the 20mg Agreement in July 2011: using the competitive threat that it would otherwise enter with its own 10mg tablets as leverage to secure a

²⁴⁹⁸ Document 202793, 'Project Harmony' presentation prepared by LEK Consulting dated 21 August 2015, slide 85.

²⁴⁹⁹ Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.

common understanding with Auden that sufficient payment from Auden would buy off that threat and prevent Waymade's entry; and

- b. Just as it had done in July 2011 in relation to 20mg hydrocortisone tablets, in October 2012 Auden responded by substantially reducing the price it charged Waymade for 10mg hydrocortisone tablets in order to buy off the threat of Waymade's competitive entry.

The supply arrangement between Auden and Waymade for 10mg hydrocortisone tablets from July 2011 to September 2012

- 6.558. As with 20mg hydrocortisone tablets, Auden was the sole supplier of 10mg hydrocortisone tablets to the UK market – a position it held since April 2008.
- 6.559. Auden had used its market power to substantially increase the price of 10mg hydrocortisone tablets from £4.54 per pack in April 2008 to £31.55 per pack in October 2012.
- 6.560. Auden had commenced supplying Waymade with 10mg hydrocortisone tablets in July 2011 – at the same time they had both entered into the 20mg Agreement. At this stage, although Waymade had started developing its own 10mg hydrocortisone tablets, it did not have a 10mg MA.
- 6.561. Consequently, the terms under which Auden initially supplied Waymade did not reflect the generosity of those extended under the 20mg Agreement.
- 6.562. Between July 2011 and September 2012, Waymade purchased an average of 1,500 packs of 10mg hydrocortisone tablets per month from Auden²⁵⁰⁰ at the prevailing market rate: between £31.50 and £34.50 per pack.²⁵⁰¹

²⁵⁰⁰ Waymade purchased 3,120 packs of 10mg tablets – one pallet – in the first month, July 2011. However, all subsequent orders were significantly lower, leading to an average between July 2011 and September 2012 of around 1,500 packs per month. When confirming the supply arrangement on 5 July 2011, [Auden Senior Employee 2] stated: '*[Auden Senior Employee 1]] thought the 10mg volume was a little on the high side but I have persuaded him to honour the initial order and well [sic] discuss next month once you've had a chance to assess the market from your side.*' Document 300189, email from [Auden Senior Employee 2] to [Waymade Senior Employee 4] and [Amdipharm Senior Employee] dated 5 July 2011. [Waymade Senior Employee 4] explained that '*It was only the first lot that ever came in that was 3,000. From there onwards it was determined that our allowance would be 1,500*'. Document 301313, transcript of [Waymade Senior Employee 4] interview dated 28 March 2018. See also Document 200010, data submitted by Waymade on its purchases of hydrocortisone tablets from Auden.

²⁵⁰¹ Document 200010, data submitted by Waymade on its purchases of hydrocortisone tablets from Auden. Waymade '*purchased significant quantities of 10mg hydrocortisone tablets at the high end of the prevailing market rate for a short-line wholesaler, which was in the region of £32.50 to £34.50 from July 2011 [...] to approximately October 2012. Waymade purchased approximately 23,640 units from Auden Mckenzie in the period July 2011 to 30 September 2012 at a price point between £31.50 and £34.50*'. Document 200003, Waymade's response to the CMA's section 26 notice dated 5 May 2016, paragraphs 11.5 to 11.6.

- 6.563. The reason Waymade did not benefit from a discounted price for 10mg tablets was that it did not hold a 10mg MA and therefore was not seen as a competitive threat by Auden.
- 6.564. In interview with the CMA, [Waymade Senior Employee 2] explained that during the period prior to October 2012, Auden could *'charge a higher price'* for its supply of 10mg hydrocortisone tablets because Waymade did not have an MA for the product: *'Waymade [...] didn't have a cheap alternative [...] it didn't have a CMO, ready to manufacture product for it... Or an MA...'*²⁵⁰²
- 6.565. [Amdipharm Senior Employee] gave a similar explanation: *'Until the point that Waymade had a marketing authorisation for the 10-milligram, then I guess it was just another customer for Auden ... Until you've got the marketing authorisation, you don't have the choice as to ... place an order on your own contract manufacturer or to source it elsewhere.'*²⁵⁰³ In the same way, prior to Auden becoming aware of Waymade's 20mg MA, Waymade had been *'just another wholesaler customer to Auden McKenzie'* – Waymade only secured its substantial discount once Auden became aware that Waymade was *'in a position where it can, in theory, bring its own product to the market'*²⁵⁰⁴ (see paragraph 6.446 above).
- 6.566. [Waymade Senior Employee 2]'s and [Amdipharm Senior Employee]'s witness evidence emphasises the direct link between the competitive threat posed to Auden (by holding an MA) and Auden's willingness to make substantial payments in the form of a significantly discounted supply price. Unless a company possessed a competitive threat, it was *'just another customer'* for Auden and would not benefit from discounted prices.

Waymade 'rushes through' obtaining a 10mg MA

- 6.567. As explained in section 3.F.III.b above, Waymade submitted an application for a 10mg MA to the MHRA in June 2011.²⁵⁰⁵ Waymade pursued its MA application with urgency, at the most senior levels.

²⁵⁰² Document 301312, transcript of [Waymade Senior Employee 2] interview dated 28 March 2018, part 2, page 33, lines 11 to 12; 16 to 17; 21; and 26 to 27; page 34, lines 1 to 2.

²⁵⁰³ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 9 lines 24 to 25 and page 10 lines 2-4.

²⁵⁰⁴ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10.

²⁵⁰⁵ Document 300185, email from [Waymade Employee] ([X]) to [Waymade Senior Employee 1], [Amdipharm Senior Employee], [Waymade Senior Employee 3] and others dated 9 June 2011. See also Document 300184, Email from [Waymade Senior Employee 3] to [X], [Waymade Senior Employee 2], [Waymade Employee], [Waymade Employee], [X], [X], [X], [X], [X] and [Waymade Employee], dated 6 June 2011 and Document 300180, Monthly Report Sovereign Medical April 2011, attached to Document 300179_email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] and others dated 11 May 2011, page 2.

- 6.568. In particular, during mid-2012, Waymade ‘rushed through’ its application for a 10mg MA with the MHRA. Waymade was prepared to accept a shorter shelf life, a narrower assay limit, and reduced indications on the 10mg MA in order to ‘*rush the license through*’.²⁵⁰⁶
- 6.569. Waymade prioritised obtaining the 10mg MA over obtaining saleable stock with which to enter the market once the MA was granted.
- 6.570. Waymade was granted a 10mg MA on 27 September 2012 (see section 3.F.III.c above). By that time Waymade had had no contact with Aesica for more than six months, despite having developed a successful production method for 10mg tablets with Aesica in 2010.²⁵⁰⁷
- 6.571. The contrast between Waymade’s ‘rushed’ approach to obtaining the 10mg MA and sedate approach to obtaining launch-ready 10mg tablets reflects the fact that, having successfully negotiated the 20mg Agreement in July 2011, [Waymade Senior Employee 1] and [Amdipharm Senior Employee] were confident that once the 10mg MA was granted, Auden would respond to the threat it posed by buying off its potential competitor to preserve Auden’s position as sole supplier, as it had done before. As explained in the sections that follow, [Amdipharm Senior Employee] stated in interview that Waymade had set out to ‘*do the same deal with Auden Mckenzie on the 10mg that we had with the 20mg*’.²⁵⁰⁸

²⁵⁰⁶ For example, following receipt of the MHRA’s proposal for a shorter shelf life for 10mg tablets in bottles, on 11 April 2012 [Waymade Senior Employee 1] instructed his staff: ‘*do not delay anything With changes just accept what they say just rush the license through mate. We can do the things later*’ (Document 300228, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 11 April 2012). While Waymade initially proposed an assay limit range of 90 to 105%, the MHRA proposed a narrower range of 95-105%. On 20 April 2012, Aesica’s [Aesica Employee] highlighted a ‘*significant risk of batch failure either on production or during stability testing*’ with this narrower range. Waymade was prepared to accept this risk in order to obtain the MHRA’s approval and planned to revisit the issue ‘*post approval*’ (Document 300232, emails between [Aesica Employee], [§], and [Waymade Employee] dated 20 April 2012. See also Document 300288, email from [Waymade Employee] to [§], [§], [§], [§], [Waymade Employee], [§] and [§] dated 10 April 2012). On 13 July 2012 [Waymade Senior Employee 1] told his staff to concede to the MHRA’s view of the orphan designation (notwithstanding any implications for Waymade’s product) and accept the reduced-indication 10mg MA: ‘*[I] do not wish to write anything re envisaging legally at this stage ... any legal threats and they will shy away and put it in a SPIN FOR YEARS IS THAT CLEAR*’ (Document 300267, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 13 July 2012 (emphasis in original)).

²⁵⁰⁷ Aesica told the CMA that ‘*Notwithstanding, process validation of 10mg hydrocortisone tablets was first completed and approved in October 2010, Aesica did not supply any validated product to Waymade, nor received any order from Waymade regarding the same*’: Document 200292, Aesica response to section 26 notice dated 15 June 2016, paragraph 5.2. Aesica informed the CMA that the ‘*last contact Aesica has been able to locate between itself and Waymade as regards 10mg hydrocortisone tablets is a purchase order dated 15 November 2011 from Waymade to Aesica relating to further process validation work to be done on that dosage*’: paragraphs 4.1 and 4.2. The CMA identified one subsequent contact between Waymade and Aesica in relation to the 10mg product. In February 2012, Waymade received two validation reports from Aesica. This confirmed that Aesica had ‘*resolved the issue with the dissolution test*’. Document 300217, email from [§] to [Waymade Senior Employee 1] dated 2 February 2012.

²⁵⁰⁸ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 15 lines 6-13.

Waymade uses its 10mg MA as leverage

- 6.572. Consistently with [Waymade Senior Employee 2]'s and [Amdipharm Senior Employee]'s witness evidence, gaining the 10mg MA dramatically changed Waymade's negotiating position with Auden. Waymade now posed a competitive threat to Auden in respect of 10mg hydrocortisone tablets. Having obtained its 10mg MA, Waymade immediately set out to reach an agreement with Auden to secure a substantial discount in the price it paid for 10mg hydrocortisone tablets, using the same strategy it had used to secure the 20mg Agreement.
- 6.573. In the words of [Amdipharm Senior Employee], Waymade ceased to be *'just another customer for Auden'*.²⁵⁰⁹ Auden was the monopoly supplier of 10mg hydrocortisone tablets and if Waymade chose to enter the market and compete it would necessarily have reduced Auden's sales volumes.
- 6.574. Accordingly, as had been the case with 20mg tablets, it would be beneficial to Auden if Waymade did not independently enter the market. Auden would be able to preserve its monopoly position and continue to be able to charge high and increasing prices.
- 6.575. In a witness statement, [Amdipharm Senior Employee] explained that the 10mg MA (and the threat of competitive entry Waymade posed to Auden as a result of obtaining it) provided Waymade with leverage to seek a lower supply price from Auden:

'Once Waymade was granted the reduced indication 10mg licence in September 2012, Waymade looked to get a better supply price from Auden Mckenzie ... I was involved in representing Waymade in these negotiations in late 2012 and I was trying to get as good a price as possible for the supply which I did by getting a slightly lower price than Aesica was quoting'.²⁵¹⁰

- 6.576. In interview, [Amdipharm Senior Employee] emphasised that the scale of the discount Waymade would seek from Auden following the grant of the MA was very significant, stating that:

²⁵⁰⁹ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 9 lines 24 to 25 and page 10 lines 2-4.

²⁵¹⁰ Document 200354, Witness statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraphs 1.19 and 1.22.

*'To get the price that we got, of £1 ... I would have been looking to get a price that approximated to what my cost of goods would be had I purchased the product from Aesica.'*²⁵¹¹

6.577. The cost of goods from Aesica was approximately [£1-£4] per pack – around 3% of the price Waymade was paying Auden for 10mg tablets at the time.²⁵¹² The 10mg MA (and the threat of competitive entry Waymade posed to Auden as a result of obtaining it) therefore provided leverage to seek a very substantially lower supply price from Auden in these negotiations.

6.578. In interview, [Waymade Senior Employee 1] explained the nature of this leverage:

*'... as far as he [[Auden Senior Employee 1]] is concerned, I have got the licence and I have got another source.'*²⁵¹³

*'His [[Auden Senior Employee 1]'s] volumes would start dropping, once we fight him in the market, which we would.'*²⁵¹⁴

*'...As soon as we come in the market, his volumes will start diminishing so his costs will start going up, and that's how the market works.'*²⁵¹⁵

6.579. Just as in relation to the 20mg Agreement, the form Waymade's leverage took is therefore clear. At this time, Auden was the sole supplier of 10mg hydrocortisone tablets in the UK and had been able to set prices without being effectively constrained. As far as Auden was concerned, Waymade had a *'licence and ... another source'* and (given the market size was finite) Auden would lose market share to Waymade if Waymade entered with that licence (*'As soon as we come in the market, his volumes will start diminishing'*).

6.580. This description is consistent with [Waymade Senior Employee 1]'s explanation of Waymade's leverage prior to entering into the 20mg Agreement: *'the fact that there's not a second player is always in their*

²⁵¹¹ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 12 line 27 and page 13 lines 1-6.

²⁵¹² Document 300303, email from [X] to [Waymade Senior Employee 1] dated 1 October 2012: *'We have a COGs for Hydrocortisone 10mg tablets 1 x 30 blister pack of [£1-£4]. This is from early 2009.'* Compare Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 17 April 2014: the cost of goods from Aesica in April 2014 was *'[£1-£4] for a 30's pack'*.

²⁵¹³ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 138, lines 12-20.

²⁵¹⁴ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 140, lines 3 to 4.

²⁵¹⁵ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 140, lines 14-16.

*[Auden's] interest*²⁵¹⁶ (see paragraph 6.419 above) – demonstrating the consistency in Waymade's approach to negotiating with Auden across both strengths.

- 6.581. [Waymade Senior Employee 1]'s interview evidence also demonstrates that Waymade's strategy for its 10mg tablets was based on the same two mutually exclusive options as had been the case with its 20mg tablets. Waymade could either launch its own 10mg hydrocortisone tablets and compete with Auden (causing the latter's volumes to '*start diminishing*'), or it could cooperate with Auden by agreeing not to enter in exchange for payment from Auden (thereby not becoming '*a second player*' and enabling Auden to maintain its pricing power as a monopoly supplier).
- 6.582. As was the case with 20mg hydrocortisone tablets, Waymade could not choose both options – the value of its 10mg MA in its negotiations with Auden was the competitive threat that it posed to Auden's sales volumes. These would necessarily have been reduced if Waymade entered the market, and it was this threat Auden wished to buy off in order to preserve its position as sole supplier and its resulting ability to continue charging high and increasing prices. Waymade understood that Auden was only prepared to do a deal with Waymade if this meant that, as a result, its volumes would not '*start diminishing*'. Indeed, in relation to the 20mg Agreement [Waymade Senior Employee 1] stated: '*They [Auden] gave the product to us at a price because we had told them that we can manufacture it at a certain price, and for them not to lose their volumes, it would be attractive for them to supply the product*'.²⁵¹⁷
- 6.583. As in relation to the 20mg Agreement, therefore, the premise of the negotiations between Auden and Waymade in relation to 10mg hydrocortisone tablets was that if Auden wished to retain its volumes, it would have to buy Waymade off.
- 6.584. This continuity is demonstrated most clearly by the statements of [Amdipharm Senior Employee] in interview. [Amdipharm Senior Employee] stated that the Agreements '*started with the 20mg, then became the 10mg. We added the 10mg to that*':

'we approached Auden Mckenzie and asked them if they would be willing to supply us ... and we did that first with the 20mg and then later when we had the 10mg licence with that also ... that started with the

²⁵¹⁶ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 14, lines 16 to 17.

²⁵¹⁷ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 1 to 3 (emphasis added).

*20mg, then became the 10mg. We added the 10mg to that ... That was around the time that Amdipharm was being sold to Cinven.'*²⁵¹⁸

...

*'if we could do the same deal with Auden Mckenzie on the 10mg that we had with the 20mg, then that would allow us to come to the market and to then be in the market with the 10mg product which was more valuable and which had been flagged up as an important asset for the sale of the company [the Amdipharm group]. So that's what we did. Again, thankfully Auden consented to that'*²⁵¹⁹

- 6.585. [Amdipharm Senior Employee] also stated specifically in relation to the negotiations leading to the 10mg Agreement:

*'maybe the inference from me is that, you know, he [[Auden Senior Employee 1]] can supply me or I'll get someone else to supply me, and if he wants to retain the manufacturing volumes, then he might agree to supply me'*²⁵²⁰

- 6.586. In a subsequent interview, when asked why Auden agreed to the £1 supply price for 10mg tablets, [Amdipharm Senior Employee] provided the same rationale as he had given for the 87% discount Waymade secured in the 20mg Agreement (see paragraph 6.425 above):

*'That was my supposition at the time, that they will lose margin on that product but they will at least retain their manufacturing volumes'*²⁵²¹

- 6.587. It is clear from [Amdipharm Senior Employee]'s statements that he approached the negotiations with Auden with the intention of concluding a deal in relation to 10mg hydrocortisone tablets on the same basis as the 20mg Agreement (*'the same deal with Auden Mckenzie on the 10mg that we had with the 20mg'*): that in exchange for a very substantial discount, Auden would retain its manufacturing volumes. It is also clear that in his view he achieved this (*'that's what we did ... Auden consented to that'*).

²⁵¹⁸ Document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 11 lines 20-24 and page 12 lines 1-4.

²⁵¹⁹ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 15 lines 7-12 (emphasis added).

²⁵²⁰ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, pages 14-15 (emphasis added).

²⁵²¹ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 65 lines 18-20.

The result of the negotiations: Auden responded by agreeing to buy off the threat of Waymade's competitive entry

- 6.588. Waymade's strategy was successful. The evidence demonstrates that in October 2012 Auden responded to the threat of Waymade's competitive entry in relation to 10mg hydrocortisone tablets by substantially reducing its supply price for 10mg tablets by 97% (from £34.50 – the price paid by Waymade until October 2012 – to £1 per pack) for 2,000 packs.
- 6.589. As explained in section 3.F.III.d above, the first order was placed on 23 October 2012 on the instructions of [Waymade Senior Employee 1]²⁵²² and fulfilled by Auden on 26 October 2012. As explained in that section, although the price listed on the order was £34.50 per pack (the price Waymade had paid Auden to date), the CMA concludes that by 23 October 2012 Auden and Waymade had agreed that the supply price for the 2,000 monthly packs of 10mg tablets would be heavily discounted. On the corresponding invoice issued by Auden, the price was circled and a handwritten note added: *'Await credit note [Waymade Senior Employee 4]'*.²⁵²³ This indicates that Auden would issue a rebate to reduce the net price. [Amdipharm Senior Employee] stated in interview:

*'At the start of the process Auden Mckenzie had been invoicing... at a high price and then rebating back to the agreed net price. We had agreed a price of a cost of goods of £1'*²⁵²⁴

- 6.590. Consistently with the explanations of [Amdipharm Senior Employee] and [Waymade Senior Employee 1] discussed above, [Auden Senior Employee 1] explained that once Waymade obtained the 10mg MA, Auden faced *'the same scenario'* as it had faced when negotiating the 20mg Agreement, and that it responded in the same way – by supplying Waymade at a substantial discount in order to maintain its manufacturing volumes. [Auden Senior Employee 1] stated in relation to the 20mg Agreement: *'they [Waymade] had*

²⁵²² On 23 October 2012 [Waymade Senior Employee 1] sent an email to [Waymade Senior Employee 4] with the subject, *'2000 hydrocort 10mg p/o at full price . pls send bu midday if possible'* [sic] (Document 300320, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 4] dated 23 October 2012). The body of the email contained only [Auden Senior Employee 1]'s email address. [Waymade Senior Employee 4] sent the purchase order to [Auden Senior Employee 1] (blind copying [Waymade Senior Employee 1]) an hour later, stating: *'Please find attached PO for the 2,000 x Hydrocortisone 10mg 30's that are required on URGENT delivery as per [Waymade Senior Employee 1]'s request'* (Document 300321, email from [Waymade Senior Employee 4] to [Auden Senior Employee 1] dated 23 October 2012). The CMA therefore infers that a discussion had taken place involving [Waymade Senior Employee 1] and [Auden Senior Employee 1] that led to this order.

²⁵²³ Document 300645, invoice dated 23 October 2012.

²⁵²⁴ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 18 lines 22-27 and page 19 line 1 (emphasis added).

their own product, they had a choice whether they wanted supply',²⁵²⁵ and went on to say in relation to the 10mg Agreement:

it was a very, a very similar situation where they had said, 'look we've got a product and we would like to take supply from you'. So again, in the same scenario as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable.'²⁵²⁶

- 6.591. [Auden Senior Employee 1]'s explanation confirms that Auden bought off the competitive threat that Waymade posed to it by giving Waymade supply at a substantial discount, which meant Auden avoided the risks associated with competition (ie its volumes were maintained). This explanation is a consistent theme of Auden Senior Employee 1]'s witness evidence throughout the CMA's investigation. For example, in an earlier interview, Auden Senior Employee 1] explained that Auden was willing to give this 97% price cut in respect of 10mg hydrocortisone tablets because '*again ... we wanted to protect the volumes that we have at the manufacturing*', just as in relation to the 20mg Agreement.²⁵²⁷

Conclusion on the beginning of the 10mg Agreement

- 6.592. The evidence set out in paragraphs 6.556 to 6.591 above demonstrates that Waymade used the competitive threat its 10mg MA posed to Auden as leverage to secure heavily discounted supply from Auden – replicating the tactics it had successfully used in entering into the 20mg Agreement. In particular, the chief negotiators of the 10mg Agreement – [Auden Senior Employee 1] for Auden and [Amdipharm Senior Employee] for Waymade – both confirmed in interviews with the CMA that the basis for the substantial discount Auden provided to Waymade was the same as the 20mg Agreement – to buy off Waymade's competitive threat.
- 6.593. The 10mg Agreement was therefore based on the same premise as the 20mg Agreement – Auden would buy off Waymade's competitive threat by means of heavily discounted supply and, in exchange, Waymade would refrain from entering the market independently with its own 10mg hydrocortisone tablets and competing with Auden.

²⁵²⁵ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 54 lines 12-13.

²⁵²⁶ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68 (emphasis added).

²⁵²⁷ Document 00729, transcript of [Auden Senior Employee 1] interview dated 26 July 2016, page 7 lines 3-5.

The Amdipharm group is sold to Cinven and the 10mg Agreement continues between Auden and AMCo

Context and summary

- 6.594. As explained in sections 3.F.III.d and e above, Waymade sold the Amdipharm group to Cinven, with the acquisition completing on 31 October 2012. Cinven then merged Amdipharm with the Mercury Pharma business to form AMCo.
- 6.595. As part of Cinven's acquisition of the Amdipharm group, AMCo acquired Waymade's 10mg MA, product development and relevant staff (replacing Waymade as Auden's potential competitor in respect of 10mg hydrocortisone tablets (see section 6.C.II.b.iv above)) and the benefit of the 10mg Agreement (see further section 3.F.III.e above).
- 6.596. Among the Waymade personnel who transferred with Amdipharm to AMCo was [Amdipharm Senior Employee]. [Amdipharm Senior Employee] retained responsibility for managing AMCo's relationship with Auden.
- 6.597. [Waymade Senior Employee 1] took a seat on the AMCo group top company board and a minority stake in the AMCo group.²⁵²⁸ Waymade plc also acted as agent for Amdipharm UK Limited in relation to the 10mg hydrocortisone tablets it obtained from Auden. [Waymade Senior Employee 1] therefore retained an interest in the 10mg Aesica development he had sold to AMCo and in the 10mg supply deal that had also transferred to AMCo.²⁵²⁹
- 6.598. As explained in the sections that follow, from 31 October 2012 until 24 June 2016, Auden/Actavis and AMCo continued the 10mg Agreement. Auden (later Actavis) continued to make monthly payments to AMCo through the transfer of margin on heavily discounted volumes of 10mg hydrocortisone tablets; and AMCo accepted those payments; sold Auden/Actavis's product for a profit and committed not to launch its own 10mg tablets.²⁵³⁰

²⁵²⁸ See section 9.B.III.d (*Liability of the Cinven Entities*) below.

²⁵²⁹ For example, on 16 June 2014, nine days before AMCo and Auden entered into the Second Written Agreement, [AMCo Senior Employee 1] wrote to [Waymade Senior Employee 1] stating that AMCo was 'trying to finalise a longer term formal supply agreement on this (or indeed launch our own product) I'll get back to you this week with some news (hopefully good news!)' (Document 202680, email from [AMCo Senior Employee 1] to [Waymade Senior Employee 1] dated 16 June 2014). As explained below, on 13 November 2012 [Waymade Senior Employee 1] told [Amdipharm Senior Employee] that he had spoken to [AMCo Senior Employee 1] and 'told him that you are handling hydrocortisone 10mg with [Auden Senior Employee 1] [sic] ... I told him that we will be looking to receive 15000 packs per month on a supply agreement' (Document 300331, email from [Waymade Senior Employee 1] to [Amdipharm Senior Employee] dated 13 November 2012).

²⁵³⁰ Just as in relation to the 20mg Agreement (see paragraphs 6.479 to 6.512 above), the parties' conduct provides further evidence of their common understanding that AMCo would not enter independently with its own product in exchange for the substantial payments it received from Auden.

- 6.599. Initially, the payments AMCo received were on the same terms that had been agreed in October 2012. In November and December 2012, AMCo ordered and received 2,000 packs of 10mg hydrocortisone tablets from Auden at £1 per pack. Those packs were worth around £65,000 in each month if sold at prevailing ASPs.
- 6.600. However, as explained in section 6.D.II.b.ii above, these payments increased over time. This was because of two factors:
- a. First, the market price of hydrocortisone tablets continued to increase (reflecting the lack of competitive constraint that was being exerted on Auden and its continued ability to share monopoly profits with AMCo). For example, between October 2012 and March 2016 Auden's 10mg price increased from £31.55 to £72.14. AMCo was able to sell the heavily discounted volumes of 10mg tablets it obtained at similar prices.
 - b. Secondly, AMCo negotiated increases in the quantity of substantially discounted packs it received from Auden on two occasions. In January 2013, the number of packs supplied tripled to 6,000 per month (worth approximately £200,000 at prevailing ASPs). In June 2014, the number of packs supplied doubled to 12,000 packs per month (worth approximately £560,000). Throughout, the supply price to AMCo (£1 until June 2014, £1.78 thereafter) represented a 97% discount to the price at which Auden supplied other customers.
- 6.601. [Auden Senior Employee 1] confirmed, consistently with the payments Auden had previously made to Waymade, that the reason Auden made these monthly payments to AMCo was to protect its market share from being eroded by competitive entry. In interview with the CMA, [Auden Senior Employee 1] explained that *'after the move from Waymade to Amdipharm ... In 2012, we supplied Amdipharm at a price of £1 per pack'*. This was because AMCo ceased to be a *'pure wholesaler'* when it acquired the 10mg MA from Waymade (just as Waymade before it had, in [Amdipharm Senior Employee]'s words, ceased being *'just another customer for Auden'* when it obtained the 10mg MA²⁵³¹ and moved *'from a position of being just another wholesaler customer to Auden Mckenzie'*²⁵³² when it exerted the threat of entry with its own 20mg tablets); and *'[w]e [Auden] wanted to protect and*

²⁵³¹ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 9 lines 24 to 25 and page 10 lines 2-4.

²⁵³² Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10 (emphasis added).

*maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]’.*²⁵³³

- 6.602. In other words, AMCo’s acquisition of the 10mg MA from Waymade meant that it represented a competitive threat to Auden. Auden’s motivation for supplying its potential competitor with significantly discounted stock (as it was at all times under the 20mg and 10mg Agreements) was to protect its volumes (and therefore its position as sole supplier) from the risk of competitive entry: to buy off that threat.
- 6.603. Auden therefore paid AMCo not to enter the market independently with its own 10mg tablets.

January 2013: Auden agrees to triple AMCo's monthly volumes at the £1 price

- 6.604. The change in identity of the owner of the Amdipharm group (and therefore the ultimate owner of the 10mg MA) made little difference to Auden. Its objective remained the same: it wished to protect its market position by buying off the potential competitive threat AMCo posed. Further, [Auden Senior Employee 1] also found a familiar face representing AMCo on matters relating to the 10mg Agreement, with [Amdipharm Senior Employee] taking on responsibility for its continuation.
- 6.605. [Amdipharm Senior Employee] remained as [X] under Cinven ownership, working with [Waymade Senior Employee2] until March 2013 and reporting to [AMCo Senior Employee 1] ([X]).²⁵³⁴
- 6.606. Following his transfer to AMCo, one of [Amdipharm Senior Employee]’s key roles was to ensure the ongoing supply of 10mg hydrocortisone tablets from Auden to AMCo. [Amdipharm Senior Employee] explained in interview:

*‘after the sale of Amdipharm to Cinven, then ensuring that continuity of supply [of 10mg hydrocortisone tablets] from Auden Mckenzie was my responsibility’.*²⁵³⁵

- 6.607. [AMCo Senior Employee 2], [X], confirmed in interview with the CMA that [Amdipharm Senior Employee] ‘was ... *managing the relationship with Auden*

²⁵³³ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.

²⁵³⁴ [Waymade Senior Employee 1] stayed at Waymade, but also became a Board member at AMCo in recognition of his minority stake in the business (see section 9.B.III.d (*Liability of the Cinven Entities*) below).

²⁵³⁵ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 67 lines 5-7.

McKenzie,²⁵³⁶ while [AMCo Senior Employee 1] described [Amdipharm Senior Employee] to colleagues as AMCo's '*corporate memory*'.²⁵³⁷

- 6.608. [Amdipharm Senior Employee]'s '*corporate memory*' included knowledge that Auden had bought off Waymade's competitive threat in respect of 10mg and 20mg hydrocortisone tablets by means of the heavily discounted supply of hydrocortisone tablets in exchange for Waymade's agreeing not to enter the market independently with its own products.
- 6.609. In January 2013, [Amdipharm Senior Employee] negotiated a substantial increase in the value of the payments AMCo received from Auden: Auden increased the number of packs it supplied to AMCo monthly at £1 per pack from 2,000 to 6,000, worth around £200,000 (as explained in section 3.F.III.e above).²⁵³⁸
- 6.610. This threefold increase in AMCo's volumes under the 10mg Agreement took place shortly after a meeting between [Amdipharm Senior Employee], [Auden Senior Employee 1] and [AMCo Senior Employee 1] in the first week of January 2013.²⁵³⁹ No record of what was discussed at that meeting has been found during the CMA's investigation.
- 6.611. The tripling of the volumes significantly increased the monthly payments made by Auden to AMCo (from around £70,000 to around £200,000 per month). Every pack sold to AMCo at £1 had a substantial opportunity cost to Auden, given that it was charging its other customers around £35 and given that hydrocortisone tablets are a prescription drug with finite demand, meaning that Auden could not recoup this cost by expanding its customer base. Accordingly, the effect of the volume increase was that Auden was now foregoing approximately an additional £130,000 each month (increasing over time as market prices increased) and instead allowing AMCo to make

²⁵³⁶ Document 201591, [AMCo Senior Employee 2] interview transcript dated 12 October 2017, page 21 lines 22-24.

²⁵³⁷ Document 202464, email from [AMCo Senior Employee 1] to [X] dated 18 November 2013.

²⁵³⁸ As explained above, in fact in January 2013 AMCo received 7,000 packs; thereafter, 6,000 packs per month. AMCo's internal review of January 2013 stated: '*Following conclusion of a supply agreement with Auden McKenzie; Hydrocortisone 10mg 30s were sold for the first time in January. Sales were £272,102 on 7,887 units*' (Document 202478, AMCo review of January 2013, page 2). This statement refers to the new arrangement agreed in January 2013. In the email that supplied the data for this report, [Waymade Senior Employee 2] noted: '*the way t [sic] currently works is that Waymade are buying the stock and then reimburse Amdipharm – this does not necessarily reflect what has been sold in the market*' (Document 202472, email from [Waymade Senior Employee 2] to [Amdipharm Senior Employee] dated 18 February 2013).

²⁵³⁹ On 29 November 2012 [AMCo Senior Employee 1] emailed [Auden Senior Employee 1], copying [Amdipharm Senior Employee], with the subject: '*Meeting up: Good to speak to you. As discussed let's you Amdipharm Senior Employee, and me meet up asap.*' Document 202378, email [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 29 November 2012. The meeting was initially to take place on 20 December 2012 (Document 202386, calendar invite '*Accepted: Meeting with [AMCo Senior Employee 1], [Amdipharm Senior Employee] & [Auden Senior Employee 1]*' dated 20 December 2012), but was rescheduled for the first week of January 2013 (Document 202425, email from [AMCo Senior Employee 1] to [Waymade Senior Employee 1] dated 21 December 2012).

that profit. The arrangement meant that Auden remained the sole supplier to the market, but the margin on these 6,000 packs per month was being made by AMCo, not Auden.

6.612. When placed in the wider context, it is clear that Auden increased its payments to AMCo in January 2013 to continue to buy off the competitive threat AMCo posed to it as a result of acquiring Waymade's 10mg MA:

- a. The CMA has already established that the reason Auden started making these payments to Waymade in October 2012 was to buy off the competitive threat Waymade posed as a result of possessing a 10mg MA. That this was the purpose of these payments is clear from the interview and witness evidence of those involved in the formation of the 10mg Agreement: [Auden Senior Employee 1], [Waymade Senior Employee 1] and [Amdipharm Senior Employee], discussed in paragraphs 6.565 to 6.587 and 6.590 to 6.591 above. Indeed, this was the consistent basis on which [Amdipharm Senior Employee] and [Auden Senior Employee 1] had dealt with each other since 2011, when the two sides had entered into a similar arrangement in respect of 20mg tablets. In particular, as explained above, [Auden Senior Employee 1] stated specifically with regard to AMCo that *'after the move from Waymade to Amdipharm ... In 2012, we supplied Amdipharm at a price of £1 per pack'* and that this was because AMCo ceased to be a *'pure wholesaler'* when it acquired the 10mg MA from Waymade, and *'[w]e [Auden] wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]'*.²⁵⁴⁰
- b. The evidence demonstrates that AMCo consistently sought to increase the payments it received from Auden in exchange for its non-entry during the course of the 10mg Agreement. For example, as the evidence set out in paragraphs 6.679 to 6.732 below will demonstrate, in June 2014 AMCo secured a further increase in the number of discounted packs Auden would supply after it threatened to launch its own product. Additionally, in 2015 AMCo devised a strategy to secure a further increase in its volumes from Actavis, *'leveraging'* the threat of entry with the 10mg hydrocortisone tablets development it had acquired with Focus Pharmaceuticals (see paragraphs 6.768 to 6.776 below).

6.613. The increase in volumes [Amdipharm Senior Employee] secured in January 2013 must be considered in this context – it was a further occasion on which

²⁵⁴⁰ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.

AMCo sought (and obtained) an increase in the payments it received from Auden in exchange for agreeing not to enter the market independently with its own 10mg hydrocortisone tablets.

AMCo's strategy for the 10mg hydrocortisone tablets project it had acquired from Waymade

6.614. As explained in section 3.F.III.f above, after acquiring the 10mg hydrocortisone tablets development and the 10mg MA from Waymade on 31 October 2012, AMCo engaged only sporadically with Aesica in the 14 months prior to the January 2014 crisis in relations with Auden. Its senior management had limited involvement in the project, which had yet to be submitted to the AMCo board for approval.

6.615. On 20 August 2013, having received a series of requests from Aesica for a production forecast for 10mg hydrocortisone tablets, [AMCo Employee] ([X]) asked [Amdipharm Senior Employee] what AMCo's strategy for its Aesica manufactured 10mg tablets was:

*'[Amdipharm Senior Employee], I need to know the future strategy for this [the Aesica product] as Aesica are pushing us to provide a production forecast'*²⁵⁴¹

6.616. The fact that AMCo's [X] approached [Amdipharm Senior Employee] with this enquiry demonstrates that [Amdipharm Senior Employee] was central to determining AMCo's strategy in respect of 10mg hydrocortisone tablets.

6.617. There is no record of [Amdipharm Senior Employee]'s response to [AMCo Employee]. Having received no response from AMCo, more than a month later (on 24 September 2013) Aesica emailed [AMCo Employee] *'to follow up on the Hydrocortisone proposal which was forwarded to you in August'*.²⁵⁴² In a later email to [Amdipharm Senior Employee], dated 7 November 2013, [AMCo Employee] noted that AMCo did not have any plans to market the Aesica manufactured tablets:

'Aesica are chasing for a forecast which to my knowledge does not exists [sic] as we currently have no plan to market Aesica manufactured material.'

²⁵⁴¹ Document 201720, email from [AMCo Employee] to [Amdipharm Senior Employee] dated 20 August 2013. Later that day [X] stated in response to Aesica's request for a 'forecast/plan' for 10mg tablets that he was 'waiting on [Amdipharm Senior Employee] to advise the strategy of this product going forward'. Document 202523, email from [AMCo Employee] to [X], [X] and [X] dated 20 August 2013.

²⁵⁴² Document 201721, email from [Aesica Employee] to [AMCo Employee] dated 24 September 2013.

6.618. [AMCo Employee] asked [Amdipharm Senior Employee]:

'Please can you advise what direction you wish for us to take with regards to this product? ...

Are we to market Aesica product, if so what is the strategy to switch from Auden and what would the marketing strategy be?'²⁵⁴³

6.619. Again, [AMCo Employee]'s enquiry shows that [Amdipharm Senior Employee] was central to determining AMCo's strategy in relation to its 10mg hydrocortisone tablets.

6.620. [AMCo Employee]'s emails are additionally significant because they provide a contemporaneous documented account of AMCo's policy in relation to the possible marketing of its 10mg tablets.

6.621. First, [AMCo Employee] referred to the fact that AMCo '*currently have no plan to market Aesica manufactured material*' – meaning that despite the compelling commercial case to enter the market, over a year after acquiring the product from Waymade AMCo had no firm plans to launch its own 10mg hydrocortisone tablets.

6.622. Secondly, in raising the question of whether AMCo's policy had changed ('*Are we to market Aesica product*') [AMCo Employee] also understood that if it had, this would mean the end of supply from Auden: AMCo would need a '*strategy to switch from Auden*' (but would not need such a strategy if it continued to take supply from Auden).

6.623. A month later (in December 2013), AMCo described its 10mg tablets as a '*Protective project to ensure continuity of supply*'. Although AMCo anticipated being ready to launch by June 2014, around six months later, one of the questions for discussion was '*Would we launch?*'²⁵⁴⁴

6.624. AMCo's 10mg tablets were a '*Protective project to ensure continuity of supply*' in two ways:

- a. By allowing it to continue to use the competitive threat of entry as leverage to secure continuity of (and increase in) payments from Auden under the 10mg Agreement (as AMCo had done in January 2013 and did again in the first half of 2014); and

²⁵⁴³ Document 202572, email from [AMCo Employee] to [Amdipharm Senior Employee] dated 7 November 2013 (emphasis added).

²⁵⁴⁴ Document 202593, PPRM slides dated 18 December 2013.

- b. By providing a back-up option in case the 10mg Agreement should end (as ultimately happened in June 2016, shortly after AMCo finally decided to launch its 10mg product, which its staff stated at the time had '*always been merely a back up until now*'²⁵⁴⁵).
- 6.625. Each of these is a contingent approach to launching AMCo's 10mg tablets, contrary to the principle that undertakings must determine independently the policy they intend to adopt on the market (as the question '*Would we launch?*' – not '*When will we launch?*', as one might expect given the context of a market continuing to increase in value – shows): AMCo would only launch its 10mg tablets if the 10mg Agreement broke down.

November 2013 to January 2014: AMCo attempts once more to triple its volumes

- 6.626. During late 2013, AMCo (through [Amdipharm Senior Employee]) was attempting to obtain a formal, forward-looking written supply contract from Auden.
- 6.627. As explained in section 3.F.III.f above, these negotiations coincided with ongoing negotiations for AMCo's potential acquisition of Auden's hydrocortisone tablets business, with AMCo feigning an interest in that acquisition in the hope that it would facilitate obtaining a new supply deal. At the same time, both parties were assessing the implications of the orphan designation for the extent of the competitive threat posed by AMCo's skinny label tablets.²⁵⁴⁶
- 6.628. [Amdipharm Senior Employee] sent a draft supply contract to [Auden Senior Employee 1] on 15 November 2013, proposing a three-year supply of 10mg hydrocortisone tablets at £1 per pack and specifying an '*Estimated Order Quantity*' of 18,000 packs per month: triple the amount Auden was supplying AMCo at this time.²⁵⁴⁷ This would therefore have meant another substantial increase in Auden's payments to AMCo: that volume of packs would have been worth around £645,000 if sold at prevailing ASPs (compared to the 6,000 packs per month AMCo was receiving at the time, which were worth around £215,000). The volume [Amdipharm Senior Employee] proposed

²⁵⁴⁵ Document 200385, online conversation between [AMCo Employee] and [AMCo Senior Employee 5] dated 3 March 2016.

²⁵⁴⁶ For example, on 24 September 2013 Auden was told by the MHRA that no competing MA granted after November 2011 could include the indication for the treatment of adrenal insufficiency in adults. Document 00632, email from [REDACTED] of the MHRA to [REDACTED] dated 24 September 2013. AMCo instructed Pinsent Masons to advise on the implications of the orphan designation. Document 201088, page 7, Advice in relation to Orphan Status Protection for Plenadren.

²⁵⁴⁷ Document 202553, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden McKenzie (Pharma Division) Limited and Amdipharm Limited. See also Document 202557, email from [Amdipharm Senior Employee] to [REDACTED] dated 15 November 2013.

corresponded to AMCo's initial estimate of the volume it stood to win if it launched its own product.²⁵⁴⁸

- 6.629. However, Auden rejected this proposal. On 18 December 2013 [Auden Senior Employee 1] told [Amdipharm Senior Employee] that *'We need to discuss Hydro volumes'*.²⁵⁴⁹ On 19 December 2013 [Auden Senior Employee 1] asked [Amdipharm Senior Employee] to *'alter the volume on the hydro agreement as discussed'*.²⁵⁵⁰ The CMA infers that a discussion therefore took place between those two emails being sent (though no record of it has been found).
- 6.630. [Auden Senior Employee 1]'s focus on volumes is key: as the mechanism for payments to AMCo was specified volumes at a low price, the agreed volume would determine the payment Auden would have to make to AMCo each month. As the rationale for the payments Auden made to AMCo was to buy off the competitive threat of entry, the volume Auden agreed to give AMCo (and therefore the size of the payment) each month reflected both parties' ongoing assessment of what buying off AMCo's threat of entry was worth.
- 6.631. The minutes of an AMCo management meeting, also on 19 December 2013, show that Auden had questioned the level of competitive threat AMCo's skinny label 10mg tablets would pose to its full label tablets (and therefore whether tripling AMCo's volumes was a price worth paying to continue buying off its entry). The minutes stated:

*'Auden are still supplying hydrocortisone but are being increasingly aggressive and threatening that the orphan drug status of their product means that our product (which does not have adrenal insufficiency as an indication) is not comparable to theirs.'*²⁵⁵¹

- 6.632. This demonstrates that negotiations between Auden and AMCo regarding the ongoing supply of 10mg hydrocortisone tablets focused on the competitive relationship between Auden's and AMCo's respective 10mg

²⁵⁴⁸ AMCo assumed that *'60% of the market available to us'* and that it could *'get 40%'* of that 60%, equivalent to 24% market share or 18,000 packs a month in 2014 if it launched its own skinny label product. Document 202660, spreadsheet titled 'model (2)' attached to Document 202659, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 4] dated 23 May 2014. Although the spreadsheet was attached to an email in May 2014, it is likely that it was prepared in late 2013: it modelled all potential scenarios, including competitive entry, from January 2014 onwards and assumed (subject *'to check'*) an Auden ASP of £40 (Auden's ASP in May 2014 reached £53.65). The information in the 'current' tab matches the numbers AMCo used for its internal forecasts in December 2013 – see for instance, Document 202597, email from [AMCo Employee] to [AMCo Senior Employee 1] and [AMCo Senior Employee 4] dated 20 December 2013. The number of packs, ASP and total sales in the email are identical to those listed in the 'current' tab of the spreadsheet (Document 202660).

²⁵⁴⁹ Document 202596, email from [Auden Senior Employee 1] to [Amdipharm Senior Employee] dated 18 December 2013.

²⁵⁵⁰ Document 202596, email from [Auden Senior Employee 1] to [Amdipharm Senior Employee] dated 19 December 2013.

²⁵⁵¹ Document 200160, minutes of Mercury Pharma Group Limited management meeting on 19 December 2013.

hydrocortisone tablets. This in itself is an unusual focus for negotiations ostensibly about the terms of a supply deal: it shows that the true rationale for Auden continuing to supply AMCo was to buy off its competitive threat. Whether AMCo's product was '*comparable*' to Auden's is not otherwise relevant to whether Auden would continue to supply AMCo and with what volumes.

- 6.633. Although '*Auden was [are] still supplying hydrocortisone*' to AMCo at this stage (and therefore adhering to its side of the 10mg Agreement), this arrangement was potentially at risk. This was because Auden was questioning the extent of the competitive threat AMCo's skinny label tablets would pose to its own tablets (Auden was '*threatening that the orphan drug status of their product means that our product is not comparable to theirs*').
- 6.634. If Auden came to believe that the competitive threat was limited, it could have decided to stop buying off AMCo's entry (by stopping the supply of heavily discounted packs of 10mg hydrocortisone tablets) or at least refused AMCo's request for increased volumes, having determined that this higher price was not worth paying.
- 6.635. For the first time since AMCo acquired the 10mg MA, the 10mg Agreement appeared to be at risk: Auden was challenging the strength of the competitive threat posed by AMCo's 10mg tablets on account of the orphan designation, and questioning whether AMCo's attempt to triple its volumes was a price worth paying for AMCo's continued non-entry.
- 6.636. For much of 2013, the 10mg Agreement had proceeded undisturbedly. Auden made its monthly payments to AMCo (having increased them significantly in January) and AMCo, in exchange, did not launch its own 10mg tablets – despite the very favourable market conditions. The two parties collaborated rather than competed.
- 6.637. However, Auden's '*increasingly aggressive*' questioning of the competitiveness of AMCo's tablets created a stimulus for both parties to reassess and (ultimately) reaffirm the 10mg Agreement. The period between January and June 2014, discussed in the sections that follow, therefore provides a valuable insight into both parties' behaviour and motivations throughout the term of the 10mg Agreement.
- 6.638. In response to Auden's challenge, in 2014 AMCo continued to deploy the strategy encapsulated in its contemporaneous description of its 10mg tablets as a '*Protective project to ensure continuity of supply*'.²⁵⁵² First, it continued

²⁵⁵² Document 202593, PPRM slides dated 18 December 2013.

to seek to use the competitive threat posed by its product as leverage in negotiations with Auden to maintain (and improve the terms of) the 10mg Agreement – with the aim that Auden would continue to buy off that competitive threat for a higher price. Secondly, concerned that Auden might walk away from the 10mg Agreement altogether, it started gearing up for launching its own, ‘back-up’ 10mg tablets.

AMCo’s use of its 10mg product as leverage in January 2014

- 6.639. Notwithstanding Auden’s ‘increasingly aggressive’ stance in December 2013, key AMCo staff were confident that its skinny label tablets would pose a significant competitive threat to Auden’s tablets and believed that AMCo should push back on the stance Auden was adopting.
- 6.640. On 2 January 2014, [AMCo Senior Employee 2] [REDACTED] was responsible both for delivering new products and for AMCo’s business strategy²⁵⁵³ – sent two emails to colleagues within AMCo. The content of these emails demonstrates his belief that AMCo’s skinny label tablets posed a significant competitive threat to Auden and therefore continued to provide AMCo with leverage. The emails also demonstrate [AMCo Senior Employee 2]’s understanding that AMCo was using the competitive threat its 10mg tablets posed as leverage in the negotiations with Auden. [AMCo Senior Employee 2] sent the first of his two emails to [AMCo Senior Employee 1] and other colleagues:

‘... I have just received the prescribing data for Hydrocortisone 10mg from [REDACTED] (see other email attached). It shows that only 22% of Rx’s are specified as Adrenal, and there are multiple other indications widely in use, not the 90+% for adrenal insufficiency that [Amdipharm Senior Employee] was once referring to. That means labelling shouldn’t be that important, hopefully ● Pharmacists will dispense our product, regardless of label, and [Auden Senior Employee 1]’s claim that we have an inferior product is irrelevant anyway, when it can be shown to be bioequivalent. It just doesn’t have the labelling for one protected indication. Therefore I think we can push back a bit harder! I’ve sent an email to [Amdipharm Senior Employee] suggesting the same.’²⁵⁵⁴

- 6.641. [AMCo Senior Employee 2] reiterated his view that ‘limited labelling’ was not a significant issue in terms of the competitive threat AMCo’s skinny label

²⁵⁵³ Document 201591, transcript of [AMCo Senior Employee 2] interview transcript dated 12 October 2017, page 7 lines 5-8 and page 8 lines 1-19.

²⁵⁵⁴ Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] (copied to [AMCo Senior Employee 8]) dated 2 January 2014 (emphasis added).

tablets would pose to Auden in the email he sent to [Amdipharm Senior Employee]:

'According to the data on IMS, only 22% of prescriptions are specifically identified as Adrenal, with a long list of others. That gives us a bit more strength to say to [Auden Senior Employee 1] that we don't mind having limited labelling. Pharmacists will use it anyway, regardless of labelling. Therefore, we should still be arguing using 100% of the market as our negotiating position for supply volumes!'²⁵⁵⁵

- 6.642. [AMCo Senior Employee 2]'s emails demonstrate that he believed that the limited indications of AMCo's own 10mg hydrocortisone tablets would not prevent its tablets from competing with Auden's product (*'pharmacists will use it [the Aesica-manufactured tablets] anyway, regardless of labelling'*).
- 6.643. [AMCo Senior Employee 2] was not alone within AMCo in holding this view. A January 2014 AMCo product development slide deck included sales projections for its Aesica product on the assumption that '*Indication limitations do not restrict sales*'. AMCo predicted that if it entered it could achieve sales volumes of 12,000 packs per month and a gross profit of 94%.²⁵⁵⁶ This equated to approximately 16% of total volumes.²⁵⁵⁷ See further section 3.E.IV.a above and Annex D to this Decision.
- 6.644. It is notable, however, that [AMCo Senior Employee 2]'s assessment of the potential competitiveness of AMCo's Aesica-manufactured tablets was not primarily in contemplation of the impending launch of those tablets.
- 6.645. [AMCo Senior Employee 2]'s primary concern was the extent of the leverage this potential competitiveness provided AMCo (and specifically [Amdipharm Senior Employee]) in its negotiations with Auden for a renewed supply arrangement. [AMCo Senior Employee 2] wanted [Amdipharm Senior Employee] to '*push back a bit harder*' in these negotiations, because the Aesica-manufactured product could potentially obtain a very significant market share (*'using 100% of the market as our negotiating position for supply volumes'*).²⁵⁵⁸

²⁵⁵⁵ Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014 (emphasis added).

²⁵⁵⁶ Document 200090, Product Development: Hydrocortisone 10mg tablets, 22 Jan 2014, PPRM, slide 10.

²⁵⁵⁷ In 2014, total volumes of 10mg hydrocortisone tablets dispensed were 919,516 packs per year or approximately 76,626 packs per month. Source: NHS BSA data for the UK.

²⁵⁵⁸ As explained in section 3.F.III.f above, the negotiations to agree a renewed 10mg supply arrangement coincided with negotiations for AMCo to acquire Auden's hydrocortisone business. The extent of the market that was contestable to suppliers of skinny label tablets was relevant to both sets of negotiations: to the proposed acquisition of Auden's hydrocortisone business because it would determine the true value of that business in the

- 6.646. In treating AMCo's competitive threat primarily as leverage, [AMCo Senior Employee 2] demonstrated that AMCo continued to work on the basis that its preferred strategy was to continue accepting payments from Auden in exchange for non-entry.
- 6.647. Just as before, the form AMCo's leverage took is clear. The purpose of Auden's payments was to buy off AMCo's competitive threat. Both parties were continuing to debate the price at which it would be worth Auden continuing to buy off that threat. What [AMCo Senior Employee 2] was seeking to achieve through his emails was to strengthen AMCo's resolve in its negotiations with Auden to increase the scale of the payments by claiming that the level of the competitive threat AMCo's tablets posed was greater than Auden was claiming, and therefore that the price of AMCo's non-entry should be higher.
- 6.648. AMCo's negotiating strategy therefore demonstrates both that AMCo continued to adhere to its commitment not to enter with its own 10mg tablets, and that it aimed to secure increased payments from Auden in exchange for that commitment. AMCo's options continued to be mutually exclusive, and its negotiating position continued to be premised on the same strategic choice as that faced by Waymade in relation to its 20mg and 10mg hydrocortisone tablets: either it could continue to work towards entering with its own tablets and compete with Auden or it could continue to cooperate with Auden by reaffirming its commitment not to enter in exchange for continued payments.

AMCo's treatment of its 10mg tablets as a 'back-up' in case the 10mg Agreement ended

- 6.649. As explained in paragraph 6.617 above, more than a year after acquiring Waymade's 10mg product development on 31 October 2012, [X] was unable to provide a production forecast to Aesica because '*we currently have no plan to market Aesica manufactured material*'.²⁵⁵⁹ Despite the

face of competition; and to renewing the 10mg supply arrangement because the terms of that arrangement, in particular the quantities Auden was to supply AMCo, depended on both parties' assessment of the volume Auden stood to lose to AMCo if it entered with its own product. This connection is demonstrated in the two emails [AMCo Senior Employee 2] sent on 2 January 2014. However, in its representations on the SSO AMCo denied that these emails were relevant to negotiations for a supply agreement. AMCo asserted in relation to Document 200165 that '*[AMCo Senior Employee 2] intended to use the prescribing data in negotiations with Auden regarding Auden's proposed sale of its hydrocortisone business, not in negotiations relative to the conclusion of a written supply agreement with Auden*' (Document 204922, AMCo's RSSO, paragraph 3.747); and in relation to Document 200164 that '*This email, too, concerns AMCo's negotiating position relative to Auden's proposed sale of Auden's hydrocortisone business*' (paragraph 3.748). It is clear in context that [AMCo Senior Employee 2] was not exclusively concerned with the negotiations for AMCo to buy Auden's hydrocortisone business. AMCo's statement in relation to Document 200164, in particular, is contradicted by the document on its face, which shows [AMCo Senior Employee 2] suggesting to [Amdipharm Senior Employee] that AMCo '*should still be arguing 100% of the market as our negotiating position for supply volumes*'.

²⁵⁵⁹ Document 202572, email from [AMCo Employee] to [Amdipharm Senior Employee] dated 7 November 2013.

compelling case for entry, AMCo preferred instead to continue cooperating with its potential competitor Auden.

- 6.650. As explained in paragraph 6.624 above, AMCo's treatment of its 10mg tablets as a '*Protective project to ensure continuity of supply*'²⁵⁶⁰ had two strands: using the competitive threat of entry with that product as leverage to ensure continuity of (and increase in) payments from Auden; and developing a '*back-up*' option in case the 10mg Agreement should end. By early January 2014 AMCo was sufficiently concerned about the status of the stalling negotiations with Auden that it took steps to bring its own 10mg tablets to launch-readiness, in pursuit of this second strand. The apparent breakdown in negotiations between AMCo and Auden in January 2014 prompted AMCo's senior management to engage with its Aesica project. The prospect that the 10mg Agreement would end sooner than anticipated meant the Aesica project became a priority and was submitted to the AMCo board for approval at the end of the month.
- 6.651. On 2 January 2014 [AMCo Senior Employee 2] emailed [AMCo Senior Employee 1] to inform him that [Amdipharm Senior Employee] had recommended that AMCo should move forward with production of its own 10mg tablets: '*[Amdipharm Senior Employee] ... said that we need to get our back-up option moving, which has been a bit of a ham-fisted effort to date*'.²⁵⁶¹
- 6.652. On the same day, [AMCo Senior Employee 2] emailed colleagues in his Business Development team, stating:
- 'We need to be in place to be able to supply the market ASAP in the event that other supply sources fail us ... our back up plan for the Amdipharm product must be focused about getting compliant product to the market on a consistent basis ASAP.*
- ... there's real risk around continuity of supply from the current source (Auden McKenzie), so we need to be able to supply the market as quickly as we can.'*²⁵⁶²
- 6.653. In interview, [AMCo Senior Employee 2] stated in relation to this email: '*There was a genuine belief that Auden McKenzie were not going to supply us, so ... this would become almost priority number one product for us to*

²⁵⁶⁰ Document 202593, PPRM slides dated 18 December 2013.

²⁵⁶¹ Document 200163, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014 (emphasis added).

²⁵⁶² Document 200020, email from [AMCo Senior Employee 2] to [AMCo Employee] dated 2 January 2014.

*deliver as quickly as possible.*²⁵⁶³ [AMCo Senior Employee 2] went on to describe the Aesica product as ‘a back-up plan in the event that supply [from Auden] failed’.²⁵⁶⁴

6.654. As a result, AMCo’s potential launch of its 10mg hydrocortisone tablets was the subject of a presentation to its PPRM in January 2014. The PPRM agreed to recommend the project to the AMCo board.²⁵⁶⁵

6.655. The recommendation to the AMCo board stated that the ‘*Rationale*’ for the project was:

*‘Back-up product to ensure continuity of supply in case our existing distribution agreement with Auden McKenzie for Hydrocortisone is not renewed.’*²⁵⁶⁶

6.656. This rationale is consistent with the presentation in December 2013, and with [AMCo Senior Employee 2]’s emails and account in interview, discussed above.

6.657. AMCo’s treatment of its Aesica product as a ‘back-up’ (like its use as leverage in negotiations with Auden) demonstrates its continued adherence to its commitment not to enter with its own 10mg tablets. It indicates a contingent approach to launching the 10mg tablets: AMCo’s preferred option remained to continue cooperating with Auden by accepting its payments; but it was preparing for the scenario where the payments from Auden were terminated. Only then would the ‘back-up’ option be required.

6.658. As explained in paragraphs 6.725 to 6.745 and 6.777 to 6.783 below, this is further confirmed by AMCo’s conduct in the second half of 2014 and in spring 2016: after re-affirming its commitment not to compete with Auden in exchange for increasing payments under the Second Written Agreement, AMCo took immediate steps to suspend its Aesica project and ensure its 10mg tablets would not be sold in the UK. Only when it was certain that the 10mg Agreement would end did AMCo actually launch its 10mg tablets. As [AMCo Employee] ([X]) explained to [AMCo Senior Employee 5] ([X]) at that time, ‘Ours [AMCo’s own 10mg tablets] has always been merely a back

²⁵⁶³ Document 201591, transcript of [AMCo Senior Employee 2] interview transcript dated 12 October 2017, pages 39-40.

²⁵⁶⁴ Document 201591, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, page 40 lines 22-23.

²⁵⁶⁵ Document 200102, Strategic Development – Monthly Report dated January 2014, page 4. See also Document 202633, Excel spreadsheet ‘PPRM Approved Projects – Monthly Report (Jan-14)’.

²⁵⁶⁶ Document 202632, January 2014 Business Development & Licensing Report PPRM Recommendations for Board Approval, page 3. See also Document 202630, January 2014 Business Development & Licensing Report EPRM approvals, slide 3.

up until now ... It may change if Auden do not renew the agreement which seems likely and is why we are stocking up on our own MA').²⁵⁶⁷

- 6.659. By mid-January 2014, some within AMCo believed that Auden would terminate the 10mg Agreement. Despite moderating its ambitions (by asking for a volume increase of only 1,000 packs per month and a one-off supply of 10,000 packs – ie indicating that it would accept a lower price from its potential competitor for its continued non-entry)²⁵⁶⁸ AMCo continued to meet resistance from [Auden Senior Employee 1].
- 6.660. On 14 January 2014 [AMCo Senior Employee 2] emailed [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8], [Amdipharm Senior Employee] and others to summarise a call he had with [Auden Senior Employee 1] earlier that day. [Auden Senior Employee 1] had threatened not to sign the formal supply agreement and to take action to protect the Auden product from AMCo's entry:

'I received a call from [Auden Senior Employee 1] today, who was not happy with the higher order being sent by SCM, before the agreement is signed (by him) and without having given an indication whether we are going to buy the product or not ... his main points were:

Why was an order sent for the higher amount? I said that I believed it was in anticipation of the newly-agreed volumes ...

He then went onto say that if we don't make an offer to buy the product, and thus he implied that he therefore wouldn't sign the supply agreement, he would then take action to protect his product by advising all parties (mentioning DoH and MHRA amongst others, including major multiples) that our product should not be dispensed against generic prescriptions.

This supply deal is not going to happen (in my opinion), and I'm not sure we want it to happen from what I hear from [AMCo Senior Employee 8]. I think we need to now get a really clear plan in place how to launch our product, and to prepare for next batch, and also to counter-lobby the relevant stakeholders and point out that our product is in no way "inferior" from a quality perspective, and to clearly establish whether the adrenal insufficiency claim is a red herring or not. Is it really 95% of prescriptions that [Auden Senior Employee 1]] claims, or

²⁵⁶⁷ Document 200385, online conversation between [AMCo Employee] and [AMCo Senior Employee 5] dated 3 March 2016.

²⁵⁶⁸ See Document 200072, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 8 January 2014; and Document 200029, draft contract attached. See also section 3.F.III.f above.

*nearer the 22% of prescriptions that was apparent from [redacted] IMS MDI data[?]*²⁵⁶⁹

- 6.661. [AMCo Senior Employee 2]'s email shows that he believed that the 10mg Agreement was likely to be terminated. As a result of the call [AMCo Senior Employee 2] had concluded that *'This supply deal is not going to happen.'* This would mean that AMCo lost its monthly payments from Auden and was left with no option but to launch its own 10mg tablets.
- 6.662. Because of this risk, [AMCo Senior Employee 2] recommended that AMCo devise *'a really clear plan'* to launch its own tablets. Significantly, [AMCo Senior Employee 2] stated, *'we need to now get a really clear plan in place how to launch our product'*, reflecting the fact that to date AMCo had no such plan.
- 6.663. The fact [AMCo Senior Employee 2] linked the possible termination of the supply arrangement with Auden to the need for AMCo to *'now get a really clear plan'* to launch its own tablets supports the conclusion that AMCo had to date continued to adhere to its commitment not to enter with those tablets. AMCo had not yet devised *'a really clear plan'* to launch – which it could have done at any time since 31 October 2012, particularly given the favourable market conditions – because it continued to receive payments from Auden; but it now set about doing so because it perceived a real threat to those payments continuing.
- 6.664. [AMCo Senior Employee 2]'s email also shows that [Auden Senior Employee 1] had threatened to *'take action to protect his product'* in the event that AMCo did enter the market. [Auden Senior Employee 1] was referring to 'Project Guardian', which was a campaign designed to highlight the fact that AMCo's tablets did not benefit from a full label indication, thereby undermining its ability to compete with Auden's tablets (see section 3.F.III.h above).
- 6.665. On 24 January 2014 AMCo therefore increased preparations for entry, by raising a purchase order with Aesica for 45,000 packs of 10mg hydrocortisone tablets for delivery on 7 May 2014.²⁵⁷⁰ See section 3.F.III.f.ii above. AMCo's re-engagement with its *'back-up'* 10mg tablets was prompted by its uncertainty about the future of the 10mg Agreement.

²⁵⁶⁹ Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4] dated 14 January 2014 (emphasis added).

²⁵⁷⁰ Document 202618, email from [AMCo Employee] to [AMCo Employee] dated 24 January 2014. In response, [AMCo Senior Employee 7] requested to *'treat this as urgent'* (see the same document).

AMCo and Auden sign the First Written Agreement and both parties anticipate that AMCo will soon launch

- 6.666. An internal AMCo email exchange of 24 January 2014 between [AMCo Senior Employee 8] and [AMCo Senior Employee 4] shows that, by this date, AMCo and Auden had agreed that, rather than increasing AMCo's payments in a new three-year forward-looking supply deal, they would simply document the terms of supply that had been in place since January 2013.²⁵⁷¹ This was confirmed in an email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] of 27 January in which [Amdipharm Senior Employee] sent a draft of the First Written Agreement.²⁵⁷²
- 6.667. On 25 February 2014 AMCo and Auden entered into the First Written Agreement for this purpose. The First Written Agreement was therefore largely retrospective – its start date was 1 January 2013 and its end date was 31 March 2014.²⁵⁷³ At this stage the parties therefore envisaged that the 10mg Agreement would last just one further month and would be terminated on 31 March 2014.
- 6.668. At this time, AMCo was on the cusp of launching its own tablets. As explained in section 3.F.III.g above, having placed the purchase order with Aesica on 24 January 2014, AMCo anticipated launching its 10mg tablets in April or May 2014.²⁵⁷⁴ As explained in section 3.F.III.h above, in the meantime Auden engaged in 'Project Guardian' in an effort to protect its market position ahead of AMCo's anticipated launch.

March/April 2014: AMCo and Auden return to the negotiating table

- 6.669. However, during March/April 2014 the negotiating positions of the parties changed with [Auden Senior Employee 1] becoming apparently more amenable to continuing the 10mg Agreement. The AMCo monthly management pack for March stated that Auden had offered to continue to supply AMCo with its 10mg hydrocortisone tablets on an '*ongoing basis*':

²⁵⁷¹ [AMCo Senior Employee 8] stated on 24 January 2014 that '[Amdipharm Senior Employee] tells me that he has agreed with Auden that we will document the agreement to date', noting that 'In terms of price/volume, this will continue the arrangement in place last year'. Document 200166, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 4] dated 24 January 2014.

²⁵⁷² On 27 January 2014 [Amdipharm Senior Employee] sent, '*Further to our recent discussion*', a revised draft of the First Written Agreement to [Auden Senior Employee 1] designed to '*reflect the agreements which have been in place during the past 12 months*' and specifying a monthly order quantity of 6,000 packs. Document 200234, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 27 January 2014.

²⁵⁷³ Document 00445, First Written Agreement.

²⁵⁷⁴ See, for example, AMCo's February 2014 strategic development report: '*Hydrocortisone tablets ... launch strategy complete ... a plan is underway to register a variation (Mar-14) to potentially be ready for launch by end-April 14*'. Document 200183, Strategic Development – Monthly Report, February 2014, page 7.

'we are considering their [Auden's] offer to continue supplying AMCo with Hydrocortisone on an ongoing basis. We would need to have a long term supply agreement with agreed price and volume for the period but if the economics are ok this would have the advantage to AMCo of selling a product with the full range of indications'.²⁵⁷⁵

- 6.670. In context, the reason for Auden's offer to continue supplying AMCo on the terms of the 10mg Agreement on an '*ongoing basis*' was that by April 2014, Auden was less confident that the orphan designation sufficiently protected it from the threat of competitive entry posed by AMCo.²⁵⁷⁶ This meant that the question of whether it should continue to buy off AMCo's entry, and if so at what price, once more became a matter for negotiation between the parties.
- 6.671. Auden's offer to continue supplying AMCo '*on an ongoing basis*' meant that the 10mg Agreement remained in force. AMCo still had a strategic choice, notwithstanding the First Written Agreement coming to an end on 31 March 2014: it could either continue working towards launching its own tablets or it could accept Auden's offer and continue to take payments from Auden in exchange for its continued commitment not to launch.
- 6.672. This renewed negotiation between Auden and AMCo (described in the sections that follow) resulted in both parties continuing to adhere to the terms of the 10mg Agreement in April and May 2014. In April 2014, Auden provided AMCo with '*bridging stock*' of two batches of 6,000 packs at £1 per pack to cover that month and May 2014.²⁵⁷⁷ Those packs were worth around £228,000 and £354,000, respectively, in the market, if sold at around Auden's ASP (£38 in April and £54 in May). AMCo did not launch its 10mg tablets.
- 6.673. Auden's and AMCo's behaviour during the negotiations that took place in the first half of 2014 is consistent with and illustrative of their behaviour

²⁵⁷⁵ Document 200108, AMCo Monthly Management Pack, March 2014, page 6. The pack was likely drafted in April and the reference to Auden's offer to continue to supply AMCo may have been inserted on the basis of [Auden Senior Employee 1] approaching [AMCo Senior Employee 1] in April 2014 (see below).

²⁵⁷⁶ Indeed, as explained below, on 22 April 2014 Auden received feedback from [Professor of Endocrinology], Consultant Endocrinologist, on its Project Guardian materials. Professor of Endocrinology] referred to '*our recent telephone conversation*' (suggesting that he gave [Auden Senior Employee 1] some feedback prior to 22 April), and noted that '*My main concern is that it looks as if you are worried about the competition rather than more altruistic reasons*'. Document 00140, email from Professor of Endocrinology] to [Auden Senior Employee 1] dated 22 April 2014. Further, evidence from shortly after April 2014 shows that Auden had trouble getting buy-in to Project Guardian from the medical profession (see section 3.F.III.i above and below), confirming that AMCo's 10mg hydrocortisone tablets would pose a significant competitive threat. Auden therefore sought to explore whether it could continue to buy off AMCo's entry to protect its position as sole supplier and its resulting pricing power.

²⁵⁷⁷ See section 3.F.III.g above.

throughout the term of the 10mg Agreement. As explained in the sections that follow, during this period:

- a. Both parties continued to separately assess, and bilaterally discuss (contrary to the principle that undertakings must determine independently the policy they intend to adopt on the market), the implications of the orphan designation for the degree of competitive threat AMCo's 10mg tablets posed to Auden, and therefore the degree of leverage AMCo held.
- b. In the meantime, the 10mg Agreement continued on the existing terms: Auden continued to make monthly payments to AMCo and in return, AMCo did not launch its 10mg tablets. The parties continued to negotiate during April to June 2014.
- c. Ultimately, Auden concluded that AMCo's skinny label tablets continued to pose a significant competitive threat that was worth continuing to buy off with even greater payments, and AMCo made a direct threat to Auden that if it did not make those payments, it would launch. The parties agreed a new, forward looking two-year supply deal (the Second Written Agreement) in which Auden committed to continue paying AMCo (and at higher monthly amounts). The evidence of the negotiations that led the Second Written Agreement, and AMCo's conduct after it was concluded, show that in exchange, AMCo confirmed its commitment to continue not competing with Auden.

April to June 2014: AMCo negotiates with Auden to double its volumes, using its 10mg product as leverage

- 6.674. Having opened the door to continuing the 10mg Agreement, Auden and AMCo conducted negotiations in the period April, May and June 2014 which resulted in the conclusion of the Second Written Agreement.
- 6.675. The negotiations and AMCo's subsequent conduct demonstrate that accepting Auden's '*offer to continue supplying AMCo with Hydrocortisone on an ongoing basis*'²⁵⁷⁸ (as AMCo ultimately did) reflected a continued common understanding between the parties that in exchange, AMCo would not enter the market independently with its own 10mg hydrocortisone tablets. This evidence also corroborates the conclusion that this common understanding between Auden and AMCo had continued since AMCo

²⁵⁷⁸ Document 200108, AMCo Monthly Management Pack, March 2014, page 6.

succeeded Waymade as counterparty to the 10mg Agreement on 31 October 2012.

- 6.676. In particular, AMCo negotiated the Second Written Agreement on the basis of the same, consistent, strategy (of using the threat of its competitive entry as leverage to obtain increased payments from Auden) as Waymade had deployed when negotiating the 10mg Agreement (and the 20mg Agreement). After securing the Second Written Agreement AMCo treated its own 10mg tablets (which had been on the threshold of launching) in the same way as Waymade had treated its 20mg tablets after securing the 20mg Agreement: by quarantining them and taking steps to make sure they would not be sold in the UK.

AMCo's negotiating strategy for the Second Written Agreement

- 6.677. During the negotiations leading to the Second Written Agreement, [AMCo Senior Employee 1] took over from [Amdipharm Senior Employee] as AMCo's lead negotiator.
- 6.678. Contemporaneous documentary evidence demonstrates that [AMCo Senior Employee 1] used the competitive threat of AMCo launching its 10mg tablets as leverage to secure the continuation of the 10mg Agreement.
- 6.679. On 19 April 2014 [AMCo Senior Employee 1] emailed [AMCo Senior Employee 2] to update him on negotiations he had held with [Auden Senior Employee 1] regarding continuing the 10mg supply arrangement between AMCo and Auden. [AMCo Senior Employee 1] wrote:

'[Auden Senior Employee 1] offered to continue to supply us [...] I think that he is not keen to get into a battle over the orphan drug status and its validity and so probably would do a better deal on better terms.

I have asked [AMCo Senior Employee 5] what our Aesica cost and volume expectations are and I would say if [Auden Senior Employee 1] could get close to them it would be worth having a long term supply agreement with him.

*I am also not keen on having a fight over the status or indeed having customers that see our product as somehow risky.'*²⁵⁷⁹

- 6.680. [AMCo Senior Employee 1] explained that [Auden Senior Employee 1] had 'offered to continue to supply' AMCo with its 10mg hydrocortisone tablets and believed that [Auden Senior Employee 1] would be willing to make the

²⁵⁷⁹ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.

terms of the 10mg supply arrangement more favourable to AMCo (*'do a better deal on better terms'*).

- 6.681. [AMCo Senior Employee 1] explained that he believed the reason why [Auden Senior Employee 1] was prepared to continue to supply AMCo was that he was *'not keen to get into a battle'* over the true impact of the orphan designation. [AMCo Senior Employee 1] himself was also concerned to avoid such a contest, informing [AMCo Senior Employee 2] that he was also *'keen'* that AMCo avoid *'having a fight'* on the issue.
- 6.682. The *'battle'* or *'fight'* over the *'orphan drug status'* to which [AMCo Senior Employee 1] referred was over the extent of the contestable market available to AMCo's tablets and would have occurred if AMCo had entered the market with its skinny label 10mg hydrocortisone tablets and competed with Auden's full label 10mg tablets. The terms are in context euphemisms for competing with Auden.
- 6.683. The negotiations between Auden and AMCo were on the basis of a common understanding that – at a certain price – it would be worth both their whiles for Auden to continue buying off AMCo's entry: [AMCo Senior Employee 1]'s assessment was that [Auden Senior Employee 1] *'probably would do a better deal on better terms'* because he was *'not keen to get into a battle'*; while for AMCo if Auden could *'get close to'* its *'cost and volume expectations'* for its own 10mg tablets *'it would be worth having a long term supply agreement'* to avoid *'a fight'*.
- 6.684. [AMCo Senior Employee 1]'s email therefore demonstrates that both [AMCo Senior Employee 1] and [Auden Senior Employee 1] approached the negotiations leading to the Second Written Agreement on the continued common understanding that, if Auden continued to supply AMCo with its 10mg hydrocortisone tablets on favourable (and improved) terms (ie if it continued to pay AMCo), they would avoid such a *'battle'* or *'fight'* as AMCo would not enter the market independently with its own 10mg tablets. In other words, AMCo would reaffirm its commitment not to launch its tablets and *'fight'* – compete with – Auden in exchange for continued payment.
- 6.685. [AMCo Senior Employee 1]'s description of his discussion with [Auden Senior Employee 1] is consistent with [AMCo Senior Employee 2]'s emails of 2 January 2014, discussed in paragraphs 6.640 to 6.648 above, which show that AMCo and Auden had been bilaterally discussing the extent of the competitive threat AMCo posed since at least that date. In interview, [AMCo Senior Employee 1] confirmed this, stating in relation to his email:

*'he [[Auden Senior Employee 1]] knew about the AMCo product, because I'd met him previously and we'd discussed this, and [Auden Senior Employee 1] was very aggressive, I would say, in terms of what he would do if we would launch our skinny-labelled product, that he would try and get us to try and get the Royal Pharmaceutical Society or the MHRA to have certain things on our packs that would warn pharmacists against dispensing them in for [sic] the right indication.'*²⁵⁸⁰

6.686. Such discussions are in themselves contrary to the principle that undertakings must determine independently the policy they intend to adopt on the market.

6.687. On 23 April 2014 [AMCo Senior Employee 2] noted that *'It seems that [Auden Senior Employee 1] isn't being quite as bold about his indication claims now, which may reflect our belief that it's not as important as he was once suggesting'*.²⁵⁸¹

6.688. [AMCo Senior Employee 2]'s email indicates that Auden and AMCo continued to discuss the extent of the competitive threat AMCo's tablets posed. In interview, [AMCo Senior Employee 2] stated:

*'clearly our negotiating position's a lot stronger if he [[Auden Senior Employee 1]] believes we have a product that's coming to market ... I can only believe that he thought that we had a product that ... we would be able to supply the market and his risk mitigation strategy is to supply us with product or ... face, you know, AMCo supplying a product to the market and getting indeterminate market share'*²⁵⁸²

6.689. [AMCo Senior Employee 2] refers to AMCo's '*negotiating position*' being '*a lot stronger*' if [Auden Senior Employee 1] '*believes we have a product that's coming to market.*' This essentially summarises AMCo's (and previously Waymade's) strategy of leveraging the competitive threat it posed to Auden in order to secure payments in exchange for non-entry. As explained in paragraph 6.565 above, Waymade had been '*just another customer for Auden*' on 10mg tablets before it obtained its 10mg MA and therefore posed a competitive threat to Auden.²⁵⁸³ Waymade had obtained the 87% discount in the 20mg Agreement by moving '*from a position of being just another*

²⁵⁸⁰ Document 201997, transcript of interview with [AMCo Senior Employee 1] dated 7 June 2018, page 18 lines 3 to 9.

²⁵⁸¹ Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 6] and [AMCo Senior Employee 1] dated 23 April 2014.

²⁵⁸² Document 201592, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, page 2 lines 13-22.

²⁵⁸³ Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 9 lines 24 to 25 and page 10 lines 2-4.

wholesaler customer to Auden Mckenzie ... to Waymade being in a position where it can, in theory, bring its product to the market'.²⁵⁸⁴

- 6.690. [AMCo Senior Employee 2] then stated that Auden supplying AMCo was Auden's '*risk mitigation strategy*' because the alternative was AMCo launching its own '*product to the market and getting indeterminate market share*'. In other words, [AMCo Senior Employee 2] explained that, faced with the risk of AMCo launching its own tablets and competing with Auden, the latter would mitigate that risk by continuing to supply AMCo (consistently with [Auden Senior Employee 1]'s explanations in interview that Auden's reason for supplying AMCo was to maintain and preserve its volumes, ie its position as sole supplier).
- 6.691. The implication of [AMCo Senior Employee 2]'s statement is clear – if Auden continued to supply AMCo, AMCo would not launch its own tablets. This would allow both parties to continue substituting the certainty of practical cooperation for the uncertainties of competition: rather than Auden face losing (and AMCo face winning) an '*indeterminate market share*', both parties would continue to know the value Auden would transfer to AMCo.
- 6.692. Contemporaneous documents demonstrate that [AMCo Senior Employee 2] fully understood the tactic of leveraging the threat of competitive entry in exchange for payment. In an email he sent to AMCo colleagues on 30 April 2014, in relation to AMCo's potential acquisition of Waymade's 20mg MA (see section 3.F.II.c above), [AMCo Senior Employee 2] stated: '*This product [Waymade's 20mg tablets] has no sales, because they've only used it to source products from Auden McKenzie*'. He went on to suggest that AMCo acquire the benefit of the 20mg Agreement from Waymade ('*AMCo takes on the 20mg product sourcing from Auden McKenzie*') and pass on a percentage of the payments from Auden on 20mg tablets '*back to [Waymade Senior Employee 1]*'. [AMCo Senior Employee 2] noted:

'He [[Waymade Senior Employee 1]] would otherwise lose these revenues by not having an MA to barter with'.²⁵⁸⁵

- 6.693. [AMCo Senior Employee 2] therefore understood that Waymade had not entered the market with its own 20mg tablets because it had used the threat of competitive entry with that product as leverage to secure the 20mg Agreement with Auden on the understanding that sufficient payments would buy off its entry ('*This product has no sales, because they've only used it to*

²⁵⁸⁴ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29 lines 6-10.

²⁵⁸⁵ Document 200109, email from [AMCo Senior Employee 2] to AMCo staff dated 30 April 2014 (emphasis added).

source products from Auden McKenzie). In particular, [AMCo Senior Employee 2] understood that it was the 20mg MA that provided the key negotiating leverage: once AMCo acquired that MA, Waymade would no longer pose a competitive threat to Auden and would therefore *‘lose these revenues [the payments in the 20mg Agreement] by not having an MA to barter with’*.

- 6.694. [AMCo Senior Employee 2]’s statements also provide further context to AMCo’s use of its 10mg MA and tablets to ensure *‘continuity of supply’* from Auden (discussed in paragraphs 6.626 to 6.648 above): not only was it necessary to obtain an MA in order to receive those payments; it was necessary to retain that MA in order to continue receiving them.

Negative response to Project Guardian stimulates the final phase of negotiations, culminating in [AMCo Senior Employee 1]’s threat to [Auden Senior Employee 1] that if Auden did not improve AMCo’s terms, *‘we will launch our own’*

- 6.695. During April and May 2014 [Auden Senior Employee 1] received at least two pieces of negative correspondence in relation to the key aims of Project Guardian – with a leading endocrinologist and the Chief Pharmaceutical Officer of NHS England both informing him that there was no patient safety reason to distinguish between skinny and full label hydrocortisone tablets.
- 6.696. The first piece of correspondence, dated 22 April 2014, was from Professor of Endocrinology], [REDACTED]. He did not believe that the distinction between full and skinny label tablets was problematic from a patient safety perspective and went so far as to suggest he believed [Auden Senior Employee 1]’s concerns regarding skinny label entry were commercial rather than relating to patient safety: *‘My main concern is that it looks as if you are worried about the competition rather than more altruistic reasons’*.²⁵⁸⁶
- 6.697. Similarly, on 20 May 2014 the Chief Pharmaceutical Officer of NHS England, [Chief Pharmaceutical Officer for NHS England], wrote to [Auden Senior Employee 1] in response to Auden’s Project Guardian materials (see section 3.F.III.i above). [Chief Pharmaceutical Officer for NHS England] had consulted the MHRA upon receiving Auden’s materials and had relied upon the MHRA to draft his response.²⁵⁸⁷ The contents of that letter again made it

²⁵⁸⁶ Document 00140, email from [Professor of Endocrinology] to [Auden Senior Employee 1] and [Auden’s External Consultant], dated 22 April 2014. See also Document 02046.B, note of call on 17 November 2017 between [Professor of Endocrinology] and the CMA: Professor of Endocrinology] *‘was not familiar with the distinction between ‘full’ and ‘skinny’ label HTs, and did not see the rationale for making such a distinction if both drugs were bioequivalent. As long as the products are HT, and so bioequivalent, there would be no risk associated with prescribing skinny label HTs’* (paragraph 3(a)).

²⁵⁸⁷ Document 206640, note of call between the CMA and the MHRA on 31 March 2021, paragraph 2.1 and Document 206557, note of call between the CMA and NHS England and NHS Improvement on 22 March 2021, paragraph 2.1.

clear there was no patient-safety basis for distinguishing between full and skinny label tablets. Accordingly, this would have emphasised the risk Auden faced to its market position had AMCo entered and therefore would have increased [Auden Senior Employee 1]’s desire to avoid getting ‘*into a battle over the orphan drug status*’²⁵⁸⁸ of AMCo’s tablets

‘Colleagues at the [MHRA] have informed me that there are no material differences between the available generic immediate release hydrocortisone tablets and they are all bioequivalent to the brand leader.

[...]

Based on the advice I have received so far, I do not see that there are any risks to patient safety that would warrant any communication to senior pharmacists.’²⁵⁸⁹

- 6.698. [Chief Pharmaceutical Officer for NHS England] stated that since skinny label hydrocortisone tablets were bioequivalent to Auden’s full label tablets, there were ‘*no material differences*’ between AMCo’s and Auden’s products and no risks to patient safety from off-label supply. Because of this, [Chief Pharmaceutical Officer for NHS England] did not think the matter warranted ‘*any communication to senior pharmacists.*’
- 6.699. [Chief Pharmaceutical Officer for NHS England]’s letter was a significant development. If he had believed that it was appropriate to inform senior pharmacists of the distinction between skinny and full label tablets, which could have reduced their willingness to stock and dispense skinny label tablets, then this would have potentially represented a significant barrier to expansion for AMCo.
- 6.700. It is also significant that [Chief Pharmaceutical Officer for NHS England] had been advised on the position he should take by the MHRA – as, if the MHRA had considered it necessary, it could have taken further steps to distinguish between skinny and full label tablets – such as requiring them to be distinguished in GP software. If the MHRA had taken this step then one of the factors that facilitated skinny label entry (open prescriptions) would have been reduced. The MHRA has previously taken this step where it has considered patient safety required it.²⁵⁹⁰

²⁵⁸⁸ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.

²⁵⁸⁹ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to Auden dated 20 May 2014, received 22 May 2014.

²⁵⁹⁰ Document 206640, note of call between the MHRA and the CMA of 31 March 2021, paragraph 4.4.

- 6.701. Auden received similar feedback from the Chief Pharmaceutical Officers for Scotland and Wales.²⁵⁹¹ The fact that neither [Chief Pharmaceutical Officer for NHS England] nor the MHRA believed any communication was warranted meant that [Auden Senior Employee 1] would have been concerned that AMCo could in fact have competed for a substantial part of the total volumes of 10mg hydrocortisone tablets if it had entered. Auden might therefore be willing to pay a higher price to continue buying off AMCo's entry.
- 6.702. Auden received [Chief Pharmaceutical Officer for NHS England]'s letter on 22 May 2014.²⁵⁹² Very shortly after receiving [Chief Pharmaceutical Officer for NHS England]'s letter, [Auden Senior Employee 1] sent a text message to [AMCo Senior Employee 1] over the weekend of 24/25 May 2014. That text message has not been recovered in the CMA's investigation. On 28 May [AMCo Senior Employee 1] wrote:

'Hi [Auden Senior Employee 1]

Many thanks for your text over the weekend. Looking forward to talking to you later this week.

*I thought it would help if I wrote down what we are looking for on Hydrocortisone. We are looking for Auden Mackenzie to supply Hydrocortisone 10mg to AMCo for a new 3 year term at a supply price of £1.00 per pack. I suggest we use the previous contract as the basis for this new agreement. We are currently forecasting 12k packs per month. We obviously would prefer our own livery though we would be happy to work towards this over the coming months.'*²⁵⁹³

- 6.703. [AMCo Senior Employee 1] therefore proposed renewing the 10mg supply arrangement 'for a new 3 year term at a supply price of £1.00 per pack' with the parties using 'the previous contract as the basis for this new agreement' (further demonstrating the continuity in AMCo's approach).
- 6.704. [AMCo Senior Employee 1] also disclosed to [Auden Senior Employee 1] that AMCo was 'currently forecasting 12k packs per month'. When placed in

²⁵⁹¹ The date of this feedback is unclear but it was received at the latest by 9 June 2014. On that date [Auden's External Consultant], Auden's external adviser on Project Guardian, noted in relation to [Chief Pharmaceutical Officer for NHS England]'s response: 'I don't think we will get any further with [Chief Pharmaceutical Officer for NHS England] until / unless we have any evidence to demonstrate a bioequivalence argument' (i.e. unless Auden could demonstrate that skinny label tablets were not bioequivalent with full label tablets). [Auden's External Consultant] also noted that he had been corresponding with the Chief Pharmaceutical Officers of Scotland and Wales, and that 'all three CPOs are effectively suggesting we pick this up with the respective prescribing advisory bodies in their jurisdiction. They personally will not take any action unless they get advice from their own agencies'.

²⁵⁹² According to a stamp on the letter.

²⁵⁹³ Document 00149, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 28 May 2014.

context, it is clear that [AMCo Senior Employee 1] was referring to AMCo's anticipated sales volumes if it entered the market with its 10mg tablets.

- 6.705. The 12,000 figure is consistent with AMCo's internal sales projections as set out in its January 2014 PPRM presentation.²⁵⁹⁴ In quoting this figure, [AMCo Senior Employee 1] was seeking to achieve an increase in the volumes Auden supplied to AMCo (and therefore its payments) by highlighting the competitive threat AMCo would pose if it launched its own 10mg tablets. In seeking an increase in the volume Auden supplied, [AMCo Senior Employee 1] was acting consistently with AMCo's negotiating strategy to date, as set out in his email to [AMCo Senior Employee 2] of 19 April (discussed above), in which he stated that [Auden Senior Employee 1] '*probably would do a better deal on better terms*' in order to avoid a '*battle over the orphan drug status*'.²⁵⁹⁵
- 6.706. An internal AMCo email chain between [AMCo Senior Employee 8], [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Senior Employee 2] and [AMCo Senior Employee 6] (%) between 13 and 15 June 2014 shows a discussion between key AMCo staff in respect of several of the core terms of what would become the Second Written Agreement. The chain began with [AMCo Senior Employee 8] sending a revised version of the draft Second Written Agreement, with Auden's amendments. [AMCo Senior Employee 8] wrote:

[AMCo Senior Employee 1], I gather that the agreement is that supply starts in June, not July. For my understanding, is that order and delivery in June, or order in June and delivery in July?

[AMCo Senior Employee 1], I gather you agreed 12,000 packs per month as a minimum volume. They are now suggesting that they would satisfy their obligations if they deliver at least 85% of the 12,000 (so they could get away with only supplying 10,200 per month). Shall I insist upon 12,000 packs per month?

²⁵⁹⁴ Document 200090, AMCo PPRM presentation of 22 January 2014, titled '*Product Development: Hydrocortisone 10mg tablets*', slide titled 'NPV (30's blister)'. Compare Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 22 April 2014: '*Monthly volumes from Auden is 6000 packs per month typically Price is £1.00. Forecast slightly higher 10000 from Aesica*'. As explained below, [AMCo Senior Employee 1] later told colleagues: '*I went in with 12k per month when I knew that [AMCo Senior Employee 4] had forecast 10k per month with the view that we would have to negotiate – I suppose at that stage I thought I would settle for 10k*'. Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014.

²⁵⁹⁵ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.

*[AMCo Senior Employee 1], for now the price is still £1 per pack and they have not raised anything about rebates.*²⁵⁹⁶

6.707. [AMCo Senior Employee 1] replied on 15 June 2014:

‘[AMCo Senior Employee 8]

...

If they fall short they should make up the following month

Having said that I went in with 12k per month when I knew that [AMCo Senior Employee 4] had forecast 10k per month with the view that we would have to negotiate – I suppose at that stage I thought I would settle for 10k

As for the start date yes it is for delivery this month so that [AMCo Senior Employee 4] can get the sales this month. I told him that if not we will launch our own.

*Interesting about the cost price though, as suggested by [AMCo Senior Employee 6] , having a bit more stock at a higher price would be fine be [sic] me – as long as it isn’t a huge difference.*²⁵⁹⁷

6.708. This email exchange demonstrates the following.

6.709. First, that [AMCo Senior Employee 1] used the threat of AMCo’s potential to enter the market independently with its own 10mg tablets as leverage in his negotiations with [Auden Senior Employee 1] by threatening to ‘launch’ AMCo’s tablets if Auden did not continue to supply AMCo on favourable terms (ie to pay AMCo) that month (*‘I told him that if not we will launch our own’*). In interview, [AMCo Senior Employee 1] confirmed this interpretation of the email, explaining that *‘I wanted him [[Auden Senior Employee 1]] to understand that we were able to launch’* because he thought *‘that it [AMCo’s ability to enter] was more likely to help him give me some better terms’*.²⁵⁹⁸

6.710. Secondly, that as a result, as it had done to date (and as Auden had agreed with Waymade previously), Auden would continue to buy off the threat of AMCo’s competitive entry by continuing to supply AMCo with 10mg tablets at a heavily discounted price (ie by continuing to pay AMCo) (*‘the agreement is*

²⁵⁹⁶ Document 200120, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 1] and others dated 13 June 2014 (emphasis added).

²⁵⁹⁷ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014 (emphasis added).

²⁵⁹⁸ Document 201997, [AMCo Senior Employee 1] interview transcript dated 7 June 2018, page 25 lines 1 and 10 to 11. See also pages 2-3.

that supply starts in June ... you agreed 12,000 packs per month ... the price is still £1 per pack – the price ultimately agreed was £1.78 per pack).

- 6.711. [AMCo Senior Employee 1] had therefore successfully used AMCo's leverage to secure a further volume (and therefore payment) increase for AMCo: not only would Auden continue to supply AMCo, [Auden Senior Employee 1] agreed to increase the number of monthly packs which Auden would supply at a heavily discounted price to 12,000 – and therefore to increase the price at which Auden would continue to buy off AMCo's entry. Those packs were worth around £560,000 if sold in the market at Auden's June ASP (£47). This was an increase in the value of the payments AMCo received of £206,000 per month when compared to May 2014. [AMCo Senior Employee 1] had therefore succeeded in negotiating a 60% increase in the value of the payments to AMCo (and those payments would continue to increase thereafter as Auden continued to increase its prices, allowing AMCo to sell at higher prices and continue to share in Auden's monopoly profits).
- 6.712. [AMCo Senior Employee 1]'s email of 15 June 2014 therefore demonstrates that the parties approached the negotiations for the Second Written Agreement with the same common understanding that they had consistently shared since 31 October 2012: that in exchange for continued payments from Auden AMCo would not enter the market independently with its own 10mg hydrocortisone tablets. This is clear from [AMCo Senior Employee 1]'s statement that he said to [Auden Senior Employee 1] *'if not we will launch our own'* – in other words AMCo would only launch its tablets if Auden did not supply it on improved terms. On the following day, 16 June 2014, [AMCo Senior Employee 1] wrote to [Waymade Senior Employee 1] with the subject *'Hydrocortisone': 'We are trying to finalise a longer term formal supply agreement on this (or indeed launch our own product)'*, further demonstrating AMCo's contingent approach to launching.

The terms of the Second Written Agreement

- 6.713. The Second Written Agreement had an effective date of 25 June 2014.²⁵⁹⁹
- 6.714. The Second Written Agreement represented a further doubling of the monthly volumes Auden agreed to supply AMCo at the 97% discounted price – and therefore a further significant increase in the monthly payments Auden agreed to make to AMCo. However, the Second Written Agreement is not in itself the 10mg Agreement. It must be read in the context of all that came before (and after) it. The evidence of the negotiations leading to the Second

²⁵⁹⁹ Document 00446, Second Written Agreement.

Written Agreement, and AMCo's conduct after entering into it, shows that in exchange for continued and increasing payments from Auden AMCo renewed its commitment to Auden not to enter the market independently with its own 10mg hydrocortisone tablets: the counter-performance that, together with the payments, formed the common understanding defined as the 10mg Agreement.

- 6.715. Indeed, AMCo accepted contractual restrictions consistent with such a renewed commitment in the Second Written Agreement. Clause 2.2 stated:

*'Amdipharm [AMCo] shall procure all its requirements in the Territory [the UK] for hydrocortisone product(s) in tablet and capsule formulation from Auden on an exclusive basis and shall not, directly or indirectly, distribute, supply or sell, in the Territory any other hydrocortisone product(s) in tablet or capsule formulation. However, for the avoidance of doubt, nothing in this Agreement prevents Amdipharm and/or its Affiliates from applying at any time for a marketing authorisation from the MHRA in relation to a hydrocortisone product (whether in tablet, capsule or other formulation) and/or manufacturing (either itself or through a contract manufacturer) and supplying in the Territory hydrocortisone product(s) under a licence granted to it or any of its Affiliates provided that Amdipharm shall not and shall procure that none of its Affiliates shall do so directly or indirectly without giving Auden at least three (3) months' written notice of its intention to do so.'*²⁶⁰⁰

- 6.716. Clause 17.2 provided that if AMCo notified Auden *'of its intention to commence supply of its own version of the Product ['Auden Mckenzie hydrocortisone 10mg Tablets'] in the Territory [the UK]'* under clause 2.2, *'Auden shall have the option to terminate this Agreement on three (3) months' written notice to Amdipharm'*.²⁶⁰¹

- 6.717. Taken together, clauses 2.2 and 17.2 of the Second Written Agreement meant that:

- a. AMCo could not enter the market with its own 10mg hydrocortisone tablets without first giving Auden three months' written notice.
- b. If AMCo notified Auden of its *'intention'* to do so, Auden could terminate supply within the same notice period. This would mean that the 10mg supplies (ie the payments to AMCo) ended on the same day as AMCo entered the market with its own 10mg hydrocortisone tablets.

²⁶⁰⁰ Document 00446, Second Written Agreement clause 2.2.

²⁶⁰¹ Document 00446, Second Written Agreement clause 17.2.

- 6.718. AMCo was under no illusion that, if it independently entered the market, Auden would continue to supply under the Second Written Agreement.
- 6.719. [AMCo Senior Employee 8], AMCo's General Counsel, summarised the effect of those clauses in this way to AMCo senior management: *'It basically means that we cannot sell any other products during the 2 year term of the Agreement which compete with Auden's hydrocortisone product, unless we first given Auden 3 months notice (and Auden can terminate supply to us on 3 months notice if we say we are going to do so).'*²⁶⁰² He gave the same explanation to Auden's and AMCo's external lawyers, stating that *'the agreement is that AMCo will not sell a product which competes with the Auden product'*; that *'AMCo will not market, distribute or sell during the Term a product which competes with Auden's product'*;²⁶⁰³ and that the agreement contained *'a clause saying that we can launch our own version at any time on 3 months notice and that, if we give such notice, Auden can duly terminate on 3 months notice as well.'*²⁶⁰⁴ [AMCo Senior Employee 8] later confirmed in a State of Play meeting with the CMA that:

*'contractually AMCo was unlikely to supply both products [its own 10mg hydrocortisone tablets and Auden's product] at the same time, as Auden would most likely terminate supply of hydrocortisone after the three month notice period'.*²⁶⁰⁵

- 6.720. In explaining the meaning of these clauses to his colleagues and external lawyers [AMCo Senior Employee 8] did not, for example, qualify them by noting that AMCo expected to launch its 10mg tablets and end the Second Written Agreement as soon as possible. AMCo remained content to continue cooperating with Auden rather than take that risk.
- 6.721. This is also evident from another clause of the Second Written Agreement. Clause 17.3 allowed for AMCo to issue a 'notice to supply', requiring Auden to make up any shortfall in its volume commitments within 14 days. The clause added: *'In the event that Auden does not supply and deliver such shortfall within fourteen (14) days of receipt of such 'notice to supply', [AMCo] shall have the right to commence supply of its own hydrocortisone product(s) immediately'*.²⁶⁰⁶ In other words, AMCo only had *'the right to commence supply'* of its own 10mg hydrocortisone tablets immediately if

²⁶⁰² Document 200120, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 1] and others dated 13 June 2014.

²⁶⁰³ Document 00162, mark-up of draft Second Written Agreement, attached to Document 00161, email from [AMCo Senior Employee 8] to [REDACTED] dated 16 June 2014.

²⁶⁰⁴ Document 201970, email from [AMCo Senior Employee 8] to Pinsent Masons dated 30 May 2014 (emphasis added).

²⁶⁰⁵ Document 200452, note of State of Play meeting dated 18 May 2016, paragraph 34 (emphasis added).

²⁶⁰⁶ Document 00446, Second Signed Agreement clause 17.3 (emphasis added).

Auden failed to adhere to its volume commitments – a contractual reflection of [AMCo Senior Employee 1]’s statement that if Auden did not supply at the agreed time, *‘we will launch our own’*.

- 6.722. [AMCo Senior Employee 2] also confirmed that this was his understanding of how the Second Written Agreement would function. When asked in interview whether AMCo could have launched its own product and continued taking supplies from Auden, [AMCo Senior Employee 2] stated: *‘I don’t think that’s a realistic scenario ... this is an either or situation. You’re either going to launch your own or you’re going to take supply from Auden Mckenzie’*.²⁶⁰⁷ [AMCo Senior Employee 2] further stated:

*‘Why would they [Auden] supply AMCo, if we had a competitive product on the market? I don’t know. So our belief would have been that they would have stopped supplying AMCo with the product ... I understand enough about the market and the dynamics of the market to understand that a supplier would not be happy if one of its “suppliees” was also to launch a second product onto the market. And unless they have an obligation to do so, I wouldn’t expect them to continue supplying that company.’*²⁶⁰⁸

AMCo suspends its own 10mg product development on the same day as entering into the Second Written Agreement

- 6.723. As explained in section 3.F.III.j.ii above, on 23 June 2014, two days prior to entering into the Second Written Agreement, AMCo was expecting to receive its commercial 10mg launch batches from Aesica around a week later, on 2 July 2014.²⁶⁰⁹ During the final stages of negotiating the Second Written Agreement it continued to forecast that it could sell 10,000 packs of its own product per month.²⁶¹⁰
- 6.724. AMCo had brought its 10mg tablets to this point – the threshold of launching – in case the 10mg Agreement should end. However, now that AMCo had successfully secured continuing payments from Auden, it had no need to take further steps to enter the market independently with its own tablets (and indeed was precluded from doing so by the 10mg Agreement).

²⁶⁰⁷ Document 201592, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, page 23 lines 13-15.

²⁶⁰⁸ Document 201591, transcript of interview with [AMCo Senior Employee 2] dated 12 October 2017, pages 42-43.

²⁶⁰⁹ Document 202684, email from [AMCo Employee] to [AMCo Employee] dated 23 June 2014.

²⁶¹⁰ [AMCo Senior Employee 1] told AMCo staff on 15 June 2014: *‘I went in with 12k per month when I knew that [AMCo Senior Employee 4] had forecast 10k per month’*. Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 8], [AMCo Senior Employee 2] and [AMCo Senior Employee 6] dated 15 June 2014.

6.725. On 25 June 2014, the day the parties signed the Second Written Agreement, [✂] [AMCo Senior Employee 5] therefore sent a record of decisions taken at a meeting that day to AMCo's most senior management in light of the fact that AMCo's negotiations with Auden had concluded successfully. The email demonstrates that AMCo took immediate steps to ensure it continued to comply with the 10mg Agreement by ensuring that its tablets would not be launched:

'Summary of agreement from today's PPRM meeting

Why *[original emphasis]*

New supply agreement signed with Auden

Will not be able to sell our own product (produced at Aesica) in the UK

Aesica *[original emphasis]*

*We will advise Aesica that the project is now parked due to delays but may be restarted in the future **(we do not mention the Auden agreement)** [original emphasis]*

We will continue with the packing of the three available batches at Aesica to complete this phase of the project

We will cancel the order for the 4th batch and any other subsequent orders that have been placed with Aesica

We would like to ensure Aesica are fully compensated for their costs that are over and above supply of the three batches (e.g. surplus materials, people costs etc)

Request Aesica to advise these costs and include in invoice upon delivery of stock

Stock *[original emphasis]*

The packed product will be held in store as a contingency against failure to supply from Auden

We wish to hold this stock at UDG (not Waymade) in quarantine, probably on a different sku.

(there is, should we wish not to hold this in reserve, possibilities to sell in a to be identified export market)

I suggest that I will write to Aesica detailing these points (plus expressing apologies and regret...blah blah blah at the cancellation of the project)

I will write to Aesica on Friday so if you have any additional comments, please let me know before midday Friday.

I will also request that supply chain ([redacted]) raises this, in due course, with UDG.²⁶¹¹

- 6.726. [AMCo Senior Employee 5]'s 'summary of agreement' of the 25 June 2014 meeting further demonstrates that AMCo had agreed with Auden that it would not launch its Aesica-manufactured tablets in the UK in exchange for further and increasing payments ('*Will not be able to sell our own product (produced at Aesica) in the UK*'; '**Why** [original emphasis]: *New supply agreement signed with Auden*').
- 6.727. [AMCo Senior Employee 5]'s record of the meeting also demonstrates that AMCo devised an action plan to ensure its ongoing compliance with the 10mg Agreement:
- a. First, in line with its commitment not to enter the market independently with its own 10mg tablets, AMCo would take steps to stop the production and launch of its Aesica-manufactured tablets. Aesica would be informed that the project was '*parked*' with '*the order for the 4th batch and any other subsequent orders that have been placed with Aesica*' cancelled;
 - b. Second, AMCo would take steps to ensure that its Aesica stock was held '*in quarantine*' and stored as an insurance policy ('*contingency*') in case Auden reneged on the 10mg Agreement ('*against failure to supply from Auden*'), consistently with AMCo's strategy to date of developing the Aesica tablets as a '*back-up*'; and
 - c. Third, AMCo would '*continue with the packing of the three available batches at Aesica*' and look to sell them outside of the UK in a '*to be identified export market*' as it was not prohibited from doing this.
- 6.728. Paragraphs 6.733 to 6.745 below describe how AMCo took these steps forward after 25 June 2014, treating its 10mg tablets in the same way as

²⁶¹¹ Document 200124, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 2], [AMCo Senior Employee 7] and [AMCo Employee], copied to [AMCo Senior Employee 1], [AMCo Senior Employee 6], [AMCo Employee], [redacted] and [AMCo Employee], dated 25 June 2014 (emphasis added except where indicated).

Waymade had treated its 20mg tablets after entering into the 20mg Agreement (see paragraphs 6.482 to 6.501 above).

- 6.729. AMCo's decision not to launch its Aesica-manufactured tablets was apparently not well received by the Strategic Projects team who had been responsible for developing them. Following that decision on 25 June 2014, [AMCo Senior Employee 2] emailed [AMCo Senior Employee 1] to raise concerns about the morale of the team and asked [AMCo Senior Employee 1] to recognise and thank them for their efforts:

'... we're a little concerned that the Strategic Projects team may be very demotivated after hearing today at PPRM that all their efforts to get Hydrocortisone ready for launch have been "wasted" because we're now not planning to sell the product. Also, this has a real adverse impact on the "new product revenues" which the whole Strat Dev team is targeted on, and I think we need to somehow recognise that:

(a) all their hard work facilitated the AM deal, and the main commercial benefit is that we now have long-term supply secured of a product with the full range of indications. This wouldn't have been possible without being launch-ready with our own product (or words to that effect); and

(b) the Aesica product gives us an excellent back-up for a very valuable and important project, in line with our Ops Excellence BAP, in the event that our new supply agreement partner defaults on supply (hence we're going to pack our 3 batches and leave in quarantine); and

*to somehow think about a compensatory element for their New Product Revenues target, which has been massively impacted in 2014 by not launching this product which they worked so hard to secure.'*²⁶¹²

- 6.730. [AMCo Senior Employee 1] replied, 'Yes you are right ... and I agree with everything you say',²⁶¹³ and sent an email to this effect on 28 June 2014:

'I just wanted to drop you a note to thank you for all the effort that you put into bringing the Aesica Hydrocortisone product to a position where we were able to launch.

As you know we have subsequently signed a deal with Auden Mackenzie [sic] to source product from them and therefore our own product will not be launched in UK. The rationale for this arrangement

²⁶¹² Document 200125, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1], copied to [AMCo Senior Employee 4] and [AMCo Senior Employee 5], dated 25 June 2014 (emphasis added).

²⁶¹³ Document 200125, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 25 June 2014.

is that their product has an indication, Adrenal Insufficiency, that our product does not and hence selling their product removes a competitive disadvantage.

What I would like to stress though is that the work that you did to provide certainty of launch of our product gave those of us who were negotiating with Auden Mackenzie confidence to achieve the best deal possible for AMCo and I am sure that, as a result, Auden Mackenzie felt that they should agree to our terms.

*We are certainly in a much better position as a result of your work so again may I reiterate my thanks to you.*²⁶¹⁴

6.731. Both [AMCo Senior Employee 2]'s email of 25 June and [AMCo Senior Employee 1]'s of 28 June 2014 further demonstrate that AMCo had used the threat of competitive entry with its Aesica-manufactured tablets as leverage in its negotiations with Auden to continue the 10mg Agreement. [AMCo Senior Employee 2] stated that the Second Written Agreement '*wouldn't have been possible without being launch-ready with our own product*', while [AMCo Senior Employee 1] reassured the Strategic Projects team that he and others '*who were negotiating with Auden Mackenzie*' had successfully used the '*certainty of launch*' of AMCo's own 10mg hydrocortisone tablets as leverage to convince Auden to continue supplying AMCo on more favourable terms (ie to continue paying, and to make greater payments to, AMCo) ('*as a result, Auden Mackenzie felt that they should agree to our terms*').

6.732. As explained in section 6.D.II.c.i and paragraphs 6.558 to 6.591 above, this was the same negotiating strategy that Waymade had successfully deployed in securing the 20mg Agreement and the 10mg Agreement. It remained AMCo's strategy throughout the lifetime of the 10mg Agreement. If this strategy succeeded (as it did), it necessarily meant that AMCo would not enter with its own tablets – as [AMCo Senior Employee 5]'s, [AMCo Senior Employee 2]'s and [AMCo Senior Employee 1]'s emails confirm.

June to December 2014: the steps AMCo took to implement the decisions summarised in [AMCo Senior Employee 5]'s email of 25 June 2014

6.733. In his email of 25 June 2014, [AMCo Senior Employee 5] set out a number of tasks that AMCo needed to complete as a result of the continuation of the 10mg Agreement. AMCo immediately took steps to implement these tasks.

²⁶¹⁴ Document 200126, email from [AMCo Senior Employee 1] to AMCo staff dated 28 June 2014 (emphasis added).

AMCo stops production and launch of the Aesica tablets

6.734. In his email of 25 June 2014, [AMCo Senior Employee 5] stated that AMCo needed to 'advise Aesica' that its development of 10mg hydrocortisone tablets was 'now parked'. [AMCo Senior Employee 5] also stated that this was because of the 'new supply agreement [AMCo] signed with Auden' – which would not be mentioned to Aesica.

6.735. On 27 June 2014, [AMCo Senior Employee 5] himself performed this task. He emailed [Aesica Employee] of Aesica and informed him that AMCo's 10mg hydrocortisone tablets project would 'be suspended for the UK territory.' [AMCo Senior Employee 5] also made it clear that AMCo's decision to suspend the launch of its 10mg tablets was not because of any dissatisfaction with Aesica's performance:

'It is with disappointment and regret that I must write to inform you that our Hydrocortisone project will be suspended for the UK territory

The various unfortunate delays to the availability of product in the first part of the year have necessitated an alternate course.

I would like thank you [sic] and the Aesica team for the efforts over the course of this project with special mention to [X] who has been our key contact throughout.

It is feasible, if circumstances change, that we may resurrect the project in the future and we would look forward to working with you again on this product for the UK. We do continue to look to develop other territories for the product and I will be sending you a request shortly for a quotation for a future opportunity in a different region.

AMCo remain committed to its relationship with Aesica and to the product portfolio that is supplied from Queensborough. Further, we look forward to extending our supply agreement with you very soon. Please be assured that the suspension of this project is not a reflection of any dissatisfaction with Aesica and will not in any way affect our decision to work on new projects with Aesica in the future.

In the meantime we would like to close off this project in a neat and mutually acceptable way. To that end, the following is proposed :-

- 1. The three validation batches should be fully completed, packed, QP released and prepared for delivery in line with current project time lines and along with any other*

obligations for documentation, results and reports required under the agreement.

2. *AMCo wish to ensure that Aesica is fully compensated for the work and efforts to include costs over and above those agreed to such as reasonable people efforts, capital investments and, of course, surplus materials etc. Could I ask you to please provide your estimate for these costs to me.*
3. *Please cancel your plans for the manufacture of further batches. AMCo will provide a formal PO cancelation via our supply chain groups.'*²⁶¹⁵

6.736. In line with [AMCo Senior Employee 5]'s email of 25 June 2014, AMCo therefore informed Aesica that:

- a. The 10mg development project would be '*suspended for the UK territory*'.²⁶¹⁶
- b. Aesica should complete packing of the three commercial batches and deliver them to AMCo.
- c. Aesica should cancel its '*plans for the manufacture of further batches*'. AMCo would compensate Aesica for its costs to date, '*over and above those agreed to*', including in relation to '*surplus materials*'.²⁶¹⁷
- d. This decision did not reflect '*any dissatisfaction with Aesica*'. AMCo remained committed to working with Aesica, looked forward to extending its supply agreement with Aesica, and would continue to work with Aesica on overseas projects. AMCo was in particular exploring selling its 10mg hydrocortisone tablets overseas ('*We do continue to look to develop other territories for the product and I will be sending you a request shortly for a quotation for a future opportunity in a different region*').

²⁶¹⁵ Document 200275, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 27 June 2014.

²⁶¹⁶ [AMCo Senior Employee 5] later described this email, to Aesica and to AMCo colleagues, as '*the cancellation of the UK project*'. Document 202717, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 14 July 2014. See also Document 202992, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 30 June 2014.

²⁶¹⁷ AMCo ultimately sold the excess stock of hydrocortisone API to Aesica in December 2014, after Aesica noted on 8 July 2014 that it '*may be in a position to purchase*' the API which it assumed '*was to be used to fulfil the original commercial demand*' but which it understood '*will no longer be required for commercial use*'. Document 202702, email from [Aesica Employee] to [AMCo Employee] and [X] dated 8 July 2014; and Document 200386, email from [X] to [X] and [X] dated 23 April 2015.

- e. If AMCo decided to '*resurrect*' the UK project in the future, it would look forward to working with Aesica on it again.

AMCo holds the Aesica stock in store 'as a contingency against failure to supply from Auden' and 'in quarantine, probably on a different sku'

- 6.737. In his summary of AMCo's meeting of 25 June 2014, [AMCo Senior Employee 5] also stated that AMCo had resolved to retain its Aesica-manufactured 10mg tablets in storage '*as a contingency against failure to supply from Auden*'. It also resolved to hold this stock '*in quarantine, probably on a different sku*'.
- 6.738. In a follow-up email to [AMCo Senior Employee 7], [AMCo Senior Employee 5] explained that the reason for treating the product in this way was '*to ensure nobody tries to sell it!*'.²⁶¹⁸
- 6.739. In interview, [AMCo Senior Employee 7] confirmed that if a product is placed in quarantine, '*the warehouse would not be able to book it out of the system*' and sell it.²⁶¹⁹
- 6.740. AMCo's decision to hold its Aesica stock as a contingency against termination of the 10mg Agreement, and to keep it in quarantine, reflected its ongoing acceptance of the terms of the 10mg Agreement: it wished to retain the product as a precaution or '*back-up*' (consistently with its approach to its own tablets to date). Moreover, AMCo also continued to adhere to the terms of the 10mg Agreement by seeking to avoid the product being accidentally sold in the UK, which would have been in breach of the 10mg Agreement.
- 6.741. On 8 August 2014, AMCo actually took delivery of the three commercial batches of its Aesica-manufactured 10mg hydrocortisone tablets.²⁶²⁰
- 6.742. Extensive contemporaneous documentary evidence demonstrates that AMCo continued to hold its Aesica-manufactured tablets in quarantine to ensure ongoing compliance with the 10mg Agreement and in accordance with [AMCo Senior Employee 5]'s email. The documentary evidence records a clear link between the fact Aesica-manufactured stock was in quarantine and AMCo's agreement with Auden that it would not launch that stock. For example:

²⁶¹⁸ Document 200128, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 7] dated 25 June 2014.

²⁶¹⁹ Document 201541, transcript of interview with [AMCo Senior Employee 7] dated 13 October 2017, track 2 page 6 lines 1-11.

²⁶²⁰ Document 201914, email from [AMCo Employee] to [AMCo Senior Employee 7] and [AMCo Employee] dated 8 August 2014. Document 200292, Aesica's response to the CMA's section 26 notice dated 15 June 2016, paragraph 11.1.

- a. On 8 August 2014, [AMCo Employee] responded to a query from AMCo staff on the batches of 10mg hydrocortisone tablets that Aesica had produced for AMCo: *'The batch manufactured at the end of last year is now packed but there is no intention to release it to the market due to contractual reasons. Two further batches have been manufactured since the above, but again these will not be marketed.'*²⁶²¹
- b. On 14 August 2014, [AMCo Employee] wrote: *'The batches won't ne [sic] sold because of contractual reasons (commercial). They are not rejected.'*²⁶²²
- c. On 20 August 2014, [AMCo Employee] further explained: *'The original plan was to sell this product in the UK (UK MA, UK packaging). However, for contractual reasons, we cannot sell this product in the UK.'*²⁶²³
- d. On 8 September 2014, after AMCo was informed by Aesica that its launch batches had been packed in foil of the wrong thickness (see section 3.E.III.I above), AMCo staff confirmed that the product had already been kept in quarantine because of the agreement with Auden: *'Batches are on hold. Batches will not get released for sale as we are not going to market our product in UK as per our agreement with Auden Mckenzie. It's a management decision.'*²⁶²⁴

AMCo explores 'possibilities to sell in a to be identified export market'

- 6.743. Although AMCo had committed that it would not sell its Aesica-manufactured 10mg tablets in the UK, that commitment did not cover sales to overseas markets.
- 6.744. One of the action points from the 25 June 2014 meeting, as recorded in [AMCo Senior Employee 5]'s email, was therefore to explore *'possibilities to sell in a to be identified export market'*.²⁶²⁵ AMCo explored such possibilities on at least two occasions. However, in both cases AMCo decided against making overseas sales of its Aesica-manufactured tablets for fear that these

²⁶²¹ Document 202721, email from [AMCo Employee] to [AMCo Employee] dated 14 August 2014 (emphasis added).

²⁶²² Document 202724, email from [AMCo Employee] to [AMCo Employee] dated 14 August 2014 (emphasis added).

²⁶²³ Document 202765, email from [AMCo Employee] to [AMCo Employee] dated 20 August 2014 (emphasis added).

²⁶²⁴ Document 202732, email from [AMCo Employee] to [AMCo Employee] dated 8 September 2014 (emphasis added).

²⁶²⁵ The possibility to sell the product in an export market was also raised in Document 202724, email from [AMCo Senior Employee 7] to [AMCo Employee] and others dated 26 August 2014 and earlier emails in the chain; Document 202765, email from [AMCo Employee] to [AMCo Employee] dated 20 August 2014; and Document 202732, email from [AMCo Employee] to [AMCo Employee] dated 8 September 2014.

tablets would be re-imported into the UK by parallel importers, thereby breaking the 10mg Agreement in place with Auden:

- a. In June 2014, AMCo considered exporting hydrocortisone tablets to Serbia. However, after discussion, AMCo concluded that this was not worthwhile because of the risk of parallel importation back into the UK. [AMCo Senior Employee 1] stated: *'Their target price is very close to Aesica CoGs and we also would be in danger of the product coming back into the UK – which is bad enough in itself but could also put us in breach of the contract that we have here with AM.'*²⁶²⁶
- b. On 20 November 2014, [AMCo Employee] responded to [AMCo Employee] about opportunities he had identified to sell 10mg hydrocortisone tablets in Sweden and Denmark. [AMCo Employee] noted in particular that *'we will supply from Aesica which means this product won't find it's [sic] way back to the UK.'*²⁶²⁷ Once again AMCo staff were concerned to ensure the Aesica 10mg tablets would not be re-imported into the UK leading to an inadvertent breach of the 10mg Agreement.²⁶²⁸

6.745. This evidence further demonstrates that AMCo considered itself bound by a commitment to ensure the Aesica-manufactured tablets were not marketed in the UK, even through parallel imports. If stock came back into the UK it *'could also put us [AMCo] in breach of the contract that we have here with AM.'* Accordingly, this evidence shows that AMCo adhered to the common understanding it had with Auden that in return for the payments it received under the 10mg Agreement, it would not enter with its own tablets.²⁶²⁹

AMCo's retrospective summary of the steps it took to implement the decisions in [AMCo Senior Employee 5]'s email of 25 June 2014

6.746. AMCo's approach to its 10mg Aesica product after entering into the Second Written Agreement on 25 June 2014 was summarised in May 2015 by

²⁶²⁶ Document 203640, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 9], [AMCo Senior Employee 8] and others dated 30 June 2014 (emphasis added).

²⁶²⁷ Document 202745, email from [AMCo Employee] to [AMCo Employee] dated 20 November 2014 (emphasis added).

²⁶²⁸ AMCo submitted that *'There is no objective basis for the CMA's inference'* that these emails (and [AMCo Employee]'s emails discussed above, stating that *'The batches won't be [sic] sold because of contractual reasons (commercial)'* and *'for contractual reasons, we cannot sell this product in the UK'*) demonstrated AMCo's commitment not to enter the market independently. Document 204922, AMCo's RSSO, paragraph 3.730. However, this is the explicit meaning of the documents on their face. This meaning is also consistent with the wider body of evidence discussed throughout this section.

²⁶²⁹ Compare Document 203642: in response to a suggestion from [AMCo Senior Employee 2] *'to somehow launch a few boxes [of the Aesica product] into a segment that AM [Auden McKenzie] won't notice'*, [AMCo Senior Employee 4] responded: *'We can't legally due to the exclusive agreement we have.'* Emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 4] dated 10 July 2014.

[AMCo Employee], AMCo's 'Technical team product owner for ... Hydrocortisone':²⁶³⁰

'about a year ago we struck a deal with Auden Mckenzie to market their product rather than our own and the project was effectively stopped. A little later it was decided we should still register our product for some European markets and the impetus was to get the batches packed off and onto stability. Note we already had complete stability studies for the validation batches manufactured in 2010 and although there were marginal assay failures there are no significant trends and the product is effectively stable'.²⁶³¹

6.747. [AMCo Employee]' email explains that at the time of the Second Written Agreement ('about a year ago') AMCo agreed with Auden that AMCo would not launch its own 10mg hydrocortisone tablets and would instead continue to sell Auden's product: 'we struck a deal with Auden Mckenzie to market their product rather than our own'. As a result, the Aesica project was 'effectively stopped'. His email also shows that AMCo had considered its 10mg Aesica product to be launch-ready at the time and had therefore decided shortly afterwards to explore selling it – but only outside the UK, in order to avoid breaching its agreement with Auden ('A little later it was decided we should still register our product for some European markets'), just as Waymade had done with its 20mg tablets after entering into the 20mg Agreement (see paragraphs 6.495 to 6.501 above). [AMCo Employee] also noted that although some further stability studies might be required, 'the product is effectively stable' and had been since 2010.

January 2015: the news that AM Pharma is to be acquired by Allergan prompts AMCo to return to its 10mg product

6.748. As explained in section 3.F.III.n above, on 26 January 2015 AM Pharma announced that it was to be sold to Actavis plc (now Allergan).

6.749. The transaction caused concern within AMCo that Actavis might terminate the 10mg Agreement and cease supplying AMCo with heavily discounted hydrocortisone tablets. This concern prompted AMCo to return to its 'back-up' 10mg project.

6.750. AMCo therefore returned to the batches of its Aesica 10mg hydrocortisone tablets that it had received in August 2014 and considered once more whether it should get ready to sell them in the UK if Actavis ceased to supply

²⁶³⁰ Document 202525, email from [REDACTED] to [REDACTED] dated 3 September 2013.

²⁶³¹ Document 202783, email from [AMCo Employee] to [REDACTED] dated 14 May 2015 (emphasis added).

AMCo. This evidence clearly demonstrates, once more, the link between AMCo's decision on whether or not to enter the market and the 10mg Agreement and AMCo's understanding that it would only launch if the 10mg Agreement collapsed.

- 6.751. On 27 January 2015, [AMCo Senior Employee 2] emailed [AMCo Senior Employee 1] and [AMCo Senior Employee 4] to raise a concern as to whether '*Actavis will continue to supply*' AMCo following the transaction and therefore enquiring whether AMCo '*should get ready to sell [its] our own product, just in case*'.
- 6.752. [AMCo Senior Employee 1] replied: '*Agreed! If I remember thought [sic] there is still some work to do to get it ready*'. [AMCo Senior Employee 2] replied: '*Not a lot [of work to do] though*'.²⁶³²
- 6.753. On the following day, 28 January 2015, [AMCo Senior Employee 5] emailed [AMCo Employee] to explain that '*We may... may... bring back our own Hydrocortisone manufactured at Aesica as we are concerned that Actavis may pull the Auden product from us*' (emphasis in original).²⁶³³
- 6.754. [AMCo Senior Employee 2]'s and [AMCo Senior Employee 5]'s emails of 27 and 28 January 2015 respectively show a clear link between AMCo considering resuming the development of its Aesica product and the possibility that Actavis might stop supplying AMCo with heavily discounted hydrocortisone tablets ('*may pull the Auden product from us*'). AMCo understood that there was '*Not a lot*' of work to do to get its own product ready; but whether it would in fact do that work and launch the product remained contingent ('*We may ... may bring back our own Hydrocortisone*'). AMCo would only do so if Actavis ceased supplying: its own hydrocortisone tablets remained a back-up to the 10mg Agreement that were held '*just in case*'.
- 6.755. On 18 February 2015, [AMCo Senior Employee 1] approved the purchase of '*2 year's worth*' of hydrocortisone API. AMCo continued to estimate that it would sell 12,000 packs a month of its skinny label tablets if they were launched.²⁶³⁴ On the same day, AMCo issued a purchase order to Aesica for

²⁶³² Document 200137, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 4] dated 27 January 2015 (emphasis added).

²⁶³³ Document 200139, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 28 January 2015.

²⁶³⁴ Document 201070, email from [AMCo Senior Employee 1] to [AMCo Employee], [AMCo Senior Employee 4], [AMCo Senior Employee 2], [AMCo Senior Employee 5] and [AMCo Senior Employee 7] dated 18 February 2015. [AMCo Employee] explained that AMCo used 6kg per batch of the product and that each batch size of finished goods was 15,000 packs. Two years' worth of product (115kg) was therefore equivalent to 287,500 packs or circa 12,000 packs per month.

30,000 packs of 10mg hydrocortisone tablets, to be delivered on 10 June 2015.²⁶³⁵

- 6.756. The context shows that AMCo placed these orders to provide it with a back-up in case the 10mg Agreement should end. [AMCo Senior Employee 7] explained to a colleague: *'The additional batches are an insurance policy and I can elaborate more tomorrow when we meet. We will only use them if required.'*²⁶³⁶ [AMCo Employee] informed a colleague in relation to these new batches: *'The deal with Auden McKenzie has fallen through and we now wish to resurrect our original plan and market our product in the UK.'*²⁶³⁷ Again, these statements by AMCo development staff clearly establish the link between AMCo's decision on whether or not to launch its hydrocortisone tablets and the 10mg Agreement: they understood that AMCo would only launch if the 10mg Agreement collapsed.
- 6.757. These were the packs with which AMCo ultimately entered the market in May 2016,²⁶³⁸ having concluded that the scale of independent entry meant it had no other option (see paragraphs 6.777 to 6.783 below). The reason for the order in February 2015, and the delay between its release for sale on 13 November 2015 and AMCo's eventual entry,²⁶³⁹ further demonstrate AMCo's commitment that it would not enter the market independently while Auden/Actavis continued to pay it.

May 2015 onwards: the 10mg Agreement continues under Allergan's ownership

- 6.758. In May 2015, Allergan completed its acquisition of AM Pharma. With effect from September 2015, Allergan transferred AM Pharma's business activities, including the sale of hydrocortisone tablets and Auden's position as counterparty to AMCo for the purposes of the 10mg Agreement, to its subsidiary Actavis UK Limited (now Accord-UK) (see section 9.B.I.a below).
- 6.759. However, despite AMCo's concerns, the change in AMCo's counterparty from Auden to Actavis from September 2015 onwards did not affect the

²⁶³⁵ Document 201932, purchase order 4500009470 issued by AMCo to Aesica on 18 February 2015.

²⁶³⁶ Document 202948, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 12 February 2015 (emphasis added).

²⁶³⁷ Document 202783, email from [AMCo Employee] to [X] dated 14 April 2015.

²⁶³⁸ Document 202931, email from [X] to [AMCo Senior Employee 5] dated 22 September 2016. AMCo's records show that the packs ordered in February 2015 were delivered on 2 November 2015 and released on 13 November 2015. 10,714 packs from this order were sold to AMCo's customers while the rest were blocked as short-dated stock.

²⁶³⁹ Document 202902, email from [AMCo Employee] to [AMCo Senior Employee 3] dated 17 May 2016. AMCo entered the market by selling 3,150 packs of hydrocortisone tablets to DE Pharma at £60 a pack. See also Document 202921, email from [X] to [AMCo Employee] dated 13 September 2016.

10mg Agreement.²⁶⁴⁰ From 1 September 2015 the 10mg Agreement, including the Second Written Agreement, continued between AMCo and Actavis,²⁶⁴¹ with AMCo issuing its purchase orders directly to Accord-UK.²⁶⁴²

- 6.760. Actavis continued to make payments to AMCo by continuing to supply it with 12,000 packs per month at £1.78 per pack while continuing to increase its ASPs to its other customers.
- 6.761. AMCo continued to benefit from the heavily discounted supply price and Actavis's increasing prices, making its largest margins under the 10mg Agreement in the period when it was supplied by Actavis (see figure 6.5 above). For example, Actavis's ASP for 10mg hydrocortisone tablets peaked at £72 in March 2016, after the transfer to Accord-UK. This meant that the 12,000 monthly packs supplied to AMCo in that month were worth around £864,000 if sold in the market at that price.
- 6.762. [Actavis Senior Employee 1], [REDACTED] at the time, confirmed in interview that he understood that the supply arrangement with AMCo protected Actavis's position as the sole supplier of 10mg hydrocortisone tablets. The Second Written Agreement meant that before it could enter with its own 10mg hydrocortisone tablets, AMCo would have to give Actavis three months' written notice (as [Actavis Senior Employee 1] acknowledged).²⁶⁴³ [Actavis Senior Employee 1] stated that '*AMCo's alternative was using their MA and getting it contract manufactured elsewhere*'.²⁶⁴⁴ [Actavis Senior Employee 1] therefore understood that AMCo was a potential competitor to Actavis and could have entered the market under its own 10mg MA; but was refraining from doing so in exchange for the payments it received from Actavis.

²⁶⁴⁰ Compare Document 202954, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 20 May 2015: '*According to [Auden Senior Employee 1] Actavis will continue his strategy*' of using the orphan designation to undermine independent entry. For completeness, on 21 October 2015, Cinven sold the AMCo group to Concordia Healthcare Corp. (now Advanz). However, this did not lead to any corporate restructuring in terms of which entities within AMCo were directly involved in the 10mg Agreement and the Agreement continued between Actavis and AMCo as before.

²⁶⁴¹ As confirmed in relation to the Second Written Agreement by Accord-UK's [REDACTED] [Actavis Senior Employee 1] in interview with the CMA: '*we inherited that agreement, and brought it into our control, from about September*' (Document 203378, [Actavis Senior Employee 1] interview transcript dated 22 July 2019, page 14, lines 11 and 12).

²⁶⁴² See, for example, purchase order numbers 4500010691 4500010692, and 4500010693 dated 3 September 2015; 4500010775 dated 11 September 2015; and 450001108 dated 4 November 2015. Purchase order number 4500010693 dated 3 September 2015 states: '*Actavis has taken over Auden & all the future orders would be supplied by Actavis*'.

²⁶⁴³ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 18 lines 16-21: '*[CMA interviewer]: So, was your understanding then for as long as you're supplying AMCo at this price, they won't be getting supply from their own alternative CMO and entering with their own product? [Actavis Senior Employee 1]: Well, that's my understanding now. And that was I think one of the terms that AMCo needed to give notice if they use their own, different source.*'

²⁶⁴⁴ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 17 line 26 and page 18 line 1.

December 2015: Actavis proposes the same type of agreement to Alissa

- 6.763. The fact that Actavis continued the 10mg Agreement with AMCo on the same common understanding as Auden before it is further confirmed by evidence dating from when Alissa entered the market in October 2015 in competition with Actavis.
- 6.764. AMCo had closely monitored Alissa's preparations for entry, aware of the possibility that Actavis would buy Alissa off in the same way as it had bought off AMCo. In May 2015 [AMCo Senior Employee 2] of AMCo noted that although Alissa had obtained an MA (via Orion), its product was '*not visible in the market*', suggesting that '*he [[Alissa Senior Employee]] has done a deal with AM to stay off the market*'.²⁶⁴⁵ In October 2015 [AMCo Employee] of AMCo noted that '*Actavis are informing customers that Alissa are launching their hydrocortisone i.e. they have not done a deal*'.²⁶⁴⁶
- 6.765. As explained in section 3.F.III.p above, shortly after Alissa entered, Actavis in fact made an offer to supply Alissa with a specified volume of 10mg tablets per month at £1.78 per pack – the same price as under the Second Written Agreement.²⁶⁴⁷
- 6.766. [Actavis Senior Employee 1] confirmed in interview that he had used the Second Written Agreement as a model for this proposal, and that he assumed that for Alissa '*it was an either/or situation that he [Alissa Senior Employee] wouldn't then take supply from another source*' – in other words, that if his proposal succeeded Alissa would not remain in the market with its own tablets.²⁶⁴⁸ [Actavis Senior Employee 1] therefore tried to buy off the competitive threat from Alissa in order to regain and preserve Actavis's position as sole supplier, just as Actavis continued to buy off AMCo.
- 6.767. Alissa did not ultimately accept Actavis's offer of a similar deal to the 10mg Agreement. Other suppliers also continued to enter the market. Though Actavis did not succeed in buying off Alissa's entry, it continued to buy off AMCo by paying AMCo under the terms of the 10mg Agreement.

²⁶⁴⁵ Document 202952, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 26 May 2015. See also Document 202803, AMCo UK Commercial Monthly Report – May 2015, page 9: '*There is still no sign of the Alissa product being launched*'.

²⁶⁴⁶ Document 202826, email from [AMCo Employee] to [AMCo Senior Employee 3] dated 19 October 2015 (emphasis added).

²⁶⁴⁷ Document 00696, email from [Actavis Senior Employee 1] to [X] dated 25 November 2015. Document 00508, email from [Alissa Senior Employee] to [Actavis Senior Employee 1] dated 11 November 2015; and email from [Actavis Senior Employee 1] to [Alissa Senior Employee] dated 22 December 2015.

²⁶⁴⁸ Document 203378, [Actavis Senior Employee 1] interview transcript dated 22 July 2019, page 68 lines 5-6.

August to December 2015: AMCo devises a strategy to secure a further increase in its payments from Auden/Actavis

- 6.768. The Second Written Agreement was due to expire in June 2016. In late 2015, AMCo therefore devised a strategy to negotiate a renewed 10mg supply arrangement with Auden/Actavis. In so doing it adopted the same consistent negotiating strategy it had used throughout the 10mg Agreement: of using the threat of competitive entry as leverage to secure greater payments. It now intended to use not only its 10mg Aesica tablets, but also the hydrocortisone tablets project it had obtained in October 2014 as part of its acquisition of Focus Pharmaceuticals (see section 3.F.III.o above), to intensify its negotiating leverage.
- 6.769. In August 2015 [AMCo Senior Employee 3] circulated to AMCo and Cinven staff some draft responses to questions for AMCo management, in preparation for a meeting with a consulting firm to discuss Cinven's sale of the AMCo group.²⁶⁴⁹ The document included the following question and response:

[Question] Could you comment on how the Focus acquisition will provide access to more supply of the 10mg tablets?

*[Response] The new MA will give us the ability to negotiate a greater volume supply. Our expectations are a total supply of 24k units a month which equates to circa 30% m.s. [market share]*²⁶⁵⁰

- 6.770. [AMCo Senior Employee 3]'s suggested response shows that AMCo viewed the hydrocortisone tablets portfolio it had obtained as part of the acquisition of Focus Pharmaceuticals as a source of further leverage to '*negotiate a greater volume supply*' from Auden/Actavis. AMCo intended to use the competitive threat that its Focus product represented – just as it had used its own Aesica 10mg product – to convince Auden/Actavis once more to double its monthly volumes under the 10mg Agreement, from 12,000 to 24,000 (and therefore significantly to increase the payments to AMCo). This was AMCo's primary strategy, in preference to entering the market with its Focus

²⁶⁴⁹ Document 200150, email from [AMCo Senior Employee 3] to various recipients dated 18 August 2015.

²⁶⁵⁰ Document 200151, draft responses to questions on Cinven's sale of the AMCo group, attached to Document 200150 (emphasis added). AMCo submitted that this was '*a highly general response*' that '*does not name Auden*' or '*identify the means whereby access to the greater volume supply could be secured*' (Document 204922, AMCo's RSSO, paragraph 3.769.1). This ignores the fact that the question and response immediately preceding this statement specifically name '*Limited supply by Auden McKenzie of the finished product*' as '*the factor limiting supply to AMCo of 10mg tablets*'; and that [AMCo Senior Employee 3] went on to identify '*Increase stock delivery from the supplier*' – Auden – as the factor that '*drives the upside not latent demand*' (Document 200151, question 5(a) and response (emphasis added) and question 5(d) and response). The statements in this document therefore do name Auden and identify the means of securing access to greater volumes.

hydrocortisone tablets.²⁶⁵¹ Again AMCo was seeking a collaborative rather than competitive relationship with Auden, its potential competitor.

- 6.771. A presentation prepared by the strategy consultants AMCo engaged to assist with these questions and responses summarised AMCo's strategy in relation to the Focus product:

'AMCO indicate that its current supply is sourced from Auden, and it has been limited in its ability to meet demand due to lack of supply.

*the Focus acquisition (of 10mg and 20mg hydrocortisone) is anticipated to provide them a more competitive position to seek increasing supplies from Auden Mckenzie*²⁶⁵²

- 6.772. The consultants described AMCo's 'management's strategy' as 'to regain supply leveraging its new competitive position.'²⁶⁵³ AMCo management used the same phraseology: in November 2015 [AMCo Employee], [REDACTED], separately referred to '*the strategy to leverage our MA*' in relation to '*Hydrocortisone Tablets*'.²⁶⁵⁴

- 6.773. AMCo's strategy therefore remained the same as Waymade's back in 2011 and 2012, when the Agreements began.²⁶⁵⁵ [AMCo Senior Employee 1]

²⁶⁵¹ See, for example, Document 200144, email from [Focus Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 5 August 2015; and document 200145, Hydrocortisone 10mg and 20mg tablet proposal, in which 'Scenario 1' was that Focus agree a supply deal with Auden/Actavis, whereas 'Scenario 2' was that Focus manufacture and supply under its own MA. Scenario 1 entailed an annual return to AMCo of just over £3 million, whereas Scenario 2 entailed a return to AMCo of just over £2.5 million.

²⁶⁵² Document 202793, 'Project Harmony' presentation prepared by LEK Consulting dated 21 August 2015, slides 82-83 (emphasis added). AMCo submitted that this statement simply '*incorporates the response*' of [AMCo Senior Employee 3] discussed in the paragraph above, and claimed that '*The CMA's [sic] is wrong to rely on this document for the same reasons*' (Document 204922, AMCo's RSSO, paragraph 3.769.2). However, AMCo omitted the end of the sentence, which reads: '*the Focus acquisition (of 10mg and 20mg hydrocortisone) is anticipated to provide [AMCo] a more competitive position to seek increasing supplies from Auden Mckenzie*'. AMCo's strategy consultants therefore stated explicitly that its management's goal was to use the Focus acquisition as leverage in negotiations for greater volumes from Auden/Actavis. If there was any doubt as to what [AMCo Senior Employee 3] meant in his response above, that doubt was removed in this presentation.

²⁶⁵³ Document 202793, 'Project Harmony' presentation prepared by LEK Consulting dated 21 August 2015, slide 85 (emphasis added).

²⁶⁵⁴ Document 202828, email from [AMCo Employee] to [REDACTED] dated 20 November 2015. AMCo submitted that this was '*a highly general statement, which does not identify hydrocortisone, Focus, or Auden*' (Document 204922, AMCo's RSSO, paragraph 3.769.4). However, the nature of the leverage and its intended target are clear from the context, including the documents discussed above. The statement does identify hydrocortisone: [AMCo Employee] wrote '*Hydrocortisone tablets: I suggest [AMCo Senior Employee 3] explain the strategy to leverage our MA*'.

²⁶⁵⁵ In late 2015 AMCo also considered using its skinny label tablet development with German CMO MIBE (an historic project begun by the Mercury Pharma group prior to Cinven's acquisition of Amdipharm) as leverage to obtain further supplies of 10mg hydrocortisone tablets from Auden/Actavis, in a similar way to its Focus product. On 6 November 2015 AMCo considered the MIBE '*project as incremental considering that we would get approx.. 4,000 boxes more a month from Auden*' once it obtained its MA in 2016. AMCo assumed that it could secure supply of 4,000 additional packs from Auden on the assumption that '*we don't have sales generated from MIBE*'. Document 202932, spreadsheet titled 'Hydrocortisone TABLETS 10MG X 30 – JANILA', see 'Cover' and 'Incremental Auden #11' tabs. However, as with the Roma/Focus proposal, AMCo ultimately decided not to pursue the MIBE development in May 2016 since '*the number of entrants reduces the need to utilise all our*

explained to [AMCo Senior Employee 3]: *'The most important job they [the Focus management] have to do for us is negotiated [sic] with Actavis/Auden and get the highest level of monthly volume (and keep it there ongoing)*.'

²⁶⁵⁶

- 6.774. In December 2015, in response to a request to provide updated information on the potential launch date of *'Hydrocortisone (Focus)'*, [AMCo Senior Employee 3] stated:

'Hydro for May 16 is fine. We just need the MA so [AMCo Senior Employee 7] needs to check when this will be. This is the date confirmed last time we spoke. We will develop some product in case but we just need the MA to secure a supply deal elsewhere.'

²⁶⁵⁷

- 6.775. AMCo's strategy of using its Focus product in an attempt to increase its payments under the 10mg Agreement demonstrates that it continued to deploy the same, consistent, negotiating strategy throughout its term as party to the 10mg Agreement: of *'leveraging its competitive position'* – the competitive threat derived in particular from the possession of an MA – to extract further volumes (and therefore higher payments) from Auden/Actavis in return for not entering under that MA (*'we just need the MA to secure a supply deal elsewhere'*).
- 6.776. However, ultimately AMCo did not pursue this further attempt to increase its payments from Auden/Actavis. This was because although the 10mg Agreement continued to be in force until 24 June 2016, the rationale for the Agreement – to buy off entry and thus protect Auden/Actavis's position as sole supplier and its resulting pricing power – was undermined by the third-party entry that started to occur from the autumn of 2015 onwards.

2016: the scale of independent entry prompts AMCo to launch its own 10mg tablets

- 6.777. AMCo had continued to treat its Aesica product as a *'back-up'* to the 10mg Agreement throughout 2013, 2014 and 2015. On 27 November 2015, [AMCo Senior Employee 3] stated:

'We have our own product MA which we source from Aesica and we have stock but we do not sell it. This is a back up in case Auden pull

developments' (Document 202910, email from [AMCo Employee] to [AMCo Employee], [AMCo Senior Employee 5] and [AMCo Senior Employee 3] dated 24 May 2016. See also Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016).

²⁶⁵⁶ Document 200155, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 3] and [AMCo Senior Employee 2] dated 1 September 2015 (emphasis added).

²⁶⁵⁷ Document 202830, email from [AMCo Senior Employee 3] to [X] dated 3 December 2015 (emphasis added). AMCo stated that this was *'a highly general statement'* that *'does not identify AMCo's counterparty to the contemplated 'supply deal' and 'clearly does not concern anything regarding Auden'* (Document 204922, AMCo's RSSO, paragraph 3.770). However, the nature of the leverage and its intended target are clear from the context, including the documents discussed above.

our supply (it is not as good a product as it does not have the orphan designation but it is a reserve)'.²⁶⁵⁸

- 6.778. However, as explained in section 3.V.b.i above, by March 2016 four independent suppliers had entered the market with their own hydrocortisone tablets (Waymade with 20mg in July 2015, Alissa with 10mg in October 2015, Resolution Chemicals and Bristol Laboratories with 10mg and 20mg in March 2016). Further launches were also on the horizon.
- 6.779. Third-party entry brought with it an erosion of Actavis's market share and both Actavis's and AMCo's prices. Since the purpose of the 10mg Agreement was for Auden/Actavis to buy off competition, it had essentially become redundant. An internal Actavis generics commercial meeting in January 2016 therefore concluded that Actavis would '*pull AMCo supply now there are more players in the market.*'²⁶⁵⁹ This again clearly demonstrates that Actavis saw the purpose of the 10mg Agreement as buying off the risk of competitive entry from AMCo, and saw that there was no longer a need to buy off AMCo given the third-party entry that occurred.
- 6.780. During March 2016, it became clear to AMCo that the 10mg Agreement was no longer sustainable. On 9 March 2016 [AMCo Senior Employee 3] emailed [AMCo Senior Employee 1], stating:

'The imperfect storm is brewing and the digging I have done with various industry types and through [X] and [X] this week is strengthening my views and recommended approach.

*We cannot delay any longer as we [...] have more arrivals entering the market, have our own agreement up for renewal in the summer, are starting to find it a little tougher to sell [...].*²⁶⁶⁰

- 6.781. By March 2016 AMCo had therefore reached the view that it could delay the launch of its Aesica product no longer, because of factors including: the arrival of further genuine competition to the market ('*more arrivals entering the market*'); the erosion of AMCo's ability to continue charging very high prices for the 10mg tablets it obtained from Actavis as a result ('*starting to find it a little tougher to sell*');²⁶⁶¹ and the uncertainty as to whether the 10mg

²⁶⁵⁸ Document 202829, email from [AMCo Senior Employee 3] dated 27 November 2015 (emphasis added).

²⁶⁵⁹ Document 02811, Accord-UK generics commercial meeting dated 13 January 2016, page 5.

²⁶⁶⁰ Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016 (emphasis added).

²⁶⁶¹ On 8 March 2016 [AMCo Employee] told [AMCo Senior Employee 3] that given further independent entry, '*buyers are likely to be buying hand to mouth from now on*' and asked for help ensuring that AMCo's allocation of stock from Actavis was released promptly so as to be available for sale: '*With the market as fluid as it is at the moment I would like to avoid any unnecessary delay in placing our stock*'. [AMCo Employee] followed up on the

Agreement would be renewed (*'our own agreement up for renewal in the summer'*). In light of this *'imperfect storm'* of factors, AMCo launched its Aesica product in May 2016.²⁶⁶²

- 6.782. AMCo therefore entered the market with its Aesica tablets when it became clear that it had no other option – entry having undermined the rationale for the 10mg Agreement and Actavis being unwilling to renew it. As it prepared to enter, [X] [AMCo Senior Employee 5] noted that its Aesica product had *'always been merely a back up until now'*.²⁶⁶³ The sales were recorded in May 2016.²⁶⁶⁴ According to Aesica, the tablets with which AMCo entered the market were identical in *'drug substance, composition, specification (including quality) and stability'* to those that had been manufactured for Waymade back in July 2010.²⁶⁶⁵
- 6.783. The 10mg Agreement ended on 24 June 2016, when the Second Written Agreement expired.²⁶⁶⁶

following day, noting that two of AMCo's customers *'have both declined to buy any stock from me this month as they are very nervous about the price dropping quickly'*. [AMCo Senior Employee 3] forwarded her email to [AMCo Senior Employee 1], stating: *'Further power to the bow of launching in my view. I am thinking we go ahead and launch Asicca [sic] (or however you spell it) product asap'* (Document 202857, emails between [AMCo Employee], [AMCo Senior Employee 3] and [AMCo Senior Employee 1] dated 8-10 March 2016). This email exchange shows that independent entry had undermined the dynamics of the 10mg Agreement: AMCo expected buyers to begin taking advantage of competition to switch their purchases quickly between skinny label entrants and thus drive down prices (*'buyers are likely to be buying hand to mouth from now on'*). While the market was now becoming *'fluid'* and customers expected to switch readily between suppliers, AMCo was less agile in continuing to sell a fixed allocation of Actavis's full label product ([AMCo Employee] also noted *'the length of time it is taking for our allocation of stock to be released for sale following delivery from Actavis'*) and its high prices were becoming unsustainable. This was a factor that finally tipped the balance in favour of launching its own product: [AMCo Senior Employee 3] separately forwarded [AMCo Employee]'s email of 8 March to [AMCo Senior Employee 1] with his comment *'We cannot delay any longer'* (Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016), while [AMCo Employee] later noted that *'The buyers are very nervous of taking any quantity of stock as the prices are falling so quickly. I am struggling to sell the allocation of Auden stock now that our mainline customers are tied into retro schemes'* (Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016).

²⁶⁶² AMCo also referred to factors including independent entry and Actavis's unwillingness to renew the 10mg Agreement as *'The Perfect Storm'* that led it to launch its Aesica product: see Document 202917, AMCo 'Commercial UK & Ireland' report July 2016, slide 14.

²⁶⁶³ Document 200385, online conversation between [AMCo Employee] and [AMCo Senior Employee 5] dated 3 March 2016.

²⁶⁶⁴ Document 201045, sales data submitted to the CMA by AMCo.

²⁶⁶⁵ Document 200302, paragraph 5.1, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

²⁶⁶⁶ The fact that AMCo did ultimately enter the market independently prior to the expiry of the Second Written Agreement does not disprove the existence of the 10mg Agreement from May to June 2016. The fact that an anticompetitive agreement may not be implemented or followed is insufficient to place it outside the scope of the Chapter I prohibition: see eg C-277/87 *Sandoz v Commission*; *WANO Schwarpulver*, OJ 1978 L232/26, [1979] 1 CMLR 403; Case 19/77 *Miller v Commission*, paragraphs 7 to 10. See also COMP/37750 *French Beer*, [2006] 4 CMLR 577, paragraph 68. In any event, AMCo entered without informing Actavis (contrary to the terms of the Second Written Agreement). This meant that it continued to receive its 12,000 packs at the £1.78 price, until the Second Written Agreement expired on 24 June 2016. AMCo entered only after the CMA had commenced its investigation, and after independent entry to the market had undermined the 10mg Agreement.

The parties' representations on the 10mg Agreement

- 6.784. Despite making extensive representations on the SSO, none of the parties provided any explanation for the 97% discount Auden gave Waymade and AMCo under the 10mg Agreement, other than that it resulted from Waymade's and AMCo's 10mg MA and Auden's desire to preserve its CMO volumes.
- 6.785. The parties' representations discussed below should be read in this context. The parties have not explained why Auden agreed to pay Waymade and AMCo thousands of pounds each month.²⁶⁶⁷

'Waymade could not have been party to the 10mg Agreement'

- 6.786. Waymade submitted that the rebate that reduced the effective price of the 2,000 monthly packs supplied by Auden under the 10mg Agreement was not agreed until November 2012 or later.²⁶⁶⁸ In particular, Waymade submitted that the handwritten annotation added to the invoice for the first order on 23 October 2012, '*await credit note*', could not have been added until after 5 November, because of the adjacent time stamp with that date.²⁶⁶⁹ Waymade submitted that the email from [Waymade Senior Employee 1] of 23 October 2012 instructing [Waymade Senior Employee 4] to order 2,000 packs of 10mg tablets²⁶⁷⁰ '*simply shows [Waymade Senior Employee 1] urging [Waymade Senior Employee 4] to obtain an allocation of 10mg tablets from Auden, on terms aligned with the existing supply lines.*'²⁶⁷¹
- 6.787. Waymade submitted that these points meant the 10mg Agreement could not have begun until after 31 October 2012, when the Amdipharm group was sold – and therefore that the Waymade undertaking could not have been party to the 10mg Agreement.
- 6.788. The CMA has carefully considered the evidence on these points. For the reasons set out in paragraphs 6.588 to 6.591 and section 3.F.III.d above, the CMA finds that the 10mg Agreement began at the latest by 23 October 2012, when the first order was submitted by Waymade to Auden.
- 6.789. The CMA therefore rejects Waymade's representations. In particular:

²⁶⁶⁷ Compare *GSK v CMA* [2021] CAT 9, paragraph 51.

²⁶⁶⁸ Document 204903, Waymade's RSSO, paragraphs 2.32 and 8.4(a).

²⁶⁶⁹ Document 204903, Waymade's RSSO, paragraph 8.20.

²⁶⁷⁰ Document 300320, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 4] dated 23 October 2012.

²⁶⁷¹ Document 204903, Waymade's RSSO, paragraph 8.57(c)(5).

- a. First, these representations are contrary to the evidence Waymade submitted to the CMA in response to a section 26 notice. In that response, Waymade stated that Amdipharm UK Limited acquired 10mg tablets from Auden '*at an effective price of £1*', '*For a short period prior to its sale in October 2012*':²⁶⁷² ie while it remained part of the Waymade undertaking.
- b. Secondly, in any event, the 23 October 2012 order was not '*on terms aligned with the existing supply lines*'. As explained in paragraphs 6.588 to 6.591 above, a new deal had been agreed between Waymade and Auden by this point. Waymade ordered its usual 1,500 packs of 10mg tablets in October 2012, in addition to this order for 2,000 packs. The parties had therefore agreed a new arrangement.
- c. Thirdly, that the rebate may not have been implemented until later does not undermine the parties' common understanding at this point. The common understanding was supply from Auden at a low price in return for non-entry by Waymade, and it was devised, negotiated and concluded before Waymade's 10mg MA transferred to Cinven's ownership. The mechanics for implementing the low supply price may have come later, but the rebate applied to this order. The consistent pattern of behaviour in this case is that the low supply price follows the MA. The CMA therefore concludes that the terms of the 10mg Agreement were in place by this point.

'Waymade would not have entered into an anticompetitive arrangement for a business it was on the brink of selling'

- 6.790. Waymade submitted that it would have been '*simply irrational*' for it to agree an anticompetitive arrangement for the benefit of the Amdipharm business, which by October 2012 it was on the brink of selling to Cinven.²⁶⁷³
- 6.791. Although Waymade may have been on the brink of selling the Amdipharm business to Cinven, there is nothing '*irrational*' about [Amdipharm Senior Employee], [X], negotiating the 10mg Agreement for the benefit of Amdipharm UK Limited while it was still part of the Waymade undertaking.
- 6.792. As explained in paragraphs 6.573 to 6.576, 6.584 to 6.587 and 6.606 to 6.609 above, [Amdipharm Senior Employee] was responsible for negotiating the 10mg Agreement for Waymade and maintaining it for AMCo in the period immediately after the sale of the Amdipharm group to Cinven. He negotiated

²⁶⁷² Document 200003, paragraphs 11.6 and 13.2 (emphasis added).

²⁶⁷³ Document 204903, Waymade's RSSO, paragraph 2.31.

the 10mg Agreement under the supervision of [Waymade Senior Employee 1], [REDACTED].

'Waymade did not seek to obtain a 10mg MA for negotiating leverage'

- 6.793. As explained in section 3.F.III.b and paragraphs 6.567 to 6.571 above, during mid-2012 Waymade 'rushed through' its application for a 10mg MA with the MHRA.²⁶⁷⁴ Waymade prioritised obtaining the MA over obtaining saleable stock with which to enter the market once the MA was granted. By the time it obtained the MA on 27 September 2012 Waymade had had no contact with Aesica for more than six months, despite having developed a successful production method for 10mg tablets with Aesica in 2010.²⁶⁷⁵
- 6.794. Waymade submitted that it did not seek to obtain the 10mg MA in order to secure leverage in a negotiation with Auden – the sole reason for the urgency with which it pursued obtaining the MA in 2012 was that it had advertised the value of it to Cinven and needed to ensure it had been granted in time to be included in the sale of the Amdipharm business.²⁶⁷⁶
- 6.795. However, this cannot be the whole context:
- a. Waymade's haste to accept the MHRA's proposals on shelf life and assay limits in April 2012 pre-dates the first approach it received from Cinven to sell the Amdipharm group (in June 2012).²⁶⁷⁷

²⁶⁷⁴ For example, following receipt of the MHRA's proposal for a shorter shelf life for 10mg tablets in bottles, on 11 April 2012 [Waymade Senior Employee 1] instructed his staff: *'do not delay anything With changes just accept what they say just rush the license through mate. We can do the things later'* (Document 300228, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 11 April 2012). While Waymade initially proposed an assay limit range of 90 to 105%, the MHRA proposed a narrower range of 95-105%. On 20 April 2012, Aesica's [Aesica Employee] highlighted a *'significant risk of batch failure either on production or during stability testing'* with this narrower range. Waymade was prepared to accept this risk in order to obtain the MHRA's approval and planned to revisit the issue *'post approval'* (Document 300232, emails between [Aesica Employee], [REDACTED] and [Waymade Employee] dated 20 April 2012. See also Document 300288, email from [Waymade Employee] to [REDACTED], [REDACTED], [REDACTED], [Waymade Employee], [REDACTED] and [REDACTED] dated 10 April 2012). On 13 July 2012 [Waymade Senior Employee 1] told his staff to concede to the MHRA's view of the orphan designation (notwithstanding any implications for Waymade's product) and accept the reduced-indication 10mg MA: *'[I] do not wish to write anything re envisaging legally at this stage ... any legal threats and they will shy away and put it in a SPIN FOR YEARS IS THAT CLEAR'* (Document 300267, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 13 July 2012 (emphasis in original)).

²⁶⁷⁵ Aesica told the CMA that *'Notwithstanding, process validation of 10mg hydrocortisone tablets was first completed and approved in October 2010, Aesica did not supply any validated product to Waymade, nor received any order from Waymade regarding the same'*: Document 200292, Aesica response to section 26 notice dated 15 June 2016, paragraph 5.2. Aesica informed the CMA that the *'last contact Aesica has been able to locate between itself and Waymade as regards 10mg hydrocortisone tablets is a purchase order dated 15 November 2011 from Waymade to Aesica relating to further process validation work to be done on that dosage'*: paragraphs 4.1 and 4.2. The CMA identified one subsequent contact between Waymade and Aesica in relation to the 10mg product. In February 2012, Waymade received two validation reports from Aesica. This confirmed that Aesica had *'resolved the issue with the dissolution test'*. Document 300217, email from [REDACTED] to [Waymade Senior Employee 1] dated 2 February 2012.

²⁶⁷⁶ Document 204903, Waymade's RSSO, paragraphs 2.35 and 8.84(e).

²⁶⁷⁷ Document 200003, Waymade's response to the CMA's section 26 notice dated 18 May 2016, paragraph 6.1.

- b. [Waymade Senior Employee 1]'s instruction to Waymade staff to concede to the MHRA's view of the orphan designation (*'any legal threats and they will shy away and put it in a SPIN FOR YEARS'*) was given on 13 July 2012, seven days after Waymade issued its information memorandum for the sale of the Amdipharm group to Cinven.²⁶⁷⁸ Waymade submitted that the 10mg MA was inadvertently included in the information memorandum and that Waymade had not intended to sell it.²⁶⁷⁹ It is not clear that a week after issuing the document, it was apparent to [Waymade Senior Employee 1] that Waymade would not be retaining its 10mg MA.

6.796. The potential sale of the Amdipharm business, and with it the 10mg MA, provided context for Waymade's actions from mid-July 2012 onwards. But the fact that this may have been one reason for the urgency with which it approached obtaining the 10mg MA from then onwards does not negate the importance of the other: its usefulness as negotiating leverage, which preceded Cinven's interest in acquiring the Amdipharm group. Waymade's strategy of using an MA and the competitive threat it posed to Auden is clearly established in relation to the 20mg Agreement, and the key individuals all agreed that once the 10mg MA was obtained, Waymade looked to secure a 10mg deal on the same basis.²⁶⁸⁰

6.797. In any event, the sale of the Amdipharm group could have fallen through at any point prior to 31 October 2012. If that had happened, the 10mg Agreement would have remained with the Waymade undertaking.

'Waymade did not progress commercialisation of its 10mg MA in October 2012 solely because of the sale of the Amdipharm group'

6.798. Waymade submitted that the only reason it did not progress commercialisation of its 10mg MA in October 2012 was the fact that it had agreed to sell the MA to Cinven. It argued that it would have been legally

²⁶⁷⁸ Document 300267, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 13 July 2012 (emphasis in original). Document 202512, slide pack entitled *'PROJECT AMPULE Information memorandum'* dated 6 July 2012.

²⁶⁷⁹ Document 200003, Waymade's response to the CMA's section 26 notice dated 27 May 2016, paragraphs 6.1 and 6.2.

²⁶⁸⁰ For example, [Amdipharm Senior Employee] stated that he had set out to *'do the same deal with Auden Mckenzie on the 10mg that we had with the 20mg'* (Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 15 lines 7-12), while [Auden Senior Employee 1] stated that once Waymade obtained the 10mg MA, Auden was faced with *'the same scenario'* as it had faced when negotiating the 20mg Agreement, and that it responded in the same way – by supplying Waymade at a substantial discount in order to maintain its manufacturing volumes:

'it was a very, a very similar situation where they had said, 'look we've got a product and we would like to take supply from you'. So again, in the same scenario as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable' (Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68).

precluded from taking any steps to commercialise the MA under the agreement for the sale of the Amdipharm business.²⁶⁸¹

6.799. The 'non-compete' in the agreement for the sale of the Amdipharm business is addressed in paragraphs 6.261 to 6.267 above.

6.800. The sale of the Amdipharm business is context to events in October 2012. But it was not the sole reason Waymade refrained from commercialising its 10mg MA. By the time the sale took place Waymade had used the 10mg MA and the threat of competitive entry it posed to Auden as leverage to secure another favourable supply deal from Auden.

'The 20mg Agreement cannot be used as context for the 10mg Agreement'

6.801. Cinven submitted that the 20mg Agreement could not be used as relevant context for the 10mg Agreement because the 10mg Agreement did not contain a buyback or 'RAMA clause'.²⁶⁸² Cinven described the absence of a buyback in the 10mg Agreement as '*an eloquent silence that is devastating for the CMA's case*'.²⁶⁸³

6.802. It is difficult to establish the rationale underlying this representation. The CMA has found that AMCo entered into the 10mg Agreement with Auden/Actavis. Under the terms of the 10mg Agreement AMCo received payment in the form of a substantially discounted supply of hydrocortisone tablets in exchange for not independently entering the market with its own 10mg hydrocortisone tablets. The mechanics of how the payment was achieved are irrelevant to the common understanding on non-entry. As explained above, the key individuals involved all agreed that Waymade secured a 10mg deal on the same basis as its 20mg deal and that this then transferred to AMCo with the Amdipharm group. For example:

- a. [Amdipharm Senior Employee] stated that he had set out to '*do the same deal with Auden Mckenzie on the 10mg that we had with the 20mg*'.²⁶⁸⁴ [Amdipharm Senior Employee] stated that once the sale of the Amdipharm group was public knowledge, '*I then had to speak to Auden to say that I was actually going as part of the Amdipharm business, that I would continue to be in that business and that I was keen for the supply to continue*',²⁶⁸⁵ and that '*after the sale of*

²⁶⁸¹ Document 204903, Waymade's RSSO, paragraphs 8.27-8.36.

²⁶⁸² Document 204967, Cinven's RSSO, paragraphs 1.29, 4.77, 4.87

²⁶⁸³ Document 204967, Cinven's RSSO, paragraph 4.81.

²⁶⁸⁴ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 15 lines 7-12.

²⁶⁸⁵ Document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 16 lines 2-8.

Amdipharm to Cinven, then ensuring that continuity of supply [of 10mg hydrocortisone tablets] from Auden Mckenzie was my responsibility'.²⁶⁸⁶

- b. [Auden Senior Employee 1] stated that once Waymade obtained the 10mg MA, Auden was faced with *'the same scenario'* as it had faced when negotiating the 20mg Agreement, and that it responded in the same way – by supplying Waymade at a substantial discount in order to maintain its manufacturing volumes: *'it was a very, a very similar situation where they had said, 'look we've got a product and we would like to take supply from you'. So again, in the same scenario as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable'*.²⁶⁸⁷ [Auden Senior Employee 1] further stated that *'after the move from Waymade to Amdipharm ... In 2012, we supplied Amdipharm at a price of £1 per pack'*. This was because AMCo ceased to be a *'pure wholesaler'* when it acquired the 10mg MA from Waymade; and *'[w]e [Auden] wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]'*.²⁶⁸⁸

6.803. Cinven (like AMCo and Auden/Actavis) failed to explain why AMCo warranted the very substantial discount it received from Auden/Actavis under the terms of the 10mg Agreement. This silence, in the face of strong contemporaneous documentary and witness evidence showing that the payments were in exchange for AMCo agreeing not to independently enter the market with its own 10mg hydrocortisone tablets, is telling.

'The CMA cannot impute Waymade's intentions to AMCo'

- 6.804. AMCo and Cinven submitted that Waymade's intentions and actions were not relevant to AMCo, which is a separate undertaking. They submitted that the CMA cannot impute Waymade's intentions to AMCo.²⁶⁸⁹
- 6.805. The CMA does not impute the intentions and actions of one undertaking to another, separate, undertaking. As explained in the analysis of the Agreements above:

²⁶⁸⁶ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 67 lines 5-7.

²⁶⁸⁷ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68.

²⁶⁸⁸ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.

²⁶⁸⁹ Document 204922, AMCo's RSSO, paragraph 5.86. Document 204967, Cinven's RSSO, paragraphs 4.111-4.113 and footnote 421.

- a. [Amdipharm Senior Employee] negotiated the 20mg Agreement for the Waymade undertaking in mid-2011, under [Waymade Senior Employee 1]'s supervision.
- b. [Amdipharm Senior Employee] negotiated the 10mg Agreement for the Waymade undertaking in September/October 2012, under [Waymade Senior Employee 1]'s supervision.
- c. In interview [Amdipharm Senior Employee] explained that both the 20mg and 10mg Agreements were concluded on the same basis: to preserve Auden's CMO volumes.
- d. At the end of October 2012, [Amdipharm Senior Employee] transferred to the AMCo undertaking with the Amdipharm group and he took the 10mg Agreement with him. Waymade's 10mg product development project, knowhow and relevant staff also transferred to AMCo. Shortly afterwards, in November 2012 [Waymade Senior Employee 1], who now held a seat on the AMCo board and a minority shareholding in AMCo, told [Amdipharm Senior Employee] that he had spoken to [AMCo Senior Employee 1] and *'told him that you are handling hydrocortisone 10mg with [Auden Senior Employee 1] at Auden mac Menzies [sic]'*.²⁶⁹⁰
- e. [Amdipharm Senior Employee] stated that once the sale of the Amdipharm group was public knowledge, *'I then had to speak to Auden to say that I was actually going as part of the Amdipharm business, that I would continue to be in that business and that I was keen for the supply to continue'*,²⁶⁹¹ and that *'after the sale of Amdipharm to Cinven, then ensuring that continuity of supply [of 10mg hydrocortisone tablets] from Auden Mckenzie was my responsibility'*.²⁶⁹²
- f. In January 2013, [Amdipharm Senior Employee] led negotiations on behalf of AMCo that resulted in the tripling of volumes AMCo received from Auden under the 10mg Agreement.
- g. [Amdipharm Senior Employee] continued to be involved in administering the 10mg Agreement (and supervising AMCo's approach to the Aesica project) on behalf of AMCo in 2013 and early 2014.

²⁶⁹⁰ Document 300331, email from [Waymade Senior Employee 1] to [Amdipharm Senior Employee] dated 13 November 2012.

²⁶⁹¹ Document 200348, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, page 16 lines 2-8.

²⁶⁹² Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 67 lines 5-7.

6.806. These facts explain the CMA's use of Waymade's and in particular [Amdipharm Senior Employee]'s actions and intentions as context for AMCo's continuation of the 10mg Agreement from 31 October 2012 onwards. Simply asserting that Waymade's actions and intentions are not relevant to AMCo does not undermine the importance of this context.

'AMCo could not be party to the 10mg Agreement before the 10mg MA was legally transferred to it'

6.807. Cinven submitted that AMCo could not have entered into the 10mg Agreement before 9 May 2013, when the transfer of the 10mg MA from Waymade plc to Amdipharm UK Limited was registered by the MHRA.²⁶⁹³

6.808. That the legal registration of the transfer of the 10mg MA did not occur until May 2013 is irrelevant.

6.809. As explained in sections 3.F.III.d and e and paragraphs 6.594 to 6.613 above:

- a. Amdipharm UK Limited was the beneficial owner of the 10mg MA from 13 October 2012 onwards;
- b. [Amdipharm Senior Employee] informed Auden shortly after the sale of the Amdipharm group was announced in mid-October 2012 that it would in future be dealing with AMCo on 10mg tablets;
- c. Waymade plc acted as agent for Amdipharm UK Limited from October 2012 onwards under the intra-group agreement that transferred the 10mg MA and the supply chain services agreement that came into effect on 31 October 2012; and
- d. Once he had transferred to AMCo, [Amdipharm Senior Employee] negotiated a threefold increase in the volumes supplied by Auden on AMCo's behalf in January 2013.

6.810. This is the key contemporaneous evidence relied upon by the CMA to show that AMCo was party to the 10mg Agreement prior to the legal transfer of the 10mg MA in May 2013. Cinven did not engage with any of this evidence or submit its own evidence in rebuttal of the CMA's case on this point, despite being directly involved in the transactions underlying the transfer of the MA.

²⁶⁹³ Document 204967, Cinven's RSSO, paragraphs 8.6 and 8.8. See also paragraphs 8.24 and 8.26. Document 203736, Cinven's RSO, paragraphs 6.18-6.21.

6.811. In any event, the change of ownership application was very straightforward as it only took 13 days for the MHRA to process. Nothing prevented AMCo from pursuing the Aesica development (e.g. ordering batches of the product) while it waited for the application to be processed. The fact that it took AMCo six months to submit a simple application is also consistent with the CMA's finding that AMCo did not engage meaningfully with the Aesica development until January 2014.²⁶⁹⁴

'There is no contemporaneous evidence of the 2013 negotiations so their nature cannot be inferred'

6.812. AMCo submitted that since there is no contemporaneous record of the negotiations leading to the increase in its volumes in 2013, the CMA cannot conclude that AMCo used its leverage to achieve it.²⁶⁹⁵ AMCo did not, however, offer any other explanation for how AMCo was able to triple its volumes under the 10mg Agreement, and therefore significantly increase the payments from Auden. As explained in paragraphs 6.604 to 6.613 above, these negotiations were preceded and followed by other negotiations between some of the same individuals, contemporaneous and witness evidence of which shows a pattern of consistent behaviour: Waymade and AMCo exerting leverage over Auden/Actavis through the threat of entry with an MA, and Auden/Actavis responding to buy off that threat.

'AMCo did not use its Aesica product as leverage in negotiations with Auden'

6.813. AMCo submitted that it was *'quite simply implausible'* that it had used its Aesica product as leverage in negotiations with Auden.²⁶⁹⁶ Cinven submitted that *'the CMA has not proven the link between the volumes of Auden Product that Auden Mckenzie supplied to AMCo and any alleged 'leverage'.*²⁶⁹⁷ AMCo and Cinven did not, however, submit a substantiated

²⁶⁹⁴ The MHRA confirmed to the CMA that change of ownership applications are standard and straightforward applications for the MHRA to process. The MHRA explained that *'[t]hey are simple transfers of the marketing authorisations from one company to another that are typically always approved'*. In the case of Waymade's 10mg MA, the MHRA told the CMA that it *'received the change of authorisation holder form from Amdipharm on 26 April 2013 and it, therefore, took a period of 13 days for the MHRA to approve the transfer of the marketing authorisation from Waymade PLC to Amdipharm UK Limited'* and specified that *'there were no requests for further information issued by the MHRA, or any issues or difficulties experienced with the application. The documents on the case folder included the application, a cancellation letter from Waymade PLC, a letter from the manufacturer confirming that it would remain the manufacturer following the CoA, and proof of payment'*. See Document 201103, note of call between the CMA and the MHRA of 9 February 2017.

²⁶⁹⁵ Document 204922, AMCo's RSSO, paragraphs 3.585-3.590 and 5.76-5.87.

²⁶⁹⁶ Document 204922, AMCo's RSSO, paragraph 3.736. See also paragraphs 3.745, 3.747-3.749, 3.753-3.755, 3.760, 3.764 and 3.769-3.770. However, AMCo's and Cinven's economic advisers stated that obtaining an MA *'provides a credible signal to be used in negotiation'* (Document 203738, CRA Report submitted by AMCo and Cinven on the 2017 SO, paragraph 71). CRA suggested that firms could use *'entering a fixed supply arrangement with an upstream incumbent ... as leverage with third party suppliers'* (paragraph 8). This is not what happened in this case: rather, AMCo used the prospect of entering with its third party supplier (Aesica) as leverage to secure an arrangement with Auden, the incumbent.

²⁶⁹⁷ Document 204967, Cinven's RSSO, paragraphs 4.65-4.74. See also paragraphs 6.67(b), 7.95 and 7.154.

alternative explanation for the significant monthly payments AMCo received under the 10mg Agreement.

- 6.814. The evidence of AMCo using its Aesica product as leverage in negotiations with Auden is set out above (see paragraphs 6.626 to 6.712). It includes in particular the contemporaneous statements to that effect made by:
- a. [AMCo Senior Employee 1] to [Auden Senior Employee 1] that if Auden did not renew the 10mg Agreement on improved terms, *'we will launch our own'*,²⁶⁹⁸ and to AMCo staff that *'the work that you did to provide certainty of launch of our product gave those of us who were negotiating with Auden Mackenzie confidence to achieve the best deal possible for AMCo and I am sure that, as a result, Auden Mackenzie felt that they should agree to our terms'*,²⁶⁹⁹ and
 - b. [AMCo Senior Employee 2] to AMCo staff that they should *'say to [Auden Senior Employee 1] that we don't mind having limited labelling. Pharmacists will use it anyway, regardless of label. Therefore, we should still be arguing using 100% of the market as our negotiating position for supply volumes'*,²⁷⁰⁰ and that securing the Second Written Agreement *'wouldn't have been possible without being launch-ready with our own product'*.²⁷⁰¹

'[AMCo Senior Employee 1]'s threat, 'if not we will launch our own', was a 'bluff'

- 6.815. AMCo submitted that in telling [Auden Senior Employee 1] *'if not we will launch our own'*,²⁷⁰² [AMCo Senior Employee 1] *'was engaging in no more than commercial bluff in order to secure prompt supply. It was a "bluff", because [AMCo Senior Employee 1] knew, but [Auden Senior Employee 1] did not, that AMCo had no product to launch'*.²⁷⁰³
- 6.816. [AMCo Senior Employee 1] also stated in interview that this statement was *'a bluff, not an agreement, it was a bluff, we didn't have a product to launch'*.²⁷⁰⁴

²⁶⁹⁸ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] dated 15 June 2014.

²⁶⁹⁹ Document 200126, email from [AMCo Senior Employee 1] to [AMCo Employee] and others dated 28 June 2014.

²⁷⁰⁰ Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.

²⁷⁰¹ Document 200125, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1], copied to [AMCo Senior Employee 4] and [AMCo Senior Employee 5], dated 25 June 2014.

²⁷⁰² Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] dated 15 June 2014.

²⁷⁰³ Document 204922, AMCo's RSSO, paragraph 3.753.

²⁷⁰⁴ Document 201566, [AMCo Senior Employee 1] interview transcript dated 20 October 2017, page 3 lines 7-8.

6.817. Cinven submitted that:

*'While AMCo did indicate to [Auden] that it would launch its own product so as to achieve the best terms possible in its commercial negotiations ... AMCo was in fact unable to enter the market during the negotiations of the Supply Agreements ... Statements regarding AMCo's independent market entry were therefore merely posturing.'*²⁷⁰⁵

6.818. The CMA's analysis in section 6.C.II.b.iv above has demonstrated that AMCo was a potential competitor to Auden in respect of 10mg hydrocortisone tablets throughout the term of the 10mg Agreement.

6.819. The CMA is not required to demonstrate that in the absence of the 10mg Agreement AMCo would immediately have entered the market. To be a potential competitor of Auden AMCo need only have taken *'sufficient preparatory steps to enable it to enter the market concerned within such a period of time as to impose competitive pressure'* on Auden.²⁷⁰⁶ It is clear that AMCo exerted such pressure on Auden and that Auden responded, in particular by improving the terms on which it supplied AMCo in the Second Written Agreement.²⁷⁰⁷

6.820. Further, the CMA does not accept the proposition that [AMCo Senior Employee 1] believed AMCo was not in a position to launch its own product and was therefore *'bluffing'* [Auden Senior Employee 1] during their telephone call on 15 June 2014. Contemporaneous documentary evidence shows that AMCo believed it was close to being able to launch its 10mg hydrocortisone tablets at this time. For example, on 23 June 2014, eight days after [AMCo Senior Employee 1] made his threat to [Auden Senior Employee 1] and two days before the parties entered into the Second Written Agreement, AMCo was preparing to pick up its launch stock from Aesica in early July 2014.²⁷⁰⁸ Three days after entering into the Second Written Agreement, on 28 June 2014, [AMCo Senior Employee 1] wrote to AMCo staff: *'thank you for all the effort that you put into bringing the Aesica*

²⁷⁰⁵ Document 203736, Cinven's RSO, paragraph 5.100.2.

²⁷⁰⁶ C-307/18, *Generics (UK) and others v CMA*, paragraphs 43 and 44. Compare C-591/16 P *Lundbeck v Commission*, paragraph 57.

²⁷⁰⁷ Compare T-472/13 *Lundbeck v Commission*, paragraphs 293, 301-310 and 313-315. The European General Court dismissed Ranbaxy's argument that it was *'merely bluffing in order to persuade them [Lundbeck] to enter into an agreement favourable to Ranbaxy'* when it made statements at a meeting with Lundbeck to the effect that it would be able to obtain an MA within eight months and/or sell its API to an existing MA holder within four months. The General Court noted that Lundbeck *'decided to conclude the Ranbaxy agreement, which shows that it took seriously the threat posed by Ranbaxy'*; and that *'even if Ranbaxy underestimated the period necessary to obtain an MA, it must be noted ... that Lundbeck nevertheless felt competitive pressure, to the point that it believed it to be in its interest to pay Ranbaxy in order to limit, or even exclude, its access to the market'*. The General Court's judgment was upheld by the European Court of Justice in C-591/16 P *Lundbeck v Commission*.

²⁷⁰⁸ Document 202684, email from [AMCo Employee] to [AMCo Employee] dated 23 June 2014.

*Hydrocortisone product to a position where we were able to launch.*²⁷⁰⁹

AMCo's June 2014 monthly report stated: '*Hydrocortisone 10mg batches manufactured and ready for sale ... however, these won't be sold due to a deal extension being signed with Auden McKenzie*'.²⁷¹⁰ AMCo was not apprised of the fact that its launch batches had been packed in the wrong foil until September 2014.

- 6.821. In any event, even if [AMCo Senior Employee 1] had been '*bluffing*', he wanted [Auden Senior Employee 1] to understand that AMCo was ready to launch, and that if Auden did not supply AMCo on the agreed terms, AMCo would launch its product. In its representations AMCo accepted that Auden '*saw AMCo's pipeline reduced indication 10mg HT as a real threat*'.²⁷¹¹ The clear implication of [AMCo Senior Employee 1]'s threat – whether it was a '*bluff*' or not – was that if Auden supplied on the agreed terms, AMCo would not launch its own 10mg product. Auden could only be expected to respond to [AMCo Senior Employee 1]'s threat if it were possible to avoid it becoming reality. The meaning of [AMCo Senior Employee 1]'s statement was therefore that if Auden did supply, it would negate this threat: AMCo would not launch. There is no other plausible reason for [AMCo Senior Employee 1] to make his threat, or for Auden to respond to it by supplying AMCo on improved terms. In fact, as explained in paragraphs 6.725 to 6.727 above, Auden responded to [AMCo Senior Employee 1]'s threat by doubling AMCo's volumes and AMCo suspended its Aesica product development on the same day.

'Project Guardian shows that Auden/Actavis did not consider there to be any common understanding that AMCo would not enter'

- 6.822. AMCo submitted that if it had agreed not to enter there would have been no need for Auden/Actavis to have engaged in Project Guardian.²⁷¹² It submitted that Auden/Actavis committed material time and effort to continuing Project Guardian from early 2014 until the end of the 10mg Agreement, showing that it did not consider that there was any common understanding that AMCo would not enter the market.²⁷¹³
- 6.823. This representation shows no recognition of the nuances in the relationship between Auden/Actavis and AMCo over time – of the ebb and flow of their negotiations and continuing assessment of whether the 10mg Agreement

²⁷⁰⁹ Document 200126, email from [AMCo Senior Employee 1] to AMCo staff dated 28 June 2014.

²⁷¹⁰ Document 200192, AMCo strategic development report for June 2014.

²⁷¹¹ Document 203737, AMCo's RSO, paragraphs 3.42 and 3.498.

²⁷¹² Document 204922, AMCo's RSSO, paragraphs 3.162, 3.206, 5.39.2, 5.95. See also Document 203737, AMCo's RSO, paragraphs 3.42, 3.327, 3.498 and 3.504.

²⁷¹³ Document 204922, AMCo's RSSO, paragraphs 3.193 and 3.195.

was in their best interests. When Project Guardian is considered in context it is entirely consistent with the CMA's findings.

- 6.824. As explained in section 3.F.III.h and paragraphs 6.660 to 6.664 above, Auden launched Project Guardian in early 2014 at a time when the relationship between itself and AMCo was deteriorating. By this time, both sides were beginning to question whether the 10mg Agreement would continue. For example, the minutes of an internal AMCo meeting on 19 December 2013 stated that *'Auden are still supplying hydrocortisone but are being increasingly aggressive and threatening that the orphan drug status of their product means that our product ... is not comparable to theirs'*.²⁷¹⁴ The implication was that Auden might terminate the 10mg Agreement.²⁷¹⁵ [Auden Senior Employee 1] made this threat in his telephone call to [AMCo Senior Employee 2] on 14 January 2014, in which he implied that he would not sign a renewed supply deal and *'would then take action to protect his product by advising all parties (mentioning DoH and MHRA amongst others, including major multiples) that our product should not be dispensed against generic prescriptions.'*²⁷¹⁶ Auden then launched Project Guardian in anticipation of AMCo launching its product.
- 6.825. However, when [Auden Senior Employee 1] launched Project Guardian he soon appreciated that the orphan designation might not shield Auden's full label hydrocortisone tablets from competition in the way he had hoped. For example, [Chief Pharmaceutical Officer for NHS England] [X] informed [Auden Senior Employee 1] (on the advice of the MHRA) in writing that *'there are no material differences between the available generic immediate release hydrocortisone tablets and they are all bioequivalent to the brand leader'* and therefore *'I do not see that there are any risks to patient safety that would warrant any communication to senior pharmacists.'*²⁷¹⁷
- 6.826. Alongside Project Guardian, [Auden Senior Employee 1] returned to the negotiating table with AMCo – with contemporaneous internal AMCo documents highlighting that [Auden Senior Employee 1] seemed to be less confident on the impact of the orphan designation and was, as a consequence, seeking to do a further deal with AMCo to avoid a *'battle'* or

²⁷¹⁴ Document 200510, Minutes of MPGL Management meeting on 19 December 2013, page 3.

²⁷¹⁵ The extent of the competitive threat posed by AMCo's product was a key point of the negotiations for a renewed supply deal. For example, on 2 January 2014 [AMCo Senior Employee 2] told [Amdipharm Senior Employee] that the latest prescription data *'gives us a bit more strength to say to [Auden Senior Employee 1] that we don't mind having limited labelling. Pharmacists will dispense it anyway, regardless of labelling. Therefore, we should still be arguing using 100% of the market as our negotiating position for supply volumes'*. Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.

²⁷¹⁶ Document 200085, email from [AMCo Senior Employee 2] to AMCo management dated 14 January 2014.

²⁷¹⁷ Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden Senior Employee 1], [Auden Senior Employee 4] and [Auden's External Consultant] dated 20 May 2014.

'fight' over the issue.²⁷¹⁸ Following the response [Chief Pharmaceutical Officer for NHS England], [Auden Senior Employee 1] approached [AMCo Senior Employee 1] by text message, beginning the final phase of negotiations that resulted in the Second Written Agreement between Auden and AMCo (see paragraphs 6.695 to 6.702 above).

- 6.827. Auden/Actavis did not in fact continue Project Guardian throughout the remainder of the 10mg Agreement, as AMCo submitted.²⁷¹⁹ After the parties concluded the Second Written Agreement Auden/Actavis took no further material steps on Project Guardian until November 2014 when, prompted by the MHRA's grant of a 10mg MA to Orion (later transferred to Alissa), Auden/Actavis returned to Project Guardian in response to a new threat from another potential entrant.^{2720,2721} See sections 3.F.III.h, i and m above.
- 6.828. Notwithstanding the 10mg Agreement, Auden/Actavis could never be certain that other competitors would not enter the market. AMCo was not the only potential entrant. As explained in section 3.F.III.p above, in late 2015, after the business of AM Pharma was transferred to Accord-UK and Alissa entered the market, the Project Guardian materials were revisited. Actavis then attempted to buy off Alissa Healthcare in the same way as AMCo, using the Second Written Agreement as a template for the payments.

'There was no 'non-compete' in the Second Written Agreement'

- 6.829. AMCo and Cinven submitted that the Second Written Agreement contained no contractual restriction on AMCo's entry. Indeed, they submitted that AMCo negotiated clauses 2.2 and 17 of the Second Written Agreement (discussed in paragraphs 6.715 to 6.720 above) specifically to ensure its freedom to launch its own product was maintained.²⁷²² They submitted that [AMCo Senior Employee 8] had resisted Auden's attempts to prevent AMCo

²⁷¹⁸ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.

²⁷¹⁹ Document 204922, AMCo's RSSO, paragraph 3.193.

²⁷²⁰ Document 00235, email from [X] (Auden Mckenzie) to [X] (MHRA) dated 28 November 2014. Document 00239, letter from [X] to [X], dated 1 December 2014. See also Document 00243, letter from [X] to [X], dated 1 December 2014; Document 00265, letter from Orion to SNS Pharmaceuticals dated 17 December 2014. The only correspondence from Auden on Project Guardian between July and November 2014 on the CMA's file consists of: an email to the MHRA dated 8 July 2014, requesting a response to Auden's letter dated 14 April 2014 (Document 00284, email from [X] to [X] dated 8 July 2014); and an exchange of emails with Rowlands Pharmacy between 18 and 21 July 2014 following Rowlands' request to see Auden's SmPC (Document 00179B, emails between [X] and [X] between 18 and 21 July 2014). These communications represent the tail end of Auden's approaches to stakeholders in February to June 2014 rather than a new wave of approaches.

²⁷²¹ That Auden considered it had bought AMCo off through the payments in the Second Written Agreement is also illustrated by the fact that on 23 June 2014, two days before entering the Second Written Agreement, Auden decided that it was no longer necessary to take any further action towards reintroducing the brand 'Hydrocortone'. See Document 00288, email from [Auden Senior Employee 4] to MAP Biopharma and [Auden Senior Employee 3] dated 23 June 2014.

²⁷²² Document 204967, Cinven's RSSO, paragraphs 2.39-2.40 and 4.30-4.39. Document 204922, AMCo's RSSO, paragraphs 3.695-3.706. See also Document 203737, AMCo's RSO, paragraph 6.27.

from entering with its own product when negotiating the Second Written Agreement, and had instead proposed ‘a *simple clear English summary of the agreed position*’ that expressly reserved AMCo’s right to launch its own product.²⁷²³

- 6.830. These representations mischaracterise the CMA’s findings.
- 6.831. The CMA has found that throughout the period from 31 October 2012 to 24 June 2016, Auden made monthly payments to AMCo in exchange for AMCo agreeing not to independently enter the market with its own 10mg hydrocortisone tablets. This common understanding is the 10mg Agreement.
- 6.832. As explained in paragraph 6.714 above, the Second Written Agreement is not in itself the 10mg Agreement. It represented continued and increasing payments from Auden to AMCo. In exchange for these continued and increased payments AMCo renewed its commitment not to enter, as is clear in particular from the evidence documenting the negotiations leading up to the conclusion of the Second Written Agreement and AMCo’s conduct after entering into the Second Written Agreement. These two elements together – payment in exchange for non-entry – constitute the common understanding defined as the 10mg Agreement. The Second Written Agreement must be read in the context of that common understanding.
- 6.833. [AMCo Senior Employee 8]’s ‘*simple clear English summary of the agreed position*’ in the Second Written Agreement is entirely consistent with the CMA’s findings.
- 6.834. [AMCo Senior Employee 8]’s amendments to the relevant clauses of the Second Written Agreement were limited to the proposed broad definitions of the ‘*Product*’. [AMCo Senior Employee 8] made these amendments because he was concerned that Auden’s proposed definition of the ‘*Product*’ might extend beyond AMCo’s Aesica product and potentially capture other steroid products in AMCo’s portfolio. This is shown [AMCo Senior Employee 8]’s contemporaneous correspondence:

*‘As mentioned previously, we have other steroids in our existing portfolio and we do not want any suggestion that these ‘compete’ with hydrocortisone.’*²⁷²⁴

²⁷²³ Document 204922, AMCo’s RSSO, paragraphs 3.695-3.699; Document 204967, Cinven’s RSSO, paragraphs 1.22 and 4.34-4.38.

²⁷²⁴ Document 200247, email from [AMCo Senior Employee 8] to [X] dated 19 June 2014.

6.835. The amendments related to the scope of the clauses (ie the number of products potentially subject to them), rather than to their terms.

6.836. [AMCo Senior Employee 8] stated:

*'We propose that the non-compete in 2.1 is therefore changed to a simply clear English summary of the agreed position which is that AMCo shall not sell other hydrocortisone tablets without giving 3 months notice (which would allow Auden to terminate on 3 months notice).'*²⁷²⁵

6.837. As explained in paragraphs 6.719 to 6.722 above, both [AMCo Senior Employee 8] and [X] [AMCo Senior Employee 2] confirmed to the CMA that AMCo would have expected Auden to exercise its right to terminate had AMCo provided notice of its intention to enter.²⁷²⁶

6.838. This evidence is consistent with and corroborates the CMA's analysis set out above which has demonstrated that the purpose of the 10mg Agreement was for Auden/Actavis to buy off the competitive threat AMCo posed to it with its skinny label hydrocortisone tablets and that AMCo itself used this competitive threat as leverage to secure payments from Auden, including significantly increased payments in the Second Written Agreement. If AMCo had independently entered the market it would have no leverage to exert over Auden/Actavis and there would have been no reason for Auden/Actavis to continue supplying the substantially discounted product.

²⁷²⁵ Document 200247, email from [AMCo Senior Employee 8] to [X] dated 19 June 2014.

²⁷²⁶ In relation to [AMCo Senior Employee 8], see Document 200452, note of state of play meeting dated 18 May 2016, paragraph 34: *'...contractually AMCo was unlikely to supply both products [its Aesica tablets and Auden's tablets] at the same time, as Auden would most likely terminate supply of hydrocortisone after the three month notice period.'* Document 201592, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, page 23 lines 13-15: when asked in interview whether AMCo could have launched its own product and continued taking supplies from Auden, [AMCo Senior Employee 2] stated: *'I don't think that's a realistic scenario ... this is an either or situation. You're either going to launch your own or you're going to take supply from Auden Mckenzie'*. [AMCo Senior Employee 2] further stated: *'Why would they [Auden] supply AMCo, if we had a competitive product on the market? I don't know. So our belief would have been that they would have stopped supplying AMCo with the product ... I understand enough about the market and the dynamics of the market to understand that a supplier would not be happy if one of its "suppliers" was also to launch a second product onto the market. And unless they have an obligation to do so, I wouldn't expect them to continue supplying that company.'* Document 201591, transcript of interview with [AMCo Senior Employee 2] dated 12 October 2017, pages 42-43. The combination of [AMCo Senior Employee 2]'s and [AMCo Senior Employee 8]'s evidence in respect of the consequences of AMCo's independent entry also refutes Cinven's representations that the Second Written Agreement would not have terminated if AMCo had independently entered the market with its own 10mg hydrocortisone tablets and that AMCo could have sold both its own tablets and Auden's tablets at the same time (Document 204967, Cinven's RSSO, paragraphs 4.41 to 4.45 and 7.31). These representations were not substantiated and ignore the weight of evidence which has demonstrated that the reason why Auden provided AMCo with a significantly discounted supply of 10mg hydrocortisone tablets (97% less than the rest of the market) was to buy off the competitive threat it posed and that AMCo suspended the development of its 10mg tablets as soon as it entered into the Second Written Agreement.

6.839. Further, it is clear from the evidence that AMCo staff understood this. For example:

- a. On 30 June 2014 [AMCo Senior Employee 1] expressed concern about parallel importation putting AMCo *'in danger of the product coming back into the UK – which is bad enough in itself but could also put us in breach of the contract that we have here with AM.'*²⁷²⁷
- b. On 14 August 2014 [AMCo Employee] wrote: *'The batches won't ne [sic] sold because of contractual reasons (commercial). They are not rejected.'*²⁷²⁸
- c. On 20 November 2014, [AMCo Employee] indicated that *'we will supply from Aesica which means this product won't find it's [sic] way back to the UK.'*²⁷²⁹

6.840. AMCo accepted in its representations that *'On their face, all three internal communications refer to AMCo's contractual obligations under the Second Written Agreement'*.²⁷³⁰

6.841. This evidence demonstrates that the Second Written Agreement must be read in the context of the wider 10mg Agreement. AMCo understood that Auden would terminate the Second Written Agreement if it notified Auden that it intended to independently enter the market with its own 10mg tablets, as it was required to do under the Second Written Agreement. This was because it understood that the payments it received from Auden were in exchange for its continued commitment not to launch its 10mg product: the counter-performance for the payments.

'AMCo suspended its Aesica development after entering into the Second Written Agreement only temporarily, as a result of a misunderstanding'

6.842. In paragraphs 6.725 to 6.783 above (and in the SSO) the CMA concluded that following its entry into the Second Written Agreement AMCo suspended its Aesica development of 10mg hydrocortisone tablets for the UK and only rekindled the project at points when it was concerned that the 10mg Agreement with Auden/Actavis might come to an end.

²⁷²⁷ Document 203640, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 9], [AMCo Senior Employee 8] and others dated 30 June 2014 (emphasis added).

²⁷²⁸ Document 202724, email from [AMCo Employee] to [AMCo Employee] dated 14 August 2014 (emphasis added).

²⁷²⁹ Document 202745, email from [AMCo Employee] to [AMCo Employee] dated 20 November 2014 (emphasis added).

²⁷³⁰ Document 204922, AMCo's RSSO, paragraph 3.731.

6.843. AMCo submitted that its *'actual conduct on the market is far removed from that of a firm that understood that it had been bought off from bringing its own product to market'*. AMCo claimed that:

'as the evidence plainly shows ... for the duration of the Second Written Agreement ... AMCo actively pursued the development of its own product with Aesica, suspending it only temporarily for a few days after the signing of the Second Written Agreement as a result of a misunderstanding' (emphasis in original).²⁷³¹

6.844. The CMA has carefully considered these representations by reference to the evidence on its file. The CMA has concluded that the evidence does not support these representations and additionally notes that AMCo itself has failed to substantiate them. Instead, a substantial volume of contemporaneous documents and witness evidence demonstrates that AMCo suspended its 10mg hydrocortisone tablets development with Aesica for the UK as a direct result of its entry into the Second Written Agreement (which ensured the continuation of the payments in the 10mg Agreement) and that that development only resumed at points when AMCo was concerned that the 10mg Agreement might come to an end.

6.845. The basis for AMCo's submission that the Aesica project was suspended *'only temporarily for a few days'* was the fact that AMCo instructed Aesica to complete packing of the three available batches.²⁷³² However, this instruction did not amount to continuing with the Aesica project. [X] [AMCo Senior Employee 5]'s summary of AMCo's decisions at the meeting on 25 June 2014, discussed at paragraphs 6.725 to 6.727 above, stated that AMCo would *'advise Aesica that the project is now parked due to delays but may be restarted in the future'*, would *'continue with the packing of the three available batches at Aesica to complete this phase of the project'*, and would *'cancel the order for the 4th batch and any other subsequent orders'*.²⁷³³ AMCo's instruction to Aesica to pack its launch batches was to close off the project. As explained in paragraphs 6.734 to 6.736 above, on 27 June 2014 AMCo told Aesica that AMCo's 10mg hydrocortisone tablets project would *'be suspended for the UK territory'*, adding: *'Please cancel your plans for the manufacture of further batches.'*²⁷³⁴ [AMCo Senior Employee 5] later described this, to Aesica and to AMCo colleagues, as *'the cancellation of the*

²⁷³¹ Document 204922, AMCo's RSSO, paragraphs 3.709-3.711. See also Document 203737, AMCo's RSO, paragraph 3.399.

²⁷³² Document 204922, AMCo's RSSO, paragraphs 3.711 and 3.392. Document 205508, transcript of AMCo's hearing on the SSO dated 10 September 2020, page 64 line 6 to page 69 line 4.

²⁷³³ Document 200124, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 2], [AMCo Senior Employee 7] and [AMCo Employee], copied to [AMCo Senior Employee 1], [AMCo Senior Employee 6], [AMCo Employee], [X] and [AMCo Employee], dated 25 June 2014.

²⁷³⁴ Document 200275, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 27 June 2014.

UK project'.²⁷³⁵ When Aesica later notified AMCo of the fact that its launch batches had been packed in the wrong foil (in September 2014) Aesica stated: *'Please could you review if these packs have been distributed from AMCO. Aesica MM believe you have not distributed this as AMCo has cancelled all orders going forward*'.²⁷³⁶

- 6.846. AMCo did not provide any basis for its representation that the suspension of the Aesica project for the UK was *'a result of a misunderstanding'*.
- 6.847. There is no contemporaneous documentary evidence to suggest that [AMCo Senior Employee 5] had misunderstood the position in his summary of the 25 June 2014 meeting. Both [AMCo Senior Employee 2] and [AMCo Senior Employee 1] (who was at the heart of AMCo's negotiations with Auden) received [AMCo Senior Employee 5]'s summary and their subsequent behaviour is consistent with what [AMCo Senior Employee 5] having set out being accurate. Neither corrected any perceived error and there is no evidence that a follow-up email was circulated to the business to correct any misunderstanding.
- 6.848. In fact, having received [AMCo Senior Employee 5]'s summary, [AMCo Senior Employee 2] contacted [AMCo Senior Employee 1] to raise a concern that the development team who had been responsible for developing AMCo's 10mg tablets in conjunction with Aesica may be demotivated as a result of *'hearing today at PPRM that all their efforts to get Hydrocortisone ready for launch have been "wasted" because we're now not planning to sell the product*'.²⁷³⁷ [AMCo Senior Employee 1] replied: *'Yes you are right ... and I agree with everything you say'*.²⁷³⁸
- 6.849. There is nothing in [AMCo Senior Employee 1]'s subsequent email to the development team in question that suggests that the suspension of the development was temporary or that [AMCo Senior Employee 5] had

²⁷³⁵ Document 202717, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 14 July 2014. See also Document 202992, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 30 June 2014. AMCo also submitted that it suspended the project because of frustration with Aesica's performance: *'Exasperated by Aesica, [X] [AMCo Senior Employee 5] suspended the Aesica development project on 27 June 2014'*. Document 204922, AMCo's RSSO, paragraph 3.889. See also Document 203737, AMCo's RSO, paragraph 3.178. This representation conflicts with AMCo's representation that it suspended the project *'only temporarily for a few days ... as a result of a misunderstanding'*. In any event, the Second Written Agreement was given as the reason for suspending the project in the *'Summary of agreement'* on 25 June 2014 (Document 200124) – that [AMCo Senior Employee 5] did not refer to this when communicating with Aesica reflects the fact that [AMCo Senior Employee 5] stated to AMCo management in the next sentence: *'We will advise Aesica that the project is now parked due to delays but may be restarted in the future (we do not mention the Auden agreement)'* (original emphasis).

²⁷³⁶ Document 200310, Aesica exception report dated 5 September 2014, page 3 (emphasis added).

²⁷³⁷ Document 200125, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1], copied to [AMCo Senior Employee 4] and [AMCo Senior Employee 5], dated 25 June 2014.

²⁷³⁸ Document 200125, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 25 June 2014.

misunderstood the situation. Instead it is entirely consistent with what [AMCo Senior Employee 5] set out (and the CMA's findings):

'I just wanted to drop you a note to thank you for all the effort that you put into bringing the Aesica Hydrocortisone product to a position where we were able to launch.

*As you know we have subsequently signed a deal with Auden Mackenzie [sic] to source product from them and therefore our own product will not be launched in UK.*²⁷³⁹

- 6.850. [AMCo Employee], one of the recipients of [AMCo Senior Employee 1]'s email, stated in interview in relation to this email that: *'we were told all the time to get it done, get it done, and we were under so much pressure to launch, to be ready to launch as soon as possible ... I probably was a bit annoyed that, you know, we were told all the time to get it done, get it done, for then the last minute not getting launched.'* She believed that her colleague [AMCo Senior Employee 7] had the same reaction, *'but other than that I really can't recall anyone else saying anything'* following [AMCo Senior Employee 1]'s email to the team.²⁷⁴⁰
- 6.851. Further contemporaneous documentary evidence demonstrates that the project was suspended because of the continued payments AMCo had secured in the Second Written Agreement. For example, as late as May 2015 [AMCo Employee] was reporting internally that *'about a year ago we [AMCo] struck a deal with Auden Mckenzie to market their product rather than our own and the project was effectively stopped.'*²⁷⁴¹
- 6.852. As explained in paragraphs 6.748 to 6.757 above, AMCo only seriously re-engaged with its own product for the UK market once it became concerned about whether Auden would continue to supply it after AM Pharma was acquired by Allergan, several months (not *'a few days'*) after entering into the Second Written Agreement. On 27 January 2015, the day after the Allergan acquisition was announced, [AMCo Senior Employee 2] wrote to [AMCo Senior Employee 1]: *'Main issue now is whether Actavis will continue to*

²⁷³⁹ Document 200126, email from [AMCo Senior Employee 1] to AMCo staff dated 28 June 2014 (emphasis added).

²⁷⁴⁰ Document 203290, transcript of [AMCo Employee] interview dated 25 June 2019, page 29 lines 25-26 and page 30 lines 5-7 and 16-18.

²⁷⁴¹ Document 202693, email from [AMCo Employee] to [AMCo] dated 14 May 2015. See also Document 202732, email from [AMCo Employee] to AMCo staff dated 14 August 2014: *'The batches won't be [sic] sold because of contractual reasons (commercial). They are not rejected'*; Document 202723, email from [AMCo Employee] to AMCo staff: *'The batch manufactured at the end of last year is now packed but there is no intention to release it to the market due to contractual reasons'*; Document 202732, email from [AMCo Employee] to AMCo staff dated 20 August 2014: *'for contractual reasons, we cannot sell this product in the UK'*; Document 202732, email from [AMCo Employee] to AMCo staff dated 8 September 2014: *'Batches will not get release for sale as we are not going to market our product in UK as per our agreement with Auden Mckenzie'*.

supply. We should get ready to sell our own product, just in case'. [AMCo Senior Employee 1] replied 'Agreed! If I remember thought [sic] there is still some work to do to get it ready', to which [AMCo Senior Employee 2] responded: '[n]ot a lot though'.²⁷⁴² This prompted AMCo to 'resurrect our original plan and market our product in the UK'.²⁷⁴³ to submit its application to vary its MA to allow for the thinner foil on its launch batches, and to order two further batches from Aesica, which it described as 'an insurance policy' that would only be used if required.²⁷⁴⁴

'AMCo's efforts to develop its own 10mg product disprove the CMA's finding that it was bought off by Auden/Actavis'

6.853. AMCo and Cinven submitted that the steps AMCo took to develop its own product during the term of the 10mg Agreement fatally undermined the CMA's finding that it had agreed to be bought off instead of entering with that product.²⁷⁴⁵

6.854. The evidence set out in section 6.D.II.b.ii above demonstrates that AMCo received substantial payments from Auden/Actavis. The evidence set out in paragraphs 6.594 to 6.783 above demonstrates that both parties understood that those payments were to buy off AMCo's competitive threat. For example:

- a. [Auden Senior Employee 1] explained that Auden supplied AMCo at a price of £1 per pack, a 97% discount to market rate, because AMCo ceased to be a 'pure wholesaler' when it acquired the 10mg MA from Waymade and '[w]e [Auden] wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]'.²⁷⁴⁶
- b. [AMCo Senior Employee 1] succeeded in doubling AMCo's payments in the Second Written Agreement by threatening to launch AMCo's product ('I told him [[Auden Senior Employee 1]] that if not we will launch our own'.²⁷⁴⁷

²⁷⁴² Document 202762, emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 27 January 2015. See also Document 202763, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 28 January 2015 (*We may ... may ... bring back our own Hydrocortisone manufactured at Aesica as we are concerned that Actavis may pull the Auden product from us*) (emphasis in original).

²⁷⁴³ Document 202783, email from [AMCo Employee] to [X] dated 14 April 2015.

²⁷⁴⁴ Document 202948, email from [AMCo Senior Employee 7] to [AMCo Employee] dated 12 February 2015.

²⁷⁴⁵ Document 204922, AMCo's RSSO, paragraphs 3.785ff. and 5.100. Document 204967, Cinven's RSSO, paragraphs 3.22ff.

²⁷⁴⁶ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20..

²⁷⁴⁷ Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8] and others dated 14 January 2014.

- 6.855. AMCo's efforts to develop its Aesica product are consistent with the evidence that both sides understood that the payments were to buy off AMCo's competitive threat.
- 6.856. As explained in section 3.F.III.f.i above, after acquiring the 10mg hydrocortisone tablets development and the 10mg MA from Waymade on 31 October 2012, AMCo engaged only sporadically with Aesica in the 14 months prior to the January 2014 crisis in relations with Auden. Its senior management had limited involvement in the project, which had yet to be submitted to the AMCo board for approval.
- 6.857. As explained in section 3.F.III.f.ii and paragraphs 6.626 to 6.665 above, the apparent breakdown in negotiations between AMCo and Auden in January 2014 prompted AMCo's senior management to engage with its Aesica project. The prospect that the 10mg supply deal would end sooner than anticipated meant the Aesica project became a priority and was submitted to the AMCo board for approval at the end of the month.²⁷⁴⁸ The '*Rationale*' for the project was to provide '*Back-up product to ensure continuity of supply in case our existing distribution agreement with Auden McKenzie for Hydrocortisone is not renewed.*'²⁷⁴⁹
- 6.858. As explained in sections 3.F.III.g and j above, AMCo then brought its Aesica product to the verge of launching. By 23 June 2014 AMCo expected its product to be available for launch during the following month, July 2014.²⁷⁵⁰ However, two days later AMCo succeeded in doubling its volumes from Auden in the Second Written Agreement and on the same day suspended its Aesica project (see paragraphs 6.725 to 6.728 above).
- 6.859. As explained in section 3.F.III.n and paragraphs 6.748 to 6.757 above, in January 2015 the news that AM Pharma was to be acquired by Allergan made AMCo concerned that the new owners would terminate the 10mg Agreement. This prompted AMCo once more to re-engage with its Aesica development, submitting its application to vary its MA for the thinner foil and ordering further batches.

²⁷⁴⁸ For example, AMCo's perception that there was '*real risk around continuity of supply from the current source (Auden McKenzie)*' (Document 202599, email from [AMCo Senior Employee 2] to [AMCo Employee], [X], [AMCo Employee] and [X] dated 2 January 2014) prompted it to '*get our back-up option moving*' (Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014) and '*get a really clear plan in place how to launch our product*' (Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8] and others dated 14 January 2014).

²⁷⁴⁹ Document 202632, January 2014 Business Development & Licensing Report PPRM Recommendations for Board Approval, page 3. See also Document 202630, January 2014 Business Development & Licensing Report EPRM approvals, slide 3.

²⁷⁵⁰ Document 202686, email from [Aesica Employee] to [AMCo Employee] dated 23 June 2014. See also Document 202684, email from [AMCo Employee] to [AMCo Employee] dated 23 June 2014.

- 6.860. As explained in sections 3.F.III.q and r and paragraphs 6.768 to 6.783 above, in March 2016 AMCo's management reached the view that the scale of independent entry and the erosion of prices it was creating made it unavoidable that it would have to launch its own product rather than continue to sell the Auden/Actavis product it obtained under the Second Written Agreement. When preparing to launch, AMCo staff confirmed that *'Ours has always been merely a back up until now. [...] It may change if Auden do not renew the agreement which seems likely and is why we are stocking up on our own MA'*.²⁷⁵¹
- 6.861. The fact AMCo sporadically continued the development of its own 10mg tablets with Aesica during the lifetime of the 10mg Agreement therefore does not undermine the CMA's findings regarding the existence of the 10mg Agreement and its terms.

'AMCo's volumes were not restricted'

- 6.862. Auden/Actavis, Cinven and AMCo submitted that the volumes Auden/Actavis supplied to AMCo under the 10mg Agreement were not limited or subject to a cap. They pointed to the specification of *'minimum'* volumes in the Second Written Agreement and the fact that on one occasion during the term of the First Written Agreement AMCo ordered more than its usual 6,000 monthly packs.²⁷⁵²
- 6.863. The evidence that the volumes available to AMCo at the heavily discounted price were limited is overwhelming. It is set out in sections 3.F.III.g.i and 3.F.III.j.i above and includes the fact that AMCo's exceptional orders for more than 6,000 packs were refused by Auden.²⁷⁵³ Although the Second Written Agreement referred to *'minimum'* volumes, Auden/Actavis was not obliged to supply more than 12,000 packs per month at the £1.78 price.²⁷⁵⁴ [AMCo Senior Employee 3] therefore referred to *'set supply quantities each month of 12k units'*,²⁷⁵⁵ while its [AMCo Senior Employee 8] stated: *'There is*

²⁷⁵¹ Document 202850, conversation between [AMCo Employee] and [AMCo Senior Employee 5] dated 3 March 2016.

²⁷⁵² Document 205217, Auden/Actavis's RSSO, paragraphs 5.16.2.1 and 5.16.5. Document 204967, Cinven's RSSO, paragraphs 4.59-4.64. See also Document 203737, AMCo's RSO, paragraph 7.174; Document 201235, Auden/Actavis's RSO2, paragraph 1.11; Document 203736, Cinven's RSO, paragraph 5.42.

²⁷⁵³ See Document 00052, emails between AMCo and Auden dated 13 and 14 January 2014, and Document 200085, emails between AMCo staff dated 14 January 2014.

²⁷⁵⁴ Document 00446, Second Written Agreement dated 25 June 2014, clauses 5.1 and 5.2 and Schedule A. See also document 200452, note of state of play meeting with AMCo dated 18 May 2016, paragraph 29: *'AMCo had pushed for – and had wanted – more volume but as far as he [[AMCo Senior Employee 8]] was aware AMCo had only ever got a volume of 12,000 packs, and AMCo at times had to push hard to even get supply at that volume. The reference to a "minimum" volume was at AMCo's request because AMCo wanted to make sure that it would definitely get at least 12,000 packs per month and that Auden would be in breach of the agreement if they did not supply this minimum amount.'*

²⁷⁵⁵ Document 200141, email from [AMCo Senior Employee 3] to AMCo staff dated 24 July 2015.

a volume cap in this OLS agreement'.²⁷⁵⁶ Auden/Actavis staff noted: *'it's a set volume at a set price' and 'I make sure that they have just the 1 order a month for 12,000 packs'*'.²⁷⁵⁷

6.864. It is therefore not credible for the parties to dispute that the volumes available to AMCo at the heavily discounted price were limited.

'Delays to AMCo's entry were due to the absence of demand for its product'

6.865. AMCo and Cinven submitted that AMCo did not launch its skinny label 10mg tablets until May 2016 because it did not believe until April 2016 that there was demand for its product.²⁷⁵⁸

6.866. The factual elements of this representation are addressed by the evidence discussed in section 3.E.IV above and in Annex D to this Decision. That evidence shows that throughout the period prior to Alissa's entry in October 2015, there was an expectation in the market that there would be demand for skinny label tablets once they were launched – as the number of suppliers that sought to enter with skinny label tablets attests – even if the extent of such potential demand was uncertain. The very fact that AMCo was able to use the threat of its entry as leverage to extract greater payments from Auden, most clearly when renewing the supply deal in the Second Written Agreement, demonstrates this. In particular, as explained in Annex D, AMCo consistently projected selling at least 10,000 to 12,000 packs per month of its skinny label hydrocortisone tablets (between 13% and 16% of total volumes) from 2014 onwards, including in mid-2014, ten days before entering into the Second Written Agreement.²⁷⁵⁹

6.867. The parties did not submit any contemporaneous evidence to support their claim that there was no demand or that there was an expectation that there would be no demand (as opposed to uncertainty about the extent of demand) for skinny label tablets before 2016, or that displaces the contemporaneous evidence discussed in section 3.E.IV and Annex D.²⁷⁶⁰

²⁷⁵⁶ Document 200203, email from [AMCo Senior Employee 8] to AMCo staff dated 23 September 2015.

²⁷⁵⁷ Document 02312, email from [Actavis Senior Employee 4] of Actavis UK to Actavis UK staff dated 28 September 2015; Document 02335, email from [§] to [Actavis Senior Employee 1] of Actavis UK dated 24 February 2016.

²⁷⁵⁸ Document 204922, AMCo's RSSO, paragraphs 3.245, 3.247, 3.488, 3.681, 3.765 and 6.33.2. Document 204967, Cinven's RSSO, paragraphs 1.14.(f), 1.19, 3.2.(c)-(d), 3.3, 3.57, 3.58, 3.98.(b), 4.73, 5.32, 5.52, 6.34, 6.38, 6.44, 6.63, 6.71, 7.43, 9.25 and 10.16.

²⁷⁵⁹ See, for example, Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014.

²⁷⁶⁰ Document 206428, Cinven's response to CMA's section 26 Notice dated 9 April 2021; and Document 206433, AMCo's response to CMA's section 26 Notice dated 9 April 2021.

6.868. In any event, uncertainty about the extent of demand is not a justification for entering into a market exclusion agreement. Undertakings are not permitted to substitute the certainty of cooperation for the uncertainties of competition.

'Delays to AMCo's entry were due to development difficulties'

6.869. AMCo and Cinven submitted that the delays to AMCo's entry with its 10mg product were also attributable to development difficulties.²⁷⁶¹

6.870. The development issues AMCo faced are explained in detail in sections 3.F.III.f, j, l and n above and in Annex C to this Decision. However, notwithstanding those issues it is clear that AMCo:

- a. Was a potential competitor of Auden/Actavis throughout the term of its involvement in the 10mg Agreement (see sections 6.C.II.b.iv and v above); and
- b. Entered into an arrangement under which it sold Auden/Actavis's product rather than its own and took active steps to suspend the development of its own product. The reason given in contemporaneous documents for AMCo's decision not to launch its own product when it believed it was ready was not development issues but AMCo's success in obtaining supply from Auden²⁷⁶² (see paragraphs 6.725 to 6.730 and 6.742 to 6.744 above).

6.871. As explained in paragraphs 6.853 to 6.861 above, AMCo's sporadic re-engagement with its own product is not inconsistent with its common understanding with Auden/Actavis that it would not launch that product in exchange for payments. That AMCo faced some delays in product development was at least in part due to its own deprioritisation of its product when confident of receiving continuing payments from Auden/Actavis.

'AMCo did not use its Focus product as leverage'

6.872. AMCo submitted that: *'It is absolutely clear on the facts that no decision was ever taken by AMCo to try to rely on the Focus development vis-à-vis Auden.'*²⁷⁶³

²⁷⁶¹ Document 204922, AMCo's RSSO, paragraphs 3.680, 3.689-3.692. Document 204967, Cinven's RSSO, paragraphs 1.14(f) and (g), 3.10, 3.54 and 7.40. See also Document 203737, AMCo's RSO, paragraphs 3.33, 3.44 and 3.146; Document 203736, Cinven's RSO, paragraphs 2.3.4 and 5.65. Compare Document 207027, letter from Macfarlanes to the CMA dated 7 July 2021, paragraphs 3.3-3.5.

²⁷⁶² See, for example, Document 202642, email from [AMCo Employee] to [AMCo Employee] dated 8 August 2014: *'Batches will not get cleared for sale as we are not going to market our product in the UK as per our agreement with Auden Mckenzie.'*

²⁷⁶³ Document 204922, AMCo's RSSO, paragraph 3.764.

- 6.873. The CMA's findings do not depend on AMCo taking a decision to use its Focus product as leverage in negotiations regarding the 10mg Agreement or succeeding in doing so.
- 6.874. However, the evidence discussed in paragraphs 6.768 to 6.776 above shows that AMCo's senior management, having used its Aesica product as leverage to secure the Second Written Agreement, subsequently formulated a strategy of using the competitive threat that the Focus product may have additionally posed to Auden to secure yet more favourable supply terms.²⁷⁶⁴
- 6.875. For example, in correspondence with [AMCo Senior Employee 3] in September 2015 [AMCo Senior Employee 1] explained what he saw as the Focus product's key role: *'The most important job they [the Focus management] have to do for us is negotiated [sic] with Actavis/Auden and get the highest level of monthly volume'*.²⁷⁶⁵ In other words, [AMCo Senior Employee 1] saw a greater value in using the Focus product as leverage to secure higher volumes of discounted 10mg hydrocortisone tablets from Auden/Actavis than in launching the Focus product independently.
- 6.876. AMCo did not ultimately proceed with this strategy because independent entry occurred in the marketplace (with Alissa launching its 10mg hydrocortisone tablets in October 2015, followed by Resolution Chemicals and Bristol Laboratories in early 2016). As [AMCo Senior Employee 3] explained to the Focus management: *'we are not in a position to move ahead. There have been some major movements in the market with Bristol, Lucis, Alissa etc. launching as well as some other unforeseen complications'*.²⁷⁶⁶ Independent entry gave rise to competition in the market and rendered AMCo's strategy of leveraging the competitive threat of further entry redundant. AMCo therefore took the view that it had no alternative but to launch its own product. For example, as explained in paragraphs 6.777 to 6.783 above, [AMCo Senior Employee 3]'s assessment of *'The imperfect*

²⁷⁶⁴ AMCo also considered using its skinny label tablet development with German CMO MIBE as leverage to obtain further supplies of 10mg hydrocortisone tablets from Auden/Actavis, in a similar way to its Focus product. On 6 November 2015 AMCo considered the MIBE *'project as incremental considering that we would get approx.. 4,000 boxes more a month from Auden'* once it obtained its MA in 2016. AMCo assumed that it could secure supply of 4,000 additional packs from Auden on the assumption that *'we don't have sales generated from MIBE'*. Document 202932, spreadsheet titled 'Hydrocortisone TABLETS 10MG X 30 – JANILA', see 'Cover' and 'Incremental Auden #11' tabs. However, as with the Roma/Focus proposal, AMCo ultimately decided not to pursue the MIBE development in May 2016 since *'the number of entrants reduces the need to utilise all our developments'* (Document 202910, email from [AMCo Employee] to [AMCo Employee], [AMCo Senior Employee 5] and [AMCo Senior Employee 3] dated 24 May 2016. See also Document 202905, email from [AMCo Employee] to [AMCo Employee] dated 17 May 2016).

²⁷⁶⁵ Document 202821, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 3] dated 1 September 2015 (emphasis added).

²⁷⁶⁶ Document 202858, emails from [AMCo Senior Employee 3] to [Focus Senior Employee 2] dated 14 March 2016.

storm’ caused by new entry, price erosion and the uncertainty of whether the 10mg Agreement would be renewed meant *‘We cannot delay any longer’*.²⁷⁶⁷

‘AMCo did not treat its Aesica development project as a ‘back-up’”

6.877. AMCo and Cinven submitted that AMCo did not treat its Aesica product as a back-up in case supply from Auden/Actavis ended.²⁷⁶⁸

6.878. The description of the Aesica product as a *‘back-up’* to supply from Auden/Actavis is one used consistently by AMCo staff and senior management in the contemporaneous evidence. This evidence is very extensive (see paragraphs 6.649 to 6.665, 6.737 to 6.740, 6.750 to 6.756 and 6.777 to 6.783 above). For example:

- a. The slides prepared for AMCo’s January 2014 EPRM and PPRM meetings stated that the *‘Rationale’* for the project was: *‘Back up product to ensure continuity of supply in case our existing agreement with Auden Mckenzie for Hydrocortisone is not renewed.’*²⁷⁶⁹
- b. [X] explained to a colleague that *‘We have our own development, which is manufactured by Aesica. We inherited this from Amdipharm, and it was recently resurrected as a back-up in the event that Auden was no longer willing to supply us.’*²⁷⁷⁰
- c. [X] [AMCo Senior Employee 3] stated: *‘We have our own product MA which we source from Aesica and we have stock but we do not sell it. This is a back up in case Auden pull our supply’*.²⁷⁷¹
- d. When AMCo finally prepared to launch its product in March 2016, its [AMCo Senior Employee 5] stated: *‘Ours has always been merely a back up until now ... It may change if Auden do not renew the agreement which seems likely and is why we are stocking up on our own MA’*.²⁷⁷²

6.879. The parties did not engage with this evidence, let alone seek to challenge, on the basis of other evidence, its probative value. AMCo simply stated, without evidence, that the phrase *‘back-up’* reflected *‘an isolated view of a*

²⁷⁶⁷ Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016. See also Document 202917, ‘Concordia Commercial UK and Ireland Jul 2016’ slide pack, slides 14 and 15.

²⁷⁶⁸ Document 204922, AMCo’s RSSO, paragraphs 3.773 and 3.782. Document 204967, Cinven’s RSSO, paragraphs 1.14(b) and 3.2(b). See also Document 203737, AMCo’s RSO, paragraphs 3.341 and footnote 1022; Document 203736, Cinven’s RSO, paragraphs 6.140-6.142 and 6.145-6.146.

²⁷⁶⁹ Document 202630, January 2014 EPRM slides; Document 202632, January 2014 PPRM slides.

²⁷⁷⁰ Document 202718, email from [AMCo Employee] to [AMCo Employee] dated 14 August 2014.

²⁷⁷¹ Document 202738, email from [AMCo Senior Employee 3] dated 27 November 2015.

²⁷⁷² Document 200385, online conversation between [AMCo Senior Employee 5] and [AMCo Employee] dated 3 March 2016.

few individuals that the commercial prospect of the Aesica product was likely nil due to the OD [orphan designation] issue'.²⁷⁷³ This is not what the contemporaneous documents, which are authored by some of the most senior members of AMCo staff, say.

²⁷⁷³ Document 204922, AMCo's RSSO, paragraph 3.782.

III. The object of the Agreements

- 6.880. The CMA finds that the Agreements had an anti-competitive objective: to share the market for hydrocortisone tablets between Auden/Actavis and each of Waymade and AMCo.
- 6.881. The CMA therefore concludes that each of the Agreements reveals in itself a sufficient degree of harm to be characterised as a restriction of competition by object having regard to its:
- a. legal and economic context;
 - b. content; and
 - c. objective.²⁷⁷⁴

a. The legal and economic context of the Agreements

- 6.882. In summary, the CMA makes the following findings on the legal and economic context of the Agreements (see section 6.C.II above):
- a. Hydrocortisone tablets are a very old drug. They were long off patent and were in the third stage of the drug lifecycle.
 - b. They were unbranded generics (as a result of Auden's action in de-branding them): as such, price would have been the key driver of any competition that might materialise (see paragraphs 6.94 to 6.106 above);
 - c. The market was highly concentrated: Auden was the sole supplier (see paragraph 6.99 above);
 - d. Auden had exploited that position to increase prices very significantly (see section 3.F.I (*Facts relevant to the Unfair Pricing Abuses*) above);
 - e. Auden's high prices meant that it was attractive for other generic manufacturers to develop their own hydrocortisone tablets to enter the market. These competing tablets were homogenous (bioequivalent) with Auden's (see section 3.D above).
 - f. Waymade and AMCo were the first two generics to develop their own hydrocortisone tablets. Both were potential competitors to Auden. The potential for entry represented a competitive threat to Auden's

²⁷⁷⁴ C-67/13 P *Groupeement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 53, citing C-32/11 *Allianz Hungaria v Commission*, EU:C:2013:160, paragraph 36 and the case law cited. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 27.

monopoly position and created scope for volume loss and price falls, including (in the case of 10mg tablets) through off-label dispensing (see paragraphs 6.107 to 6.113 and sections 6.C.II.b.ii, iii and iv above);²⁷⁷⁵ but

- g. Each of the parties stood to gain if competition was avoided. Price falls would be avoided and prices would remain high or increasing, with them sharing what continued to be monopoly profit (see paragraphs 6.114 to 6.115 above).²⁷⁷⁶

b. Content and objectives of the Agreements

- 6.883. The content and objectives of the Agreements must be considered in light of the context outlined above.
- 6.884. The CMA finds that the 20mg and 10mg supply agreements were a sham: their true purpose was for Auden/Actavis to make substantial monthly payments to Waymade and AMCo.
- 6.885. The CMA has found that Auden/Actavis agreed to make these substantial payments in exchange for each of Waymade and AMCo agreeing not to enter the market independently with its own hydrocortisone tablets.
- 6.886. The Agreements therefore represented a “*buying off*” of competition’.²⁷⁷⁷ By entering into the Agreements the parties substituted practical cooperation for the risks of competition.²⁷⁷⁸
- 6.887. It is important that hydrocortisone tablets have been long off patent, are unbranded generic drugs in the third phase of the drug lifecycle and that the Agreements were not patent litigation settlement agreements. Therefore, while the principles underlying the *Lundbeck*, *Paroxetine* and *Servier* judgments are relevant, the Agreements are considerably more straightforward arrangements: simple agreements for exclusion of potential competitors from the market or for market sharing.²⁷⁷⁹ Waymade’s and AMCo’s entry would have been, in principle, favourable to competition, beginning a process resulting in potentially lowering the cost of healthcare. The object of the Agreements was to prevent that.

²⁷⁷⁵ Compare *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 69 and 244.

²⁷⁷⁶ Compare *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 200 and 83.

²⁷⁷⁷ Opinion of Advocate General Trstenjak in C-209/07 *BIDS*, EU:C:2008:467, paragraph 77 (followed in C-209/07 *BIDS*, EU:C:2008:643). Compare T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 352; and T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 233.

²⁷⁷⁸ Compare C-307/18 *GSK v CMA*, paragraph 83, citing C-209/07 *BIDS*, EU:C:2008:643, paragraph 34.

²⁷⁷⁹ Compare *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 244; and C-307/18 *GSK v Commission*, paragraph 76.

6.888. The Agreements were therefore market sharing agreements that aimed to exclude Waymade and AMCo from the market, thereby protecting Auden/Actavis's volumes, its dominant position and its associated ability to charge high prices. In exchange, a portion of Auden/Actavis's monopoly profits was shared with Waymade and AMCo. It is well-established that such agreements have as their object the restriction, distortion or prevention of competition.

c. The parties' representations on the object of the Agreements

i. 'The Agreements were not by their very nature harmful to normal competition'

6.889. Auden/Actavis submitted that the Agreements were not harmful by their very nature to '*normal competition*' for generic drugs. It submitted that economic theory and observation show that the second entrant usually prices around the same level as the incumbent.²⁷⁸⁰ It submitted that the Agreements therefore caused no harm to '*normal competition*' – absent the Agreements market prices would have been the same.²⁷⁸¹

6.890. This argument sidesteps the CMA's findings and the evidence set out in this section 6. It is no more than an assertion that the CMA should have assessed whether the Agreements were restrictive of competition by effect.

6.891. The CMA has found the Agreements to be restrictive of competition by object. It is trite law that a market exclusion agreement is an object restriction.²⁷⁸² There is no need to consider economic theory or a counterfactual to show this. As the European General Court held in *Lundbeck*:

'The examination of a hypothetical counterfactual scenario – besides being impracticable since it requires the Commission to reconstruct the events that would have occurred in the absence of the agreements at issue, whereas the very purpose of those agreements was to delay the market entry of the generic undertakings ... is more an examination of the effects of agreements at issue on the market than an objective examination of whether they are sufficiently harmful to competition.'

²⁷⁸⁰ Document 205217, Auden/Actavis's RSSO, paragraphs 5.22-5.25 and 5.28-5.29.

²⁷⁸¹ Document 205217, Auden/Actavis's RSSO, paragraphs 1.13.2, 1.16.2, 5.7, 6.30.1-6.30.2 and 7.175.1. See also Document 207027, letter from Macfarlanes to the CMA dated 7 July 2021, paragraphs 1.2.1, 2.1 and 2.2.

²⁷⁸² See, e.g., C-373/14 *Toshiba Corporation v Commission*, EU:C:2016:26, paragraph 28; C-449/11 *Solvay Solexis v Commission*, EU:C:2013:802, paragraph 82; and C-408/12 *YKK and Others v Commission*, EU:C:2014:2153, paragraph 26.

Such an examination of effects is not required in the context of an analysis based on the existence of a restriction of competition by object

...

*what matters is that those undertakings had real concrete possibilities of entering the market at the time the agreements at issue were concluded with Lundbeck, with the result that they exerted competitive pressure on the latter. That competitive pressure was eliminated for the term of the agreements at issue, which constitutes, by itself, a restriction of competition by object’.*²⁷⁸³

- 6.892. This aspect of the General Court’s judgment was expressly upheld by the European Court of Justice,²⁷⁸⁴ which noted that:

*‘unless the clear distinction between the concept of ‘restriction by object’ and the concept of ‘restriction by effect’ arising from the wording itself of Article 101(1) ... is to be held not to exist, an examination of the ‘counterfactual scenario’, the purpose of which is to make apparent the effects of a given concerted practice, cannot be required in order to characterise a concerted practice as a ‘restriction by object’.*²⁷⁸⁵

- 6.893. Competition law protects potential competition as well as actual competition: how the market might behave when potential competition transitions into actual competition is inherently uncertain and undertakings are not permitted to substitute for that uncertainty the certainty of cooperation.²⁷⁸⁶ Market exclusion agreements are therefore a classic example of the type of coordination that can be regarded, by its very nature, as harmful to the proper functioning of normal competition, such that there is no need to examine its effects. Such agreements cannot be justified by an analysis of their economic context.²⁷⁸⁷

- 6.894. In any event, even if Auden/Actavis’s submissions about ‘*normal competition*’ for generic drugs were accepted, a delay to independent entry is a delay to the process of competition and the benefits that will ultimately accrue to consumers. It is that process itself that is significantly harmed by

²⁷⁸³ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraphs 473-474. See also T-141/89 *Trefileurope v Commission*, paragraph 60, citing C-277/87 *Sandoz v Commission*, paragraph 15.

²⁷⁸⁴ C-591/16 P *Lundbeck v Commission*, paragraphs 139-143.

²⁷⁸⁵ C-591/16 P *Lundbeck v Commission*, paragraph 140.

²⁷⁸⁶ See T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 471.

²⁷⁸⁷ C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraphs 26-28; C-67/13 P *Groupement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraphs 49-50; and C-239/11, C-489/11 and C-498/11 *Siemens and Others v Commission*, EU:C:2013:866, paragraph 218.

market exclusion agreements. As the European General Court stated in *Lundbeck* (cited with approval by the CAT in *Paroxetine*):

*'If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes.'*²⁷⁸⁸

6.895. Similarly, the European Court of Justice in *Paroxetine* noted (in relation to 'the proper functioning of normal competition' and specifically the UK):

*'the medicines sector is particularly sensitive to a delay in the market entry of the generic version of an originator medicine. Such a delay leads to the maintenance on the market of the medicine concerned of a monopoly price, which is very appreciably higher than the price at which generic versions of that medicine would be sold following their market entry and which has considerable financial consequences, if not for the final consumer, at least for social security authorities.'*²⁷⁸⁹

6.896. As explained in section 6.C.II above, these statements apply *a fortiori* to this case, in which all competition was generic and Auden was no originator.

6.897. The CMA has explained the economic and legal context to the Agreements in that section. In *Lexon (UK) Limited v CMA* [2021] CAT 5, the CAT held that similar factors in a purely generic market meant that it could not 'seriously be contended' that anti-competitive activity was incapable of having any significant effect on the market; and that such factors were 'clearly sufficient for the CMA to conclude that the seriously harmful nature of the conduct in question was not negated by its economic and legal context'.²⁷⁹⁰ The CAT therefore dismissed Lexon's argument that 'in the real world, the conduct in question could not have an adverse, or a sufficiently adverse, effect on competition in the market concerned'.²⁷⁹¹ The same reasoning applies to Auden/Actavis's submission in the present case.

²⁷⁸⁸ T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 171, cited with approval in *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 158.

²⁷⁸⁹ C-307/18 *GSK v Commission*, paragraphs 67-70.

²⁷⁹⁰ *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 200, 201 and 207.

²⁷⁹¹ *Lexon (UK) Limited v CMA* [2021] CAT 5, paragraphs 170, 199, 207, 231 and 244.

ii. The parties' representations on the object of the supply deals

- 6.898. Each of the parties responded to the CMA's provisional findings on the object of the Agreements in the SSO by redefining the agreements to exclude the commitment of Waymade and AMCo not to enter the market.²⁷⁹² Their submissions on restriction by object focused on the object of the supply agreements alone, without the counter-performance.²⁷⁹³
- 6.899. It is not the supply agreements in themselves that the CMA has found to restrict competition, but the Agreements as defined in paragraphs 6.3 to 6.4 and 6.17 to 6.18 above, which include the reciprocal commitments by Waymade and AMCo not to enter the market. These submissions depend on ignoring that counter-performance. They focus only on why Waymade and AMCo took the supply deals from Auden/Actavis but provide no answer to what the common understanding of the parties was: they do not explain why Auden/Actavis would agree to give Waymade or AMCo those deals.
- 6.900. These representations therefore sidestepped the case entirely.²⁷⁹⁴ They are addressed for completeness only.

'The CMA applied the wrong legal test for restriction by object'

- 6.901. Applying their mischaracterisation of the case, the parties submitted that the pay for delay cases were irrelevant:
- a. Auden/Actavis submitted that the pay for delay cases were irrelevant because *'Neither AMCo nor Waymade entered into any agreement*

²⁷⁹² For example, in the first paragraph of its RSSO, Cinven redefined the 10mg Agreement to encompass only the supply deals, without the counter-performance of non-entry, thus sidestepping the case. See Document 204967, Cinven's RSSO, paragraphs 1.1, 1.26, 1.31, 7.4(b), 7.12, 7.20 and 7.39. See also Document 204922, AMCo's RSSO, paragraphs 3.604, 3.688, 3.692 and 5.28; Document 205217, Auden/Actavis's RSSO, paragraphs 1.12, 1.13, 5.2, 5.6 and 5.33; Document 204903, Waymade's RSSO, paragraphs 2.20, 2.25, 7.23, 7.49, 7.151 and 8.86.

²⁷⁹³ See, for example, Document 204922, AMCo's RSSO, paragraph 5.28; Document 204967, Cinven's RSSO, paragraphs 1.31, 7.12, 7.20 and 7.39; Document 205217, Auden/Actavis's RSSO, paragraphs 1.12, 1.13, 5.2, 5.6 and 5.33; Document 204903, Waymade's RSSO, paragraphs 7.141-7.153 and 8.136-8.141.

²⁷⁹⁴ For example, Waymade, AMCo and Cinven submitted that the object of the supply agreements was simply to provide Waymade and AMCo with supply of hydrocortisone tablets, as a 'stop-gap' until their own products were ready. Document 204903, Waymade's RSSO, paragraphs 2.20, 2.25, 7.23, 7.49, 7.151 and 8.86; Document 204922, AMCo's RSSO, paragraphs 3.604, 3.688 and 3.692; Document 204967, Cinven's RSSO, paragraphs 1.26, 7.4(b) and 7.47ff. This argument is in any event unconvincing on its own terms. As explained above, Waymade explicitly linked its entry into the 20mg Agreement with its decision to 'freeze' its 20mg product and pause work on reformulation. As explained in section 3.F.III.j.ii above, at the time of entering into the Second Written Agreement AMCo believed that it would imminently be receiving launch-ready product from Aesica. It took steps to suspend its Aesica project on the same day as entering into that agreement, when it believed that the product was saleable. This behaviour is not consistent with Waymade or AMCo looking for a 'stop-gap' while they sought to resolve the issues with their own products. Cinven and Auden/Actavis also submitted that a value transfer is not in itself anticompetitive (Document 204967, Cinven's RSSO, paragraphs 4.49, 4.58, 7.84 and 7.86. Document 205217, Auden/Actavis's RSSO, paragraphs 5.7.1, 5.27 and 6.29). The CMA does not allege that the payments Auden/Actavis made to Waymade and AMCo were in themselves anticompetitive. It is the 10mg Agreement, under which Waymade and AMCo agreed not to enter in exchange for those payments, that is anticompetitive.

whereby they committed not to enter the market'.²⁷⁹⁵ Auden/Actavis submitted that: *'The supposed effect of the agreement on the prices of Hydrocortisone Tablets and each of AMCo and Waymade's incentives alone is not sufficient to demonstrate an anti-competitive object (absent a concurrence of wills between the Parties to such an objective)'*.²⁷⁹⁶

- b. AMCo submitted that the pay for delay cases, which arose in the context of patent disputes, *'are of no application to the circumstances of this case'*.²⁷⁹⁷ It submitted that the pay for delay cases cannot *'properly be relied on to find a commitment not to enter the market independently'*.²⁷⁹⁸ AMCo also submitted that the General Court's judgment in *KRKA v Commission* establishes that the simple fact that the terms of a supply agreement are favourable is not enough to establish an object infringement.²⁷⁹⁹
- c. Waymade submitted that the facts of the pay for delay cases *'bear no resemblance to those of this case'*.²⁸⁰⁰
- d. Cinven submitted that the situation in the pay for delay cases *'has nothing to do with the present case'*.²⁸⁰¹

6.902. The relevance of the pay for delay cases, and the differences between the facts of those cases and the present case, are explained in paragraphs 6.120 to 6.122 and 6.339 to 6.356 above. As the caselaw recognises, pay for delay agreements are a form – indeed *'an extreme form'* – of market sharing.²⁸⁰²

6.903. In this case the CMA has found a concurrence of wills between the parties to market exclusion agreements. That concurrence of wills is demonstrated by a body of evidence – not simply the fact that the terms of the supply agreements were favourable or created incentives for Waymade and AMCo.

6.904. While on the one hand submitting that the pay for delay cases were irrelevant, the parties on the other submitted that, based on those cases, the CMA should be held to a higher legal standard than that set out in *Cartes Bancaires*:

²⁷⁹⁵ Document 205217, Auden/Actavis's RSSO, paragraphs 6.17-6.21.

²⁷⁹⁶ Document 205217, Auden/Actavis's RSSO, paragraph 6.8 (emphasis added).

²⁷⁹⁷ Document 204922, AMCo's RSSO, paragraph 1.45.2.

²⁷⁹⁸ Document 204922, AMCo's RSSO, paragraph 6.92. See also paragraph 6.87.

²⁷⁹⁹ Document 204922, AMCo's RSSO, paragraphs 6.64 and 6.83.

²⁸⁰⁰ Document 204903, Waymade's RSSO, paragraphs 7.143-7.146.

²⁸⁰¹ Document 204967, Cinven's RSSO, paragraph 7.85.

²⁸⁰² T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 435.

- a. AMCo submitted that in *Paroxetine* the European Court of Justice ‘*laid down a strict test for a finding of a market sharing agreement*’: where an agreement can be justified by a legitimate commercial consideration, ‘*a finding of a restriction by object must be excluded and the CMA must conduct an effects analysis*’.²⁸⁰³ Since on AMCo’s case the orphan designation meant ‘*competition with Auden was plainly not possible*’, it submitted that there could be no object infringement.²⁸⁰⁴
 - b. Auden/Actavis submitted, citing the European Court of Justice’s judgment in *Paroxetine* and Advocate General Kokott’s Opinion in *Lundbeck*, that an agreement cannot be considered a restriction of competition by object unless it is entered into with the sole aim of disguising a market exclusion agreement. It submitted that there can only be a restriction by object where there is no other explanation for the agreement.²⁸⁰⁵ Auden/Actavis stated that ‘*the Court of Justice’s decision in Paroxetine raises the bar such that the CMA must demonstrate that the “sole aim” of the Supply Agreements is the restriction of competition.*’ Auden/Actavis further submitted that since the Agreements could be explained by Auden/Actavis’s legitimate aim of maintaining its CMO volumes, the CMA could not find a restriction by object and must conduct an effects analysis.²⁸⁰⁶
- 6.905. When the full terms of the Agreements – payment in exchange for non-entry – are considered, their sole aim is indeed to restrict competition. These submissions therefore fail on the facts before the legal test is even discussed.
- 6.906. In any event, the European Court of Justice did not lay down any new ‘*strict legal test*’ for a finding of a restriction by object or ‘*raise the bar*’ in *Paroxetine*.²⁸⁰⁷ The Court simply observed that where no other explanation for value transfers can be found, or where it is apparent that an arrangement was designed with the sole aim of disguising a market exclusion agreement, a characterisation of a restriction by object must be adopted.²⁸⁰⁸ That is not the same as saying that an agreement can only be a restriction by object in these circumstances.

²⁸⁰³ Document 204922, AMCo’s RSSO, paragraph 6.21.

²⁸⁰⁴ Document 204922, AMCo’s RSSO, paragraph 6.33.1. See also paragraphs 5.150, 6.34, 6.45, 6.64, 6.79 and 6.83.

²⁸⁰⁵ Document 205217, Auden/Actavis’s RSSO, paragraph 6.30.2.

²⁸⁰⁶ Document 205217, Auden/Actavis’s RSSO, paragraphs 6.30.2 and 6.38.

²⁸⁰⁷ See *GSK v CMA* [2021] CAT 9, paragraph 42

²⁸⁰⁸ C-307/18 *GSK v Commission*, paragraphs 76, 85-87 and 111. Compare C-591/16 P *Lundbeck v Commission*, paragraphs 113-114.

- 6.907. In the pay for delay cases the agreement of the generic not to enter the market was not in dispute, since it was provided as a written contractual commitment. Nor was the existence of a payment to the generic. However, it was necessary to consider whether the generic agreed not to enter in recognition of the strength of the patent (which could be legitimate) or in exchange for the payment (which would be an illegitimate buying-off of competition): whether the ‘pay’ was ‘for delay’.²⁸⁰⁹
- 6.908. In order to determine whether the value transfers were given in exchange for non-entry in those cases, and therefore whether the agreements in issue were object restrictions, the Courts considered whether the value transfers could ‘*prove to be justified*’ by reference to factors such as ‘*sums that correspond in fact to compensation for the costs of or disruption caused by the litigation*’, or ‘*that correspond to remuneration for the actual supply, immediate or subsequent, of goods or services*’; or by the corresponding release of a cross-undertaking in damages. The Courts held that if there is no legitimate ‘*quid pro quo*’ for the value transfers, and the ‘*net gain*’ to the generic from those transfers (meaning the net value transferred to the generic in the context of the settlement agreement, not in comparison to the generic’s expected profits from entry²⁸¹⁰) is sufficiently large to encourage the potential entrant not to enter, the value transfers could only be explained by the parties’ mutual interest in avoiding competition and the agreements must be characterised as an object restriction.²⁸¹¹ In that situation it is established that the ‘pay’ was ‘for delay’.
- 6.909. It was the specific context of a potential ‘*genuine dispute*’ relating to a patent that led the Courts to consider such issues in the pay for delay cases.²⁸¹²
- 6.910. This is the context for the Advocate General’s statement in *Lundbeck* that if a value transfer from the incumbent has no explanation other than the common interest of the parties in not competing, the settlement agreement is akin to an object restriction.²⁸¹³ This was confirmed in the European Court of Justice’s judgment, in which the Court found that the settlement agreements

²⁸⁰⁹ See, for example, T-679/14 *Teva v Commission*, EU:T:2018:919, paragraph 220; and Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraphs 604 and 660.

²⁸¹⁰ See *GSK v CMA* [2021] CAT 9, paragraphs 43-45.

²⁸¹¹ C-307/18 *GSK v Commission*, paragraphs 84-95 and 111; *GSK v CMA* [2021] CAT 9, paragraphs 37-51. Compare C-591/16 P *Lundbeck v Commission*, paragraphs 113-115.

²⁸¹² See C-307/18 *GSK v Commission*, paragraph 59; *GSK v CMA* [2021] CAT 9, paragraphs 47-48; C-591/16 P *Lundbeck v Commission*, paragraphs 117-118 and 134.

²⁸¹³ Opinion of Advocate General Kokott in C-591/16 P *Lundbeck v Commission*, paragraph 128. Paragraph 129 makes this explicit. Compare the Commission’s and European General Court’s analysis of the settlement agreement between Lundbeck and Neolab Limited. The General Court agreed with the Commission that under that agreement ‘*the actual object of the reverse payment was to settle a dispute between the parties, without, however, delaying the market entry of generics*’. T-469/13 *Generics (UK) Ltd v Commission*, paragraphs 293-294. Upheld in C-588/16 P *Generics (UK) Ltd v Commission*, paragraph 91.

would amount to an object restriction whether or not they were characterised as market exclusion or market sharing agreements.²⁸¹⁴

- 6.911. As explained in section 6.C.II above, that is not the context for the present case, in which the CMA finds a direct link between the payments and the commitment not to enter, which was made in return for those payments. The present case, which concerns unbranded, long off-patent generic drugs in the third stage of the drug lifecycle, is more analogous to ‘classic’ market sharing cases than the pay for delay cases. With a market exclusion agreement such as the BIDS arrangements or those in *Toshiba*, without a patent context, such considerations did not form part of the test applied by the Courts to confirm that the arrangements at issue were ‘restrictions by object’. In such a context ‘*a mere commitment not to act*’ – not to enter a market – may simply ‘go without saying’.²⁸¹⁵
- 6.912. The legal test for a restriction of competition by object remains that established in *Cartes Bancaires*. It is clear that the Agreements reveal a sufficient degree of harm to competition such that there is no need to examine their effects.²⁸¹⁶
- 6.913. It is, further, trite law that an agreement may be restrictive of competition by object even where it also pursues other, legitimate, objectives. Provided the parties had a common understanding whose terms, assessed objectively, pursued an anti-competitive objective, any ancillary or subjective motivations they may have had for entering into that deal are irrelevant.²⁸¹⁷
- 6.914. In any event, the Agreements cannot be justified by a legitimate commercial consideration:
- a. As explained in section 3.E.IV.a above and Annex D to this Decision, while the extent of demand for skinny label hydrocortisone tablets was uncertain pre-entry, there was never any doubt that there would be some demand. The uncertainty as to the extent of the contestable market at the time the 10mg Agreement was entered into is not a legitimate justification for entering into a market exclusion agreement. Undertakings should not substitute the certainties of cooperation for the

²⁸¹⁴ C-591/16 P *Lundbeck v Commission*, paragraphs 113-118.

²⁸¹⁵ T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraphs 141 and 269.

²⁸¹⁶ C-67/13 P *Groupeement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 49. Compare C-591/16 P *Lundbeck v Commission*, paragraphs 139-141.

²⁸¹⁷ C-209/07 *Competition Authority v Beef Industry Development Society*, EU:C:2008:643, paragraph 21; T-168/01 *GlaxoSmithKline Services Unlimited v Commission*, EU:T:2006:265, paragraph 77 (upheld on appeal in Joined cases C-501/06P etc *GlaxoSmithKline Services Unlimited v Commission*, EU:C:2009:610). See also C-614/16 P *Merck v Commission*, paragraph 92: ‘characterisation as a ‘restriction by object’ does not require that parties to those agreements pursue an anticompetitive objective, even though such an objective may nevertheless be taken into consideration’.

uncertainties of competition. AMCo's proposed legitimate explanation in any event could not explain what consideration Auden/Actavis received under the Agreements: if '*competition with Auden was plainly not possible*', why would Auden agree to make significant payments to AMCo?²⁸¹⁸

- b. As explained in the section that follows, maintaining Auden/Actavis's CMO volumes is not a legitimate explanation – it is a euphemism for market exclusion.

The supply deals 'sought to maintain Auden/Actavis's CMO volumes'

- 6.915. None of the parties has provided any legitimate explanation for the substantial discounts Auden/Actavis gave to Waymade and AMCo.
- 6.916. The only rationale that the parties did suggest for Auden/Actavis's willingness to supply Waymade and AMCo at a discount of 87% and 97% respectively was that it did so in order to maintain the volumes of hydrocortisone tablets that Auden/Actavis ordered from its CMO, Tiofarma (its CMO volumes).²⁸¹⁹ Auden/Actavis stated that '*The risk to Auden was that, absent such volumes, Tiofarma might either increase prices (across the portfolio of products it supplied Auden) and/or cease to support certain products entirely*'.²⁸²⁰
- 6.917. The fact that the incumbent supplier may face negative consequences if entry occurs and it is no longer able to supply the entire market (whether those consequences are purely a drop in profits or entail some form of contractual penalty from the incumbent supplier's manufacturer) is a natural risk of competition and cannot form a justification for entering into an anti-competitive agreement that substitutes cooperation for that risk.
- 6.918. It is not possible to verify what Tiofarma might have done had Auden reduced the volumes in its monthly orders for hydrocortisone tablets before July 2015, when Waymade became the first entrant. However, events following entry suggest that Tiofarma would not have sought to 'penalise' Auden in this way. Tiofarma continued to supply Auden and subsequently Actavis despite its CMO volumes dropping significantly as a result of entry from July 2015 onwards.

²⁸¹⁸ Compare *GSK v CMA* [2021] CAT 9, paragraph 51.

²⁸¹⁹ Document 205217, Auden/Actavis's RSSO, paragraphs 5.33 and 6.30.2.1. Document 204903, Waymade's RSSO, paragraph 2.20. See also paragraphs 7.46-7.48 and 7.139(b) and (c). Document 204967, Cinven's RSSO, paragraph 4.55.

²⁸²⁰ Document 205217, Auden/Actavis's RSSO, paragraph 6.30.2.1. See also paragraph 5.33.

6.919. In any event, the parties' submission that Auden/Actavis's motivation was to protect its CMO volumes is entirely consistent with the CMA's findings. Maintaining Auden/Actavis's CMO volumes necessarily entails preventing entry and the inevitable reduction of Auden/Actavis's sales volumes that would follow. While Auden/Actavis asserted that the CMA had *'failed to demonstrate that the parties considered there to be a link between the upstream manufacturing volumes and the downstream market shares in the supply of tablets'*,²⁸²¹ the link is self-evident and acknowledged by the key players involved in concluding the Agreements. As explained in section 6.C.II above, since Auden/Actavis was the sole supplier of a product whose overall volumes were subject to a ceiling from the number of prescriptions issued, it stood to lose CMO volumes if another supplier entered the market and made any sales (as Auden/Actavis in fact did when entry took place). As [Auden Senior Employee 2] of Auden stated in interview:

'if we didn't supply them [Waymade] at, you know, the wholesale price, that we didn't to everybody else [i.e. the 'special' price], then they would have certainly gone elsewhere to source the 20mg, which wouldn't have aided our objective of maintaining the volumes that we were keen to maintain with our contract manufacturer ...

*I suppose there's a finite number of prescriptions there, so if [Waymade] had their own manufacture and brought product into the market we would then naturally reduce our volumes.'*²⁸²²

6.920. This representation therefore supports the CMA's findings that Auden/Actavis made the supply deals available in order to buy off its competitors' entry.

'The supply agreements were not a sham'

6.921. AMCo and Cinven made extensive representations to the effect that the supply deals were bona fide and not a sham, dealing with the actual terms of the 10mg Agreement only as a secondary point.²⁸²³ They submitted that the CMA had not established, as it must to sustain the allegation that the supply deals were a sham, that everyone involved in the negotiation of the First and

²⁸²¹ Document 205217, Auden/Actavis's RSSO, paragraph 7.90. See also paragraph 7.161 and Document 204903, Waymade's RSSO, paragraph 7.44; and Document 201235, Auden/Actavis's RSO2, paragraphs 10.23, 13.3 and 14.13.

²⁸²² Document 00717, transcript of [Auden Senior Employee 2] interview dated 21 September 2016, part 2, page 2 lines 8-14 and page 4 lines 14-16.

²⁸²³ Document 204922, AMCo's RSSO, paragraphs 1.21-1.22, 1.41, 2.33, 2.54, 2.81, 5.15 and 5.52. Document 204967, Cinven's RSSO, paragraphs 1.10, 1.24, 1.28, 1.33, 2.34, 4.78, 7.37 and 7.43.

Second Written Agreements, including external counsel, was engaged in an elaborate deception to cloak their true intentions.²⁸²⁴

6.922. The description of the supply deals as a sham simply means that the CMA has found their true purpose to be for Auden/Actavis to pay AMCo, rather than simply to give it product to sell as in a genuine bona fide distribution deal.²⁸²⁵ The supply agreements, under which Auden/Actavis supplied AMCo at a 97% discount to its other customers, would not have existed on these terms in the absence of counter-performance from AMCo. The CMA has found that the counter-performance was AMCo's agreement not to enter the market independently. The parties have not proposed any legitimate counter-performance.

6.923. The CMA has not found or alleged an elaborate conspiracy beyond the terms of the 10mg Agreement.

'The supply agreements were vertical 'CMO deals' and not inherently anticompetitive'

6.924. The parties submitted that the supply deals were ordinary vertical distribution arrangements.²⁸²⁶ They submitted that they were 'CMO deals', under which Auden/Actavis supplied AMCo and Waymade 'on a CMO basis' – as if it were Aesica, AMCo and Waymade's CMO.²⁸²⁷ The parties submitted that such arrangements are not inherently anticompetitive. Indeed, Cinven submitted that the supply deals were in fact pro-competitive, by creating competition where there would otherwise have been none.²⁸²⁸

6.925. As explained in section 6.C.II above, each of Waymade and AMCo was a potential competitor of Auden/Actavis when it entered into the relevant Agreement. When the full legal and economic context is taken into account, the relationship between Auden/Actavis and each of Waymade and AMCo was therefore horizontal, not vertical.²⁸²⁹

²⁸²⁴ Document 204967, Cinven's RSSO, paragraphs 1.28, 1.33, 2.34, 4.78 and 7.43.

²⁸²⁵ Compare *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 179 to 180, and *GSK v CMA* [2021] CAT 9, paragraph 47.

²⁸²⁶ Document 204903, Waymade's RSSO, paragraphs 2.20 and 8.112. Document 204922, AMCo's RSSO, paragraphs 5.13, 5.42, 5.65 and 6.61. Document 204967, Cinven's RSSO, paragraphs 2.3, 4.54 and 7.89. See also Document 203737, AMCo's RSO, paragraph 7.53, Document 201235, Auden/Actavis's RSO2, paragraph 1.9.

²⁸²⁷ Document 204922, AMCo's RSSO, paragraphs 3.662, 3.668, 3.670, 3.718, 5.30, 5.62.1, 6.61-6.62 and 6.67. Document 204967, Cinven's RSSO, paragraphs 4.50(a) and 4.55-4.56. Document 204903, Waymade's RSSO, paragraph 7.43. Document 205217, Auden/Actavis's RSSO, paragraphs 5.18 and 7.88. See also Document 203737, AMCo's RSO, paragraphs 3.38, 3.408 and 3.356.

²⁸²⁸ Document 204967, Cinven's RSSO, paragraphs 1.15, 1.33, 4.78, 7.4(b) and 7.43. Document 203736, Cinven's RSO, paragraphs 2.3.6 and 2.12. See also Document 203738, CRA Report submitted by AMCo and Cinven on the 2017 SO, paragraphs 8 and 66-67.

²⁸²⁹ Compare *Lexon (UK) Ltd v CMA* [2021] CAT 5, paragraphs 208-211.

- 6.926. As explained in section 3.E.II above, a CMO is a Contract Manufacturing Organisation, which is essentially a manufacturer to whom an MA holder can outsource the manufacturing of the medicine for which the manufacturer holds an MA. The CMO tends not to hold the MA. Neither AM Pharma nor Accord-UK is a CMO.
- 6.927. These representations take the supply deals as exhaustive of the terms of the Agreements and ignore the common understanding on non-entry that the CMA has found. However, the supply deals amounted to substantial payments to Waymade and AMCo and were only part of the Agreements. The counter-performance for those payments was the common understanding that in return, the recipient would not enter. The Agreements therefore neutralised the constraint Waymade and AMCo exerted on Auden/Actavis through potential competition and delayed the appearance of actual competition. Having their own credible source of supply and having met the regulatory conditions for entering the market on the basis of their MAs, it was not open to Waymade and AMCo to enter into an agreement with the incumbent supplier under which they agreed that instead of entering the market they would take payments from Auden/Actavis.
- 6.928. When their full terms are taken into account, the Agreements were therefore market exclusion agreements that prevented, not created, competition. The anti-competitive object of such agreements cannot be called into question by the fact that Waymade and AMCo may have charged marginally lower prices than Auden/Actavis when reselling the specified volumes they were given under the supply deals. This was the result of Auden/Actavis ceding a part of the market to its potential competitors and not of a normal competitive process.²⁸³⁰

²⁸³⁰ Compare C-591/16 P *Lundbeck v Commission*, paragraphs 133 and 137; C-586/16 P *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission*, paragraphs 82-84. See also *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 297-298 and 308, C-307/18 *GSK v Commission*, paragraphs 103-110, and *GSK v CMA* [2021] CAT 9, paragraphs 54, 57 and 103-106. See also Opinion of Advocate General Kokott in C-591/16 P *Lundbeck v Commission*, paragraph 142.

IV. The parties' subjective intentions

6.929. As explained in section 6.D.I above, the parties' subjective intentions are not a necessary element in the assessment of whether the Agreements were restrictive of competition. They may, however, be taken into account as corroboration of the objective assessment.²⁸³¹

6.930. The subjective intentions of Auden/Actavis, Waymade and AMCo support the assessment of the Agreements' content and objective. The evidence shows that each acted in full knowledge of the objective of the Agreements, which was to make substantial payments to Waymade and AMCo in exchange for each of Waymade and AMCo agreeing not to enter the market independently with its own hydrocortisone tablets.

d. Auden/Actavis

6.931. Auden/Actavis's subjective intention was to preserve its position as sole supplier of hydrocortisone tablets in the UK, and the ability to charge high and increasing prices that it derived from that position. In order to achieve this, it was willing to make payments to Waymade and to AMCo. As explained above:

- a. [Auden Senior Employee 1] stated that Auden needed Waymade's business to maintain sales volumes of Auden's product (manufactured by Tiofarma), and therefore Auden's order volumes from Tiofarma: *'it was always in our interest to try to keep the volumes reasonably level at the CMO. This is why we entered into the arrangement with Waymade for a low supply price'*.²⁸³² As explained above, maintaining Auden's CMO volumes necessarily entails avoiding independent entry.
- b. From the outset, Auden had therefore sought to calibrate a deal that ceded around a third of the market by value to Waymade, on the understanding that Waymade would make *'cost savings ... in not bringing the product to market'*. Auden acknowledged that both parties had an interest in maintaining a high resale price – which the preservation of its position as sole supplier would allow. As [Auden Senior Employee 2] stated in his 28 June 2011 proposal to [Auden Senior Employee 1]: *'Would be happier allowing a lower price on the 20mg because it would be in their [Waymade's] interest to maintain*

²⁸³¹ C-67/13 P *Groupeement des Cartes Bancaires v Commission*, EU:C:2014:2204, paragraph 54; and C-286/13 P *Dole v Commission*, EU:C:2015:184, paragraph 118. See also C-32/11 *Allianz Hungaria v Commission*, EU:C:2013:160, paragraph 37 and the case law cited.

²⁸³² Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.16.

high resale price'.²⁸³³

- c. [Auden Senior Employee 1] stated: '*I recall having an internal discussion which acknowledged Waymade was our competitor and that we could supply it with hydrocortisone tablets...*'.²⁸³⁴ Waymade's status as a potential competitor (signified most clearly by its MAs) was what prompted Auden to offer it the 20mg Agreement, and later the 10mg Agreement.
- d. '[Auden Senior Employee 1]'s terms to us [Waymade]' were that '*If and when we see another 20mg licence granted on RAMA, then we'll have to come to discuss, but until that happens, the deal is sound*'.²⁸³⁵ In other words, the payments in the 20mg Agreement were contingent on the absence of independent entry.
- e. The 10mg Agreement was reached on the same basis as the 20mg Agreement: Auden saw this as another way of protecting its volumes and therefore its position as sole supplier in the market.²⁸³⁶
- f. Actavis, which took over sales of hydrocortisone tablets from 1 September 2015, acknowledged at the time that '*currently in Uk we have all the market*' – though '*we expect competition which will impact volume and price*' following genuine independent entry.²⁸³⁷
- g. When other potential entrants emerged, Actavis continued the approach of Auden. Not only did Actavis continue making payments to AMCo under the 10mg Agreement and implement its own 'communications plan' (see section 3.F.III.p above), drawing on the Project Guardian materials AM Pharma had prepared;²⁸³⁸ it also attempted to agree a similar deal with another competitor, Alissa (see paragraphs 6.763 to 6.767 above). Though Alissa ultimately did not accept this offer, this demonstrates that having taken on Auden's

²⁸³³ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

²⁸³⁴ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.16 to 1.17.

²⁸³⁵ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

²⁸³⁶ For example, [Auden Senior Employee 1] stated that once Waymade obtained the 10mg MA, Auden was faced with '*the same scenario*' as it had faced when negotiating the 20mg Agreement, and that it responded in the same way – by supplying Waymade at a substantial discount in order to maintain its manufacturing volumes: '*it was a very, a very similar situation where they had said, 'look we've got a product and we would like to take supply from you'. So again, in the same scenario as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable*' (Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68).

²⁸³⁷ Document 02312, email from [Actavis Senior Employee 4] to Actavis staff dated 28 September 2015.

²⁸³⁸ See also Document 202954, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 20 May 2015: '*According to [Auden Senior Employee 1] Actavis will continue his strategy*' of using the orphan designation to undermine potential entrants.

business, Actavis continued Auden's strategy of attempting to buy off competition on hydrocortisone tablets.

6.932. This evidence demonstrates that Auden/Actavis had a consistent intention when dealing with its potential competitors: it would make payments available to a counterparty in possession of an MA which it perceived as a threat to its position as sole supplier, with the expectation that in return the potential competitor would refrain from entry and allow Auden/Actavis to prolong its position as sole supplier and associated ability to charge high prices.

e. Waymade

6.933. Waymade's subjective intention was to use its MAs – and the threat of competitive entry that they represented – as leverage to secure favourable supply terms (ie payments) from Auden. This would allow it to share in the high and increasing profits Auden derived from its position as sole supplier, rather than face the uncertainty of competition after entry. As explained above:

- a. From the outset, Waymade had intended to negotiate a supply deal with Auden alongside developing its own product, noting that: *'the earliest launch of our Hydrocortisone product in glass bottles is May or June 2011'* and that *'With regards to a negotiation with Auden Mckenzie, I suggest that opening a discussion in January would be about right.'*²⁸³⁹
- b. [Amdipharm Senior Employee] confirmed that the fact that Waymade had an MA for 20mg hydrocortisone tablets helped it to secure a significantly lower supply price from Auden: *'The marketing authorisation changed Waymade's position towards Auden Mckenzie.'*²⁸⁴⁰ This change in position was reflected in the fact that during those negotiations, Auden reduced its proposed supply price from £34.50 to £4.50 in the space of two weeks.
- c. [Amdipharm Senior Employee] explained: *'They [Auden] know that we can get product made at our own CMO, or they can supply us at a price which we feel is competitive ... then we have a choice as to whether we take product from them or whether we manufacture it ourselves.'*²⁸⁴¹ He

²⁸³⁹ Document 300138, email from [Waymade Senior Employee 3] to [Waymade Senior Employee 1] dated 23 December 2010.

²⁸⁴⁰ Document 200354, Witness Statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraphs 1.14 to 1.15.

²⁸⁴¹ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 26, line 26 and page 27, lines 1 to 8.

stated: *'at some point in our discussions, I may have made it clear that Waymade had a marketing authorisation [for 20mg hydrocortisone tablets]'. When asked why, he said, 'so that we could negotiate a better supply price'. He went on to say that 'if we made the product elsewhere, then they [Auden] would lose those volumes' because Waymade would enter and take business from Auden.²⁸⁴² He gave the same rationale for the 10mg Agreement, noting that Auden *'will lose margin on the product but they will at least retain their manufacturing volumes.'*²⁸⁴³*

- d. [Waymade Senior Employee 1] provided a similar explanation: *'we had agreed that we had a licence and we could produce the product at £4.50, and by buying it from him [[Auden Senior Employee 1]], then we wouldn't produce it, even though we were paying him more than it would cost us.'*²⁸⁴⁴ He went on to explain: *'If we..., when we came to the market, they could have actually lost a lot of the market share to us, therefore they would have said, "Look, we'll supply you or we will come to an agreement".'*²⁸⁴⁵ He noted that *'the fact that there's not a second player is always in their [Auden's] interest',²⁸⁴⁶* and went on to say: *'if I had my product, I would be able to penetrate the market. ... I suppose he [[Auden Senior Employee 1]] was selling us a product which he [[Auden Senior Employee 1]] would normally not have sold if we were in the market, that is all it is. Simple. You see? They make a certain amount for a finite market and when there is a second player in it, his sales would be diminished.'*²⁸⁴⁷
- e. When asked how Waymade was able to secure such a low supply price from Auden, [Waymade Senior Employee 3] explained that *'the fact that the product is there in the warehouse in Basildon, is the leverage in that Waymade could have placed that product on the market ... the leverage is it's in the warehouse in, in Basildon, it could be released for sale.'*²⁸⁴⁸ When asked separately what Waymade's leverage was, [Waymade Senior Employee 3] said: *'the product could be*

²⁸⁴² Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 34, lines 18 to 23.

²⁸⁴³ Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 65, lines 18 to 20.

²⁸⁴⁴ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 37, lines 10 to 13 (emphasis added).

²⁸⁴⁵ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 12 to 20 (emphasis added).

²⁸⁴⁶ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 14, lines 16 to 17.

²⁸⁴⁷ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 34, lines 12 to 20.

²⁸⁴⁸ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 12, line 27 and page 13, lines 1 to 7.

launched'.²⁸⁴⁹

- f. Waymade approached the 10mg Agreement in the same way:
- i. In relation to the 10mg Agreement, [Waymade Senior Employee 1] stated: *'His [[Auden Senior Employee 1]'s] volumes would start dropping, once we fight him in the market, which we would'*.²⁸⁵⁰ He stated: *'They gave the product to us at a price because we had told them [Auden] that we can manufacture it at a certain price, and for them not to lose their volumes, it would be attractive for them to supply the product'*.²⁸⁵¹
 - ii. In relation to the 10mg Agreement, [Amdipharm Senior Employee] stated: *'maybe the inference from me is that, you know, he [[Auden Senior Employee 1]] can supply me or I'll get someone else to supply me, and if he wants to retain the manufacturing volumes, then he might agree to supply me'*.²⁸⁵²

f. AMCo

6.934. AMCo – which acquired Waymade's 10mg MA, its project to develop its own 10mg hydrocortisone tablets, and key individuals who had negotiated and implemented the 10mg Agreement (especially [Amdipharm Senior Employee]) – had the same subjective intention as Waymade. It used its 10mg MA – and the threat of competitive entry that it represented – as leverage to preserve and improve the terms of the 10mg Agreement, allowing it to substitute for the uncertainty of competition the certainty of sharing in Auden/Actavis's high profits. For example, as explained above:

- a. In the interim period between the currency of the two Written Agreements, [AMCo Senior Employee 1] noted that [Auden Senior Employee 1] *'would probably do a better deal on better terms'* as he was *'not keen to get into a battle'*. *'I am also not keen'*, he stated, *'on having a fight'*.²⁸⁵³
- b. During the negotiation of the Second Written Agreement, [AMCo Senior Employee 8] asked in an internal email to [AMCo Senior Employee 1]

²⁸⁴⁹ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 2, page 31, line 14.

²⁸⁵⁰ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 140, lines 3 to 4.

²⁸⁵¹ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 1 to 3.

²⁸⁵² Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, pages 14-15.

²⁸⁵³ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014 (emphasis added).

when supply would begin. [AMCo Senior Employee 1] replied to [AMCo Senior Employee 8], *'As for the start date yes it is for delivery this month ... I told him [[Auden Senior Employee 1]] that if not we will launch our own'*.²⁸⁵⁴ [AMCo Senior Employee 1] intended [Auden Senior Employee 1] to understand that if Auden did not supply AMCo on the agreed terms that month, AMCo would launch its 10mg hydrocortisone tablets.

- c. [AMCo Senior Employee 1] later explained to AMCo staff that he had used the threat of AMCo's launch to secure the Second Written Agreement, on the understanding that this meant AMCo would not enter the market: *'we have subsequently signed a deal with Auden Mackenzie [sic] to source product from them and therefore our own product will not be launched in UK'; 'the work that you did to provide certainty of launch of our product gave those of us who were negotiating with Auden Mackenzie [sic] confidence to achieve the best deal possible for AMCo and I am sure that, as a result, Auden Mackenzie [sic] felt that they should agree to our terms'*.²⁸⁵⁵

²⁸⁵⁴ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] dated 15 June 2014 (emphasis added).

²⁸⁵⁵ Document 200126, email from [AMCo Senior Employee 1] to [AMCo Employee] and others dated 28 June 2014 (emphasis added).

7. DURATION

7.1. The duration of the Infringements is a relevant factor for determining the financial penalties that the CMA has decided to impose.

7.2. The CMA has concluded that:

- a. the 10mg Unfair Pricing Abuse had a duration of nine years and 10 months, that is, from 1 October 2008 to 31 July 2018;
- b. the 20mg Unfair Pricing Abuse had a duration of eight years and three months, that is, from 1 October 2008 to 8 January 2017;
- c. the 20mg Agreement had a duration of three years and 10 months, that is, from 11 July 2011 to 30 April 2015; and
- d. the 10mg Agreement had a duration of three years and eight months, that is, from 23 October 2012 to 24 June 2016.

7.3. Waymade and Cinven submitted that the CMA is required to show evidence *'of facts sufficiently proximate in time for it to be reasonable to accept that the infringement continued uninterruptedly between two specific dates'*.²⁸⁵⁶ Citing T-655/11 *FSL v Commission*, they submitted that the duration of the Agreements must be limited to those periods when there was specific evidence of participation in the infringements, and could not include times when Waymade's and AMCo's internal documents stated an intention to launch their own products, or when extraneous factors such as development problems meant they were unable to do so.²⁸⁵⁷

7.4. The CMA rejects these submissions for the following reasons.

7.5. *FSL v Commission* is not a relevant authority for this case. In *FSL* the European General Court upheld the European Commission's finding that the parties engaged in an agreement and/or concerted practice by fixing banana prices, despite the sparse and fragmentary evidence – but found that this was not a single and continuous infringement (as the Commission had found) because there was no evidence of contact for five months of the eight-month infringement period. Since banana prices were set weekly, this meant there was no evidence for coordination during 20 negotiation cycles.

²⁸⁵⁶ Document 204967, Cinven's RSSO, paragraph 8.27. See also Document 204903, Waymade's RSSO, paragraph 2.49.

²⁸⁵⁷ Document 204967, Cinven's RSSO, paragraphs 8.29-8.30. Document 204903, Waymade's RSSO, paragraph 2.50.

The infringement was therefore interrupted and was characterised as single and repeated.²⁸⁵⁸ In reaching this finding the General Court stated:

*‘the principle of legal certainty requires that, if there is no evidence directly establishing the duration of an infringement, the Commission should adduce at least evidence of facts sufficiently proximate in time for it to be reasonable to accept that that infringement continued uninterruptedly between two specific dates’*²⁸⁵⁹

- 7.6. This case is very different. As the General Court emphasised, whether a temporal gap in evidence constitutes an interruption in the infringement must be assessed in the context of the functioning of the infringement in question.²⁸⁶⁰ The expected pattern of contacts in the present case, involving a commitment not to enter a market, would be very different from a case such as *FSL* involving price fixing in relation to weekly set prices. In the case of a market exclusion agreement, the General Court has held that a commitment not to enter the market is based on a simple concept which may be implemented easily and this implementation does not require interaction between the parties.²⁸⁶¹
- 7.7. In this case the CMA has found two anticompetitive agreements each lasting for as long as the common understanding existed between the relevant parties. That common understanding was consistent throughout the term of each Agreement and there is evidence directly establishing the duration of the Agreements without any temporal gaps: in particular, Auden/Actavis paid Waymade and AMCo each month and Waymade and AMCo sent purchase orders and invoices to receive their monthly payments. There are also multiple pieces of evidence confirming at various points throughout the duration of the Agreements that Waymade and AMCo would not enter the market in exchange for those payments. This is evidence *directly* establishing the duration of each Agreement.
- 7.8. As explained in paragraphs 6.537 to 6.543 and 6.853 to 6.861 above, Waymade’s and AMCo’s unilateral approaches to their own products (to which they returned at points during the Agreements) while receiving payments does not undermine their common understanding with

²⁸⁵⁸ T-655/11 *FSL v Commission*, paragraphs 497-498.

²⁸⁵⁹ T-655/11 *FSL v Commission*, paragraph 482 (emphasis added).

²⁸⁶⁰ T-655/11 *FSL v Commission*, paragraph 483.

²⁸⁶¹ T-112/07 *Hitachi v Commission*, paragraph 91.

Auden/Actavis that in exchange for those payments, Waymade and AMCo would not enter.²⁸⁶²

²⁸⁶² Compare the Court of Justice's rejection of Lundbeck's argument that the Commission had erred '*by failing to limit the duration of the infringements in question solely to the period during which manufacturers of generic medicines were actually ready to enter the market*' in C-591/16 P *Lundbeck v Commission*, paragraphs 174-177. To limit the duration of the Agreements to periods when Waymade and AMCo were actually ready to enter the market with their own products would be to confuse potential competition with actual competition.

8. EFFECT ON TRADE

- 8.1. The Chapter I prohibition applies to agreements between undertakings which may affect trade within the UK, and have as their object or effect the prevention, restriction or distortion of competition within the UK.²⁸⁶³ For the purposes of the Chapter I prohibition, the UK includes, in relation to an agreement which operates or is intended to operate only in a part of the UK, that part.²⁸⁶⁴
- 8.2. The Chapter II prohibition applies to conduct by a dominant undertaking which may affect trade within the UK.²⁸⁶⁵ For the purposes of the Chapter II prohibition, the UK includes any part of the UK.²⁸⁶⁶
- 8.3. To infringe the Chapter I or Chapter II prohibition, the conduct does not actually have to affect trade as long as it is capable of doing so.²⁸⁶⁷ The concept of effect on trade is also not read as importing a requirement that the effect on trade within the UK should be appreciable.²⁸⁶⁸
- 8.4. Each of the Infringements was implemented in the UK and was capable of having an effect on the price paid in the UK for hydrocortisone tablets. Accordingly, the CMA concludes that each of the Infringements may have affected trade in the buying and selling of drugs within the whole or part of the UK.

²⁸⁶³ Section 2(1) of the Act.

²⁸⁶⁴ Section 2(7) of the Act.

²⁸⁶⁵ Section 18(1) of the Act.

²⁸⁶⁶ Section 18(3) of the Act.

²⁸⁶⁷ See, for example, T-228/97 *Irish Sugar plc v Commission*, EU:T:1999:246, paragraph 170.

²⁸⁶⁸ *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, paragraphs 459 and 460.

9. UNDERTAKINGS AND ATTRIBUTION OF LIABILITY

A. Legal framework for undertakings and attribution of liability

I. Undertakings

- 9.1. Competition law refers to the activities of ‘undertakings’. An undertaking is any entity engaged in economic activity, regardless of its legal status and the way in which it is financed.²⁸⁶⁹ An entity is engaged in ‘economic activity’ where it conducts any activity *‘of an industrial or commercial nature by offering goods and services on the market’*.²⁸⁷⁰
- 9.2. The definition of an undertaking is therefore a functional one that is ‘*context-sensitive*’.²⁸⁷¹ In the context of the Chapter I and II prohibitions, the term ‘undertaking’ *‘must be understood as designating an economic unit for the purpose of the subject-matter of the agreement [or conduct] in question, even if in law that economic unit consists of several persons, natural or legal’*.²⁸⁷²
- 9.3. It is thus well established that an undertaking does not correspond to the commonly understood notions of a legal entity or corporate group, for example under English commercial or tax law; and that a single undertaking may comprise one or more legal and/or natural persons.²⁸⁷³

II. Attribution of liability

- 9.4. Where an undertaking infringes the competition rules, it falls to that undertaking to answer for that infringement.²⁸⁷⁴
- 9.5. However, in order to enforce competition law it is necessary to attribute liability for the undertaking’s infringement to legal entities.²⁸⁷⁵
- 9.6. The Act, the CMA Rules and the CMA’s guidance do not stipulate which legal or natural person the CMA is obliged to hold responsible for the infringement or to punish by the imposition of a financial penalty.²⁸⁷⁶

²⁸⁶⁹ C-41/90 *Hofner and Elser v Mactrottron*, paragraph 21; C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraph 54 and the case law cited.

²⁸⁷⁰ C-118/85 *Commission v Italian Republic*, EU:C:1987:283, paragraph 7.

²⁸⁷¹ *Sainsbury’s v MasterCard* [2016] CAT 11, paragraph 360.

²⁸⁷² Case 170/83 *Hydrotherm* [1984] ECR 2999, paragraphs 11-12. See also C-217/05 *Confederación Española de Empresarios de Estaciones de Servicio v CEPESA* [2006] ECR 784, paragraph 40; and *Sainsbury’s v MasterCard* [2016] CAT 11, paragraph 397: ‘It is to be borne in mind that any relevant “undertaking” must relate to the restriction which is said to offend Article 101 [or the conduct which is said to breach Article 102] TFEU’.

²⁸⁷³ *Sepia Logistics Limited v Office of Fair Trading* [2007] CAT 13, paragraph 70.

²⁸⁷⁴ T-372/10 *Bollore II* [2012] OJ C235/13, paragraph 52.

²⁸⁷⁵ C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 54 to 57.

²⁸⁷⁶ The same is true for the European Commission under the EU competition rules: see C-516/15 P *Akzo Nobel and Others v Commission*, EU:C:2017:314, paragraph 51 and the case-law mentioned there.

- 9.7. In *Sainsbury's Supermarkets Ltd v Mastercard*, the CAT concluded that 'In our view the current state of the law in this regard is most clearly expressed in the Advocate General's Opinion (endorsed by the Court of Justice) in Case C-231/11 P to C-233/11 P *Commission v Siemens*'.²⁸⁷⁷ The CAT quoted the following passage from the Advocate General:

'in the case of an undertaking made up of various legal persons, the persons who have participated in the cartel, as well as the ultimate parent company which exercises a decisive influence over them, may be regarded as legal entities collectively constituting a single undertaking for the purposes of competition law which may be held responsible for the acts of that undertaking. Consequently, if the Commission establishes that the undertaking has, either intentionally or negligently, committed an infringement of EU competition rules, it may determine the personal and collective liability of all the legal persons who make up the economic unit and who, by acting together, have participated, directly or indirectly, in the commission of the infringement.

*It is specifically for that reason that the Court has found it to be compatible with the principle of personal responsibility – as well as with the objective of the effective implementation of the competition rules – to require the legal persons who participated in the infringement and, along with them, the person who exercised decisive influence over them, to bear joint and several responsibility, specifically because those persons form part of a single economic unit and, therefore, form a single undertaking...'*²⁸⁷⁸

- 9.8. The CAT therefore went on to hold that: 'a legal person may be liable for a breach of competition law:

(i) Because he, she or it has in some way participated in that breach, as a part of the single economic unit or "undertaking" that has infringed the law; and/or

*(ii) Because he, she or it has exercised decisive influence over one or more of the persons within the "undertaking" who have participated in the infringement.'*²⁸⁷⁹

²⁸⁷⁷ *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(21).

²⁸⁷⁸ Opinion of Advocate General Mengozzi in C-231/11 P *Commission v Siemens*, EU:C:2013:578, paragraphs 80-81 (emphasis added), quoted in *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(8).

²⁸⁷⁹ *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

a. Direct participants in an infringement

- 9.9. When attributing liability, the starting point is therefore that those legal entities that directly '*participated in th[e] breach*' are liable.

i. Economic continuity

- 9.10. When an entity that has committed an infringement of competition law subsequently sells the assets which contributed to the infringement and withdraws from the market in question, it may be held liable for the infringement if it has not ceased to exist.²⁸⁸⁰
- 9.11. However, where a business is transferred from one entity (the transferor) to another (the transferee), at a time when transferor and transferee form part of the same undertaking, liability for past behaviour of the transferor may pass to the transferee by application of the principle of economic continuity.²⁸⁸¹
- 9.12. It is settled caselaw that a penalty for an infringement committed by the transferor can be imposed in its entirety on the transferee, in particular where the transferor and transferee '*have been subject to control by the same person within the group and have therefore, given the close economic and organisational links between them, carried out, in all material respects, the same commercial instructions*', so that '*the two entities [transferor and transferee] constitute one economic entity*'.²⁸⁸² In *ETI v Commission*, the Grand Chamber of the Court of Justice held that if the transferor and transferee were subject to the control of the same parent entity at the time of their infringing conduct:

'it would have to be concluded that the principle of personal responsibility does not preclude the penalty for the infringement commenced by [the transferor] and continued by [the transferee] from being imposed in its entirety on [the transferee]'.²⁸⁸³

- 9.13. The Court of Justice when on to hold:

²⁸⁸⁰ C-49/92 P *Commission v Anic Partecipazioni SpA* EU:C:1999:356, paragraphs 47 to 49 (summarising the CFI judgment, upheld by the CJEU in paragraphs 144-145).

²⁸⁸¹ C-204/00 P, C-205/00 P, C-211/00 P, C-217/00 P and C-219/00 P *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraphs 354 to 360; T-43/02 *Jungbunzlauer v Commission* EU:T:2006:270, paragraphs 132 to 133; T-117/07 and 121/07 *Areva and Others and Alstom v Commission* EU:T:2011:69, paragraphs 66 to 69.

²⁸⁸² C-280/06 *ETI and Others* EU:C:2007:775, paragraphs 48 to 49.

²⁸⁸³ C-280/06 *ETI and Others* EU:C:2007:775, paragraphs 48 to 52 (emphasis added). See also C-434/13 P *Commission v Parker-Hannifin* EU:C:2014:2456, paragraph 41; and C-511/11 *Versalis v Commission* EU:C:2013:386, paragraph 52.

*'in the case of entities answering to the same [parent], where conduct amounting to one and the same infringement of the competition rules was adopted by one entity and subsequently continued until it ceased by another entity which succeeded the first, which has not ceased to exist, that second entity may be penalised for the infringement in its entirety if it is established that those two entities were subject to the control of the said [parent].'*²⁸⁸⁴

9.14. This does not, however, require that the transferee continue the infringement.²⁸⁸⁵ The relevant date for establishing the existence of economic continuity is the date of *the* transfer of the activities.²⁸⁸⁶ There may thus be economic continuity:

- a. where the transfer of activities took place during the infringement period and structural links between the transferor and the transferee existed during that period;²⁸⁸⁷ and/or
- b. where that transfer took place after the infringement had come to an end, provided that the structural links existed at the time of that transfer.²⁸⁸⁸

9.15. The structural links that exist on the date of the transfer must be sufficient for the two entities to be considered to form a single undertaking at that time.²⁸⁸⁹ The links do not, however:

- a. need to '*subsist throughout the rest of the infringement period or until the adoption of a decision penalising the infringement*'; or
- b. '*subsist for a minimum period*'.²⁸⁹⁰

9.16. Nor do the structural links have to exist from the start of the infringement period: the principle applies equally to an intragroup transfer after a new parent acquires an infringing business.²⁸⁹¹

²⁸⁸⁴ C-280/06 *ETI and Others* EU:C:2007:775, paragraph 52. The Court of Justice has confirmed elsewhere that '*the scope of the judgment in ETI and Others is not limited ... to cases in which the entities concerned are controlled by a public authority*' (C-511/11 *Versalis v Commission*, paragraph 57).

²⁸⁸⁵ C-434/13 P *Commission v Parker Hannifin* EU:C:2014:2456, paragraph 49; C-204/00 P *Aalborg Portland and Others v Commission*, EU:C:2004:6, paragraphs 356 to 360.

²⁸⁸⁶ C-434/13 P *Commission v Parker-Hannifin*, paragraphs 49 to 52.

²⁸⁸⁷ C-280/06 *ETI and Others* EU:C:2007:775, paragraphs 45 and 50; and C-434/13 P *Commission v Parker-Hannifin* EU:C:2014:2456, paragraph 49.

²⁸⁸⁸ C-204/00 P *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraphs 59, 351, 356 and 357; and C-434/13 P *Commission v Parker-Hannifin* EU:C:2014:2456, paragraph 49.

²⁸⁸⁹ C-434/13 P *Commission v Parker-Hannifin* EU:C:2014:2456, paragraph 51.

²⁸⁹⁰ C-434/13 P *Commission v Parker-Hannifin*, paragraphs 49 and 51 to 52.

²⁸⁹¹ C-434/13 P *Commission v Parker-Hannifin*, paragraphs 45 to 55.

- 9.17. The motivation behind the transfer is also not a necessary factor in determining whether the principle should apply:

'The taking into consideration of the economic reasons which led to the creation of a subsidiary, or the objective, in the long- or short-term, of transferring that subsidiary to a third-party undertaking, would introduce into the application of the principle of economic continuity subjective factors which are incompatible with a transparent and predictable application of that principle'.²⁸⁹²

- 9.18. The businesses of the transferor and transferee do not need to be identical: what matters is that the infringing business is transferred and that the transferee continues its economic activities on the relevant market, such that it can be regarded as its '*economic successor*'.²⁸⁹³ This means that, for the purposes of attributing liability for the infringement in question, '*the undertaking run by [the transferee after the transfer] is the same as that previously run by [the transferor]*'.²⁸⁹⁴

- 9.19. Equally, the fact that the entity that committed the infringement still exists after the transfer does not preclude imposing a penalty on the entity to which its economic activities were transferred by virtue of the principle of economic continuity (as is clear from the Grand Chamber's judgment quoted above).²⁸⁹⁵ The original entity (the transferor) does not need to cease to exist in law²⁸⁹⁶ – it is enough that the transferee has succeeded the transferor as economic actor on the relevant market. This does not require that the transferor has ceased all economic activity,²⁸⁹⁷ though the EU Court of

²⁸⁹² C-434/13 P *Commission v Parker-Hannifin*, paragraph 53.

²⁸⁹³ C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 45 to 52. The Court of Justice held that the principle of economic continuity could apply where transferor and transferee were subject to the control of the same public authority, notwithstanding the referring court's observation (in paragraph 11) that the transfer of activities '*made a clear break of continuity with the previous model of organisational management*'. See also *NMH Stahlwerke v Commission*, paragraphs 106, 126, 130 and 133: the facts that the transferor and transferee '*were never run by the same persons*'; that the transferee did not acquire all of the rights and obligations of the transferor; and that the transferee only took over 14% of the transferor's fixed assets (and did not, for example, acquire its land and buildings) did not preclude the application of the principle of economic continuity.

²⁸⁹⁴ C-204/00 P *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraph 357.

²⁸⁹⁵ C-434/13 P *Commission v Parker-Hannifin*, EU:C:2014:2456, paragraphs 51 to 54.

²⁸⁹⁶ See C-204/00 P, C-205/00 P, C-211/00 P, C-217/00 P and C-219/00 P *Aalborg Portland v Commission* EU:C:2004:6, paragraphs 354 to 360; T-43/02 *Jungbunzlauer v Commission* EU:T:2006:270, paragraphs 132 to 133; C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 48 and 49.

²⁸⁹⁷ See, for example, T-43/02 *Jungbunzlauer v Commission* EU:T:2006:270, in which the transferor, Jungbunzlauer GmbH (JG), continued producing and marketing citric acid (even setting policy on quantities and prices) following the transfer of management activities on the market for citric acid to its sister company Jungbunzlauer AG (JAG). This did not prevent JAG being held liable for the conduct of JG prior to the transfer via the application of economic continuity. See especially paragraphs 116 and 124 to 134 of the judgment. See also the EU Court of Justice's ruling in C-280/06 *ETI v Commission* EU:C:2007:775, paragraph 45: '*ETI [the transferee] continued AAMS' [the transferor] economic activities on the market affected by the cartel. In those circumstances, even though AAMS continued to exist as an economic operator on other markets, ETI could be regarded ... as the economic successor of AAMS*'. In giving this ruling the Court rejected the referring court's suggestion that the fact that the transferor '*still carries on an economic activity that is subject to competition law*'

Justice has stated that a '*penalty imposed on an undertaking that continues to exist in law, but has ceased economic activity, is likely to have no deterrent effect*'.²⁸⁹⁸

- 9.20. For example, in *NMH Stahlwerke v Commission*, the EU General Court upheld the Commission's attribution of liability to NMH:
- a. from July 1988 to 30 June 1990, by application of the principle of economic continuity as transferee of the infringing business; and
 - b. from 1 July 1990 to 31 December 1990, as a direct participant in the infringement (the transferor having ceased trading) since it continued on its own behalf the economic activity of steel beam production.
- 9.21. In relation to the economic continuity period, the Court held that NMH '*must be considered to be [the transferor]'s economic successor and, as such, it must answer for the infringements committed by that undertaking during the period prior to 30 June 1990*'. This was notwithstanding the fact that the transferor continued to exist in law, and that the transferee only acquired part of its steel-making activities and management. The Court confirmed that the principle in *Anic v Commission* that the continued existence of the original infringing entity means it could be held liable does not preclude an authority from taking a different approach.²⁸⁹⁹

b. Parental liability

- 9.22. Legal entities may also be held liable on the basis of parental liability, if they '*exercised decisive influence over one or more of the persons within the "undertaking" who have participated in the infringement*'.²⁹⁰⁰ An entity that exercises decisive influence over a directly infringing entity need not be a 'parent' in the literal sense of owning shares: the term 'parental' encompasses other forms of decisive influence.²⁹⁰¹

argued against the application of economic continuity, where the transferor no longer carried out commercial activities in the economic sphere concerned (paragraph 11).

²⁸⁹⁸ C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 40 to 41.

²⁸⁹⁹ T-134/94 *NMH Stahlwerke GmbH v Commission*, paragraphs 122 to 138.

²⁹⁰⁰ *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

²⁹⁰¹ For example, the Court of Justice has confirmed that decisive influence can be exercised by a legal entity that holds the voting rights in a subsidiary (without necessarily holding the shares): C-595/18 P *Goldman Sachs v Commission*, paragraphs 29-36, upholding T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 50 to 52. Elsewhere, the courts have held that ownership is one, but not the only or a necessary reason for a finding of decisive influence. For example, in C-293/13 P *Fresh Del Monte v Commission*, EU:C:2014:2439, AG Kokott noted that the principles of decisive influence '*can also easily be applied to the case of a partnership*' rather than a '*parent company-subsidiary relationship in the traditional sense*', and that '*All the parties to the proceedings were in agreement on this point, and the General Court likewise rightly took that premiss as its starting point*' (paragraph 75). The Court of Justice followed this Opinion, acknowledging that this involved classifying a partnership as equivalent to a parent-subsidiary relationship: C-293/13 P *Fresh Del Monte v Commission*, EU:C:2015:416, paragraphs 79-80.

- 9.23. Where a parent exercises decisive influence over a direct participant in an infringement, parent and subsidiary together form a single economic entity in relation to the infringement.²⁹⁰²
- 9.24. This means that the parent can be held jointly and severally liable for the infringement with the directly participating subsidiary and is deemed itself to have participated in the infringement:

'it cannot be disputed that the imputation to the parent company of the infringement committed by the subsidiary, on the ground that those companies form a single undertaking for the purposes of EU competition law and, therefore, that the parent company is regarded as having participated in the infringement on the same basis as its subsidiary, is also clearly apparent under EU law, according to the long-established case-law of the Court of Justice and this Court [the EU General Court].

...

the basis of the liability of the parent company ... is not strict liability incurred on behalf of another but liability for its own misconduct and personal in nature.

...

If the parent company is part of that economic unit, it is regarded as jointly and severally liable with the other legal persons making up that unit for the infringements of competition law ... In such a situation, the parent company is penalised for an infringement which it is deemed to have committed itself'.²⁹⁰³

- 9.25. Where a directly participating subsidiary is subject to the decisive influence of successive parents during an infringement period, that subsidiary and its successive parents form 'one and the same undertaking which, in its various successive configurations, committed the infringement at issue' and can 'be

²⁹⁰² See, for example, Opinion of AG Kokott in C-97/08 *Akzo Nobel v Commission*, paragraphs 42-45. The Court of Justice followed the Advocate General's Opinion. See also C-628/10 *Alliance One v Commission*, paragraphs 42-44; C-597/13 *Total v Commission*, paragraphs 32-35; C-516/15 *Akzo Nobel v Commission*, paragraphs 46-53.

²⁹⁰³ T-372/10 *Bolloré II* [2012] OJ C235/13, paragraphs 37, 51 to 52 (emphasis added) and the case law cited. Compare T-69/04 *Schunk v Commission*, EU:T:2008:415, paragraphs 73 to 74. The principles of attributing liability to a parent apply equally, whether the underlying infringement is of the Chapter I prohibition / Article 101(1), or the Chapter II prohibition / Article 102. For example, these principles have been applied in a Chapter II/Article 102 context in cases such as: CE/1217-02 *Predation by Aberdeen Journals Limited*, CMA Decision of 16 September 2002, paragraph 11; *Aberdeen Journals* [2002] CAT 4, paragraph 4; C-6/72 *Europemballage Corporation and Continental Can Company v Commission*, EU:C:1973:22, paragraph 15; and Joined cases 6 and 7-73 *Istituto Chimioterapico Italiano and Commercial Solvents v Commission*, EU:C:1974:18, paragraphs 36 to 41.

*held jointly and severally liable for payment of a single fine as entities forming part of one and the same undertaking to which the infringement at issue is imputable.*²⁹⁰⁴

- 9.26. The Court of Justice summarised the legal framework for attributing liability to parents in *Akzo Nobel v Commission*:

'It is clear from settled case-law that the conduct of a subsidiary may be imputed to the parent company in particular where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company ... having regard in particular to the economic, organisational and legal links between those two legal entities ...

That is the case because, in such a situation, the parent company and its subsidiary form a single economic unit and therefore a single undertaking ... Thus, the fact that a parent company and its subsidiary constitute a single undertaking ... enables the Commission to address a decision imposing fines to the parent company, without having to establish the personal involvement of the latter in the infringement'^{2905,2906}

- 9.27. The legal test for parental liability is therefore that the 'parent' entity exercises '*decisive influence*' over a direct participant in an infringement. The question is whether '*the parent company, by reason of the intensity of its influence, can direct the conduct of its subsidiary to such an extent that the two must be regarded as one economic unit*'.²⁹⁰⁷ If so, the parent forms part of the economic entity that committed the infringement and may be held jointly and severally liable with its subsidiary for that infringement:

²⁹⁰⁴ C-823/18 P *Commission v GEA Group AG*, paragraphs 70 and 72.

²⁹⁰⁵ C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 58 to 59 (emphasis added). See also C-516/15 P *Akzo Nobel v Commission*, EU:C:2017:314, paragraphs 52 to 58; C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 27 citing C-93/13 P and C-123/13 P *Commission and Others v Versalis and Others*, EU:C:2015:150, paragraph 40; C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 44; *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 15 to 22.

²⁹⁰⁶ Applying this legal framework '*does not in any way constitute an exception to the principle of personal responsibility, but is the expression of that very principle. That is because the parent company and the subsidiaries under its decisive influence are collectively a single undertaking for the purposes of competition law and responsible for that undertaking*': *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(3), citing Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraphs 97 to 99. Nor does this legal framework infringe the right to be presumed innocent: T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 187 to 191. See also C-611/18 P *Pirelli v Commission*, paragraphs 70, 73 and 95.

²⁹⁰⁷ T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraphs 87 to 94. See also T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraph 70 and the caselaw cited.

*'the parent company to which the unlawful conduct of its subsidiary is attributed is held individually liable for an infringement of the EU competition rules which it is itself deemed to have infringed, because of the decisive influence which it exercised over the subsidiary'.*²⁹⁰⁸

- 9.28. This does not require that the parent was involved in, or even aware of, the infringement by its subsidiary.²⁹⁰⁹ However, evidence that the parent was aware of the infringement and did not intervene can be relevant.²⁹¹⁰

i. The presumption of decisive influence (the Akzo presumption)

- 9.29. It is settled caselaw that where a parent company holds (directly or indirectly)²⁹¹¹ 100% (or nearly 100%)²⁹¹² of the shares or voting rights²⁹¹³ in a subsidiary which has infringed the competition rules, not only is that parent company able to exercise decisive influence over the conduct of its subsidiary, but there is a rebuttable presumption that the parent company does in fact exercise such decisive influence over the conduct of its subsidiary (the '**Akzo presumption**'). The two entities can therefore be regarded as a single economic unit and held jointly and severally liable for the infringement and any resulting fine.²⁹¹⁴

²⁹⁰⁸ C-516/15 P *Akzo Nobel v Commission*, EU:C:2017:314, paragraphs 56 to 58.

²⁹⁰⁹ C-90/09 P *General Química SA v Commission*, EU:C:2011:21, paragraph 102: '*what counts is not whether the parent company encouraged its subsidiary to commit an infringement ..., or whether it was directly involved in the infringement committed by its subsidiary, but the fact that those two companies constitute a single economic unit and thus a single undertaking ... which enables the Commission to impose a fine on the parent company*'. See also C-97/08 *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 59 and 77, and T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraph 367 and the caselaw cited.

²⁹¹⁰ See, for example, Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the facts that Mylan was aware of the relevant agreement involving its subsidiary Matrix Laboratories as part of its due diligence for the acquisition of that subsidiary, but did not raise any objections, were relevant factors in the Commission's decision to hold Mylan liable. The Commission found that based on its due diligence Mylan '*was aware that Matrix had agreed to stay out of the market with perindopril in return for a large sum of money*', and therefore knew, or ought to have known, that the relevant agreement was anti-competitive. However, Mylan never raised any objections to the agreement or took any measure aimed at terminating it, showing that '*Mylan tacitly approved the infringement and this, in itself, amounts to additional evidence that Mylan exercised decisive influence over the conduct of Matrix*': paragraphs 3041-3044. The Commission's attribution of liability to Mylan was upheld on appeal in T-682/14 *Mylan v Commission*, EU:T:2018:907. The EU General Court noted that '*The control exercised by the parent company over its subsidiary does not necessarily have to have a connection with the unlawful conduct*' and did not rely on this point for its finding that Mylan exercised decisive influence (since it held that the Commission had established this based on other factors) – but noted that '*that the applicants do not dispute that Mylan was aware of the Agreement at the time it acquired a majority shareholding in Matrix*' (paragraphs 349-368).

²⁹¹¹ C-90/09 P *General Química and Others v Commission*, EU:C:2011:21, paragraphs 86 to 87.

²⁹¹² T-217/06 *Arkema France, Altuglas International SA, Altumax Europe SAS v Commission* EU:T:2011:251, paragraph 53.

²⁹¹³ T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 50 to 52 and 64, upheld in C-595/18 P *Goldman Sachs v Commission*, paragraphs 35-36.

²⁹¹⁴ C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraphs 46 to 48; C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 28 and the case law cited; C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 60 to 61; see also 107/82 *Allgemeine Elektrizitäts-Gesellschaft AEG-Telefunken AG v Commission*, EU:C:1983:293, paragraph 50; *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 15 to 18.

- 9.30. Where the *Akzo* presumption applies, it suffices for the purposes of attribution of liability. In such circumstances, it is for the party in question to rebut the presumption by adducing sufficient evidence.²⁹¹⁵
- 9.31. The CMA may nonetheless also rely on additional economic, organisational and legal links to demonstrate the exercise of decisive influence, other than the parent's shareholding or voting rights in the subsidiary.²⁹¹⁶
- 9.32. For example, in the *Power Cables*²⁹¹⁷ cartel case, the General Court upheld the European Commission's finding that Goldman Sachs exercised decisive influence over its fund's subsidiary Prysmian, applying the *Akzo* presumption and on the basis of additional links including:
- a. The power to appoint and remove directors (albeit indirectly through its funds) and to call shareholder meetings;
 - b. Goldman Sachs' representation on the subsidiary's board;
 - c. The management powers of Goldman Sachs' board representatives; and
 - d. Goldman Sachs' receipt of regular updates and monthly reports.²⁹¹⁸
- 9.33. The Court of Justice upheld the General Court and rejected Goldman Sachs' argument that these factors did not suffice to establish decisive influence.²⁹¹⁹

ii. Cases where the *Akzo* presumption does not apply

- 9.34. Where the *Akzo* presumption does not apply, because the parent owns less than (nearly) 100% of the shares or voting rights in the subsidiary, the '*principal question*' is whether the parent actually exercises decisive influence over the conduct of the subsidiary during the relevant period, since '*if it were to be established ... that ... the [parent] did in fact exercise decisive influence over the conduct of [the directly infringing entity], that would necessarily imply that they were in a position to do so*'.²⁹²⁰

²⁹¹⁵ C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 47, citing C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraph 61; see also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 19 to 21; C-595/18 P *Goldman Sachs v Commission*, paragraph 40.

²⁹¹⁶ C-628/10 P and C-14/11 P *Alliance One & Others v Commission*, EU:C:2012:479, paragraph 49.

²⁹¹⁷ AT.39610 *Power Cables*, Commission Decision of 2 April 2014.

²⁹¹⁸ T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445.

²⁹¹⁹ C-595/18 P *Goldman Sachs v Commission*.

²⁹²⁰ T-24/05 *Alliance One and Others v Commission*, EU:T:2010:453, paragraphs 165 to 167, upheld in C-628/10 P and C-14/11 P *Alliance One and Others v Commission*, EU:C:2012:479. See also T-104/13 *Toshiba Corp. v European Commission*, EU:T:2015:610, paragraph 95; and C-172/12 P *El du Pont de Nemours v Commission*, EU:C:2013:601, paragraph 44; and T-541/08 *Sasol v Commission*, EU:T:2014:628, paragraph 43.

- 9.35. Such decisive influence is not limited to and does not require influence on commercial conduct. The CAT has confirmed that: *'The factors to which the court may have regard, when considering the issue of decisive influence, are not limited to commercial conduct but cover a wide range as described by the Advocate General and the General Court [in Akzo].'*²⁹²¹ In that case, the Court of Justice approved the statement of Advocate General Kokott that: *'the absence of autonomy of the subsidiary in terms of its market conduct is only one possible connecting factor on which to base an attribution of responsibility to the parent company. It is not the only connecting factor'*.²⁹²²
- 9.36. Whether the parent exercises decisive influence therefore turns on the economic, organisational and legal links between the parent and subsidiary, which vary from case to case.²⁹²³ The test focuses on substance over form and does not depend on technicalities of company law. Rather, it asks whether, as a matter of *'economic reality'* and in light of those economic, organisational and legal links, the parent can be said to have exercised decisive influence.²⁹²⁴

Economic, organisational and legal links indicating decisive influence

- 9.37. There is no exhaustive set of criteria or 'checklist' to complete in assessing the economic, organisational and legal links indicating decisive influence.²⁹²⁵ The EU Court of Justice has also confirmed that *'The existence of an economic unit may ... be inferred from a body of consistent evidence, even if some of that evidence, taken in isolation, is insufficient to establish the existence of such a unit.'*²⁹²⁶ Examples of links that have been considered to confer decisive influence include:

²⁹²¹ *Durkan Holdings Limited v OFT* [2011] CAT 6, paragraph 22.

²⁹²² Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 87, approved in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 73 to 74: *'It is clear, as the Advocate General pointed out ..., that the conduct of the subsidiary on the market cannot be the only factor which enables the liability of the parent company to be established, but is only one of the signs of the existence of an economic unit'*. See also T-24/05 *Alliance One & Others v Commission*, EU:T:2010:453, paragraph 170: *'It is also necessary to reject the applicants' argument that the decisive influence that a parent company must exercise in order to have liability attributed to it for the infringement committed by its subsidiary must relate to activities which form part of the subsidiary's commercial policy stricto sensu and which, furthermore, are directly linked to that infringement'*. See also T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraph 32, and T-682/14 *Mylan v Commission*, paragraph 347.

²⁹²³ C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 72 to 74.

²⁹²⁴ C-440/11 *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV*, EU:C:2013:514, paragraphs 66 to 68. The EU Court of Justice followed the Opinion of Advocate General Kokott, EU:C:2012:763, paragraphs 71 to 76: *'the decisive factor is ultimately economic reality, since competition law is guided not by technicalities, but by the actual conduct of undertakings'*. Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 46: *'In examining whether the parent company is able to exercise decisive influence over the market conduct of its subsidiary, account must be taken of all the relevant factors relating to the economic, organisational and legal links which tie the subsidiary to its parent company and, therefore, account must be taken of the economic reality'*. See also Joined cases C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraph 76.

²⁹²⁵ *Alliance One*, EU:C:2012:479, paragraph 45; T-141/07 *General Technic-Otis v Commission*, paragraph 103.

²⁹²⁶ C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, paragraph 65.

- a. A majority shareholding;
- b. Rights under a shareholders' agreement to determine the composition of the subsidiary's board and/or to veto strategic commercial decisions;
- c. The presence of parent representatives on the subsidiary's board;
- d. The receipt of information on strategic and commercial plans; and
- e. The nature of the parent's business model, where relevant to its investment in the subsidiary.

A majority shareholding

- 9.38. Although a majority shareholding is not necessary to establish decisive influence, the General Court has confirmed that, if a parent holds a majority interest in the subsidiary's share capital, that can enable it to exercise decisive influence over its subsidiary and, in particular, over the subsidiary's market conduct.²⁹²⁷

Rights under a shareholders' agreement

- 9.39. The ability to exercise decisive influence may also be demonstrated on the basis of links other than a majority shareholding, such as the management powers that the parent has over the subsidiary.²⁹²⁸ An agreement between parent companies in relation to management of their subsidiary is a relevant legal link for the assessment of decisive influence. Implementation of such an agreement is an indication that decisive influence is exercised.²⁹²⁹

- 9.40. For example, the General Court has held that:

'the ability to decide upon the composition of the board of directors of a company constitutes an objective factor which determines, in itself, whether it is possible to control the decisions that may be adopted by the board and, therefore, by the company concerned. The board of directors constitutes, by definition, the body responsible for administering and representing the company.'²⁹³⁰

- 9.41. Further, veto rights constitute an important legal link between the parent and the subsidiary, which can enable the parent to exercise decisive influence

²⁹²⁷ T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 182; T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 96.

²⁹²⁸ T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 183.

²⁹²⁹ T-314/01 *Avebe v Commission*, EU:T:2006:266, paragraph 138.

²⁹³⁰ T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 91 (emphasis added).

over the subsidiary.²⁹³¹ It is not necessary for veto rights *'to relate to measures connected with the day-to-day management of the business or, specifically, with the company's conduct on the market; it is enough for those rights of veto to afford the partner concerned, in very general terms, a sufficient influence over the company's commercial policy in the broadest sense'*.²⁹³²

- 9.42. The mere holding of a veto right over certain strategic decisions (such as the adoption of a business plan or budget) can in itself confer decisive influence.²⁹³³ The holder need not actually veto decisions (though if it does, that is strong evidence). Where a parent holds a veto right and attends meetings at which it could veto decisions, that amounts to exercising its right, since its approval is a prerequisite.²⁹³⁴ Even where decisions are taken by the subsidiary's management, *'the fact that the parent company or its representatives must approve those proposals and therefore has the right to reject them is, in fact, evidence of a decisive influence'*.²⁹³⁵
- 9.43. However, a parent may exercise decisive influence over a subsidiary even when it does not make use of any actual rights to determine its conduct and refrains from giving any specific instructions or guidelines to its subsidiary.²⁹³⁶ The parent's influence over strategic decisions such as whether the subsidiary's business activities shall be expanded or down-

²⁹³¹ For example, in T-104/13 *Toshiba v Commission*, EU:T:2015:610, factors in the EU General Court's finding that Toshiba exercised decisive influence over a joint venture company (upheld by the EU Court of Justice) included Toshiba's veto rights over: material investments; the formation, capital participation in or acquisition of a company or business for a price above a certain threshold; and the provision of loans over a certain threshold to subsidiary companies and other entities (paragraphs 106 to 113, upheld in C-623/15 P *Toshiba v Commission*, EC:C:2017:21).

²⁹³² Opinion of Advocate General Kokott in C-293/13 *Del Monte*, EU:C:2014:2439, paragraph 89 (followed by the EU Court of Justice).

²⁹³³ C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67. Compare T-543/08 *RWE v Commission*, EU:T:2014:627, paragraphs 30 to 32: *'The conduct on the market of the subsidiary is under the decisive influence of the parent company, in particular, where the subsidiary carries out, in all material respects, the instructions given to it by the parent company in that respect ... The subsidiary's conduct on the market is, in general, also under the decisive influence of the parent company where the latter retains only the power to define or approve certain strategic commercial decisions, where appropriate by its representatives in the bodies of the subsidiaries, while the power to define the commercial policy stricto sensu of the subsidiary is delegated to the managers responsible for its operational management, chosen by the parent company and representing and promoting the parent company's commercial interests'* (emphasis added). See also T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

²⁹³⁴ Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 73: *'the holder of a right of veto over certain decisions of an undertaking must necessarily be consulted before the adoption of any decisions which it is capable of vetoing and must approve those decisions'*.

²⁹³⁵ T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 114 and caselaw cited, upheld in C-595/18 P *Goldman Sachs v Commission*.

²⁹³⁶ T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605. See also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraph 22(b). See also C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 41, citing C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraphs 96 and 97.

sized, whether investments or acquisitions shall be made and whether it shall be sold and for what price, can be particularly important.²⁹³⁷

The presence of parent company representatives on the subsidiary's board

9.44. The General Court has held that:

'the fact that, when acquiring a company, a company replaces some of the directors constitutes evidence that the acquiring company in fact exercises decisive influence over the conduct of the company that has been acquired'.²⁹³⁸

9.45. The General Court has confirmed that appointee directors on a subsidiary board can act in more than one capacity, where the interests of parent and subsidiary are aligned. The fiduciary duties of directors to their company cannot determine the composition of a single economic unit any more than the separate legal personality of that company can. The General Court emphasised that the parent's conduct in appointing representatives *'would not have made sense if the applicant had intended that the supervisory board be composed of persons entirely independent from the applicant.'* Since the appointee directors could not be considered *'solely as [the applicant's] representatives'*, they acted in a dual capacity.²⁹³⁹

9.46. A parent may therefore exercise decisive influence via the presence, in leading positions of the subsidiary, of individuals who occupy managerial posts within the parent company;²⁹⁴⁰ or other personal links between the companies.²⁹⁴¹ Those individuals need not be representatives only of the parent, but may owe duties to multiple entities without risk of conflict where their interests align.

9.47. The presence on the subsidiary's board of directors of individuals who also hold managerial posts within the parent therefore constitutes an organisational and personal link between the two entities. The facts that these individuals may simultaneously be directors of many other companies,

²⁹³⁷ AT.39610 *Power Cables*, Commission Decision of 2 April 2014, paragraph 779. The courts have therefore rejected the argument that *'residual control over 'strategic decisions' and financial supervision are not enough to found a conclusion that [a parent] actually exercised control over its subsidiary'*: T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

²⁹³⁸ T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 100; see also T-497/07 *CEPSA v Commission*, EU:T:2013:438, paragraph 176.

²⁹³⁹ T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraphs 75-77.

²⁹⁴⁰ T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 184; T-76/08 *El du Pont de Nemours and Company, DuPont Performance Elastomers LLC and DuPont Performance Elastomers SA v Commission*, EU:T:2012:46, paragraphs 70 and 74.

²⁹⁴¹ C-440/11 *Commission v Stichting Administratiekantor Portielje*, EU:C:2013:514, paragraphs 67 and 68.

and may not be involved in day-to-day operations, are not inconsistent with a finding that this link enables the exercise of decisive influence.²⁹⁴²

- 9.48. The General Court has held that: *‘Such an accumulation of posts necessarily places the parent company in a position to have a decisive influence on its subsidiary’s market conduct since it enables members of the parent company’s board to ensure, while carrying out their managerial functions within the subsidiary, that the subsidiary’s course of conduct on the market is consistent with the line laid down at management level by the parent company’*. The Court confirmed that *‘[t]hat objective can be attained even though member(s) of the parent company who take on managerial functions within the subsidiary do not have authority as agents of the parent company’*.²⁹⁴³
- 9.49. In *Toshiba* the Court of Justice therefore held that a parent exercised decisive influence over a subsidiary based among other things on the parent’s appointment of four directors out of the total 10 on the subsidiary’s board (one of whom simultaneously occupied a management position within the parent); and the appointment as the subsidiary’s vice president and representative from time to time of individuals who had previously acted at a high management level within the parent, and who subsequently returned to it, showing that – as the EU General Court held, *‘even if they had not retained contractual links with the [parent] and were no longer under its direct authority’* – they *‘necessarily had thorough knowledge of Toshiba’s policy and its commercial objectives and were in a position to cause the [subsidiary]’s policy and Toshiba’s interests to converge’*.²⁹⁴⁴
- 9.50. Such personal links are not only relevant where there is *‘an accumulation of posts’* with both parent and subsidiary concurrently. In *Goldman Sachs* the Court of Justice upheld the General Court and Commission’s findings that Goldman Sachs exercised decisive influence over its fund’s portfolio company Prysmian in part through the personal links Goldman Sachs had with two ‘independent’ non-executive directors on Prysmian’s board, who were not directors, officers, employees or managers of Goldman Sachs.

²⁹⁴² For example, where one such individual was simultaneously a board member of around 40 other companies, and was not *‘hands-on’*, instead receiving mainly reports on finance and *‘major moves’* from the relevant subsidiary’s managing director around three times a year, that did not prevent the individual from *‘dealing fairly intensively with’* the relevant subsidiary, or contributing to the finding that the parent exercised decisive influence. The courts have recognised that *‘the position of member of the board of directors of a company entails, by its very nature, legal responsibility for the activities of the company as a whole, including the company’s market conduct ... Once [the relevant individuals] assumed those responsibilities, it is of little significance that they did not, in practice, deal with the undertaking’s commercial strategy’*: T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraphs 53 to 60; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

²⁹⁴³ T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 184.

²⁹⁴⁴ C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 14-17. See also T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 116. The EU Court of Justice upheld the EU General Court’s judgment (see in particular paragraph 77).

Their personal links to Goldman Sachs consisted of ‘previous advisory services’ and ‘consultancy agreements’. The Court of Justice held that:

*‘The relevance of such personal links lies in the fact that they may suggest that a person, although active for a given company, actually pursues, in view of his or her links with another company, the interests of the latter.’*²⁹⁴⁵

- 9.51. Even the presence of a single parent company representative on the board of the subsidiary can be a relevant link among others conferring the ability to exercise decisive influence.²⁹⁴⁶

The receipt of information on strategic and commercial plans

- 9.52. It is not necessary for the parent to have control over the subsidiary’s day-to-day operations; rather, what counts is ‘influence over the general strategy which defines the orientation of the undertaking’.²⁹⁴⁷
- 9.53. The exercise of such influence may be supported (and demonstrated) by the parent’s rights to obtain information about its subsidiary:

*‘a flow of information between a parent company and its subsidiary and, a fortiori, an obligation to report to the parent company, also constitutes an indication of the exercise of control over the subsidiary’s decisions (see, to that effect, judgments of 20 January 2011, General Química and Others v Commission, C-90/09 P, EU:C:2011:21, paragraph 107; of 6 March 2012, FLSmidth v Commission, T-65/06, not published, EU:T:2012:103, paragraph 31; and the Opinion of Advocate General Mengozzi in Evonik Degussa and AlzChem v Commission, C-155/14 P, EU:C:2015:529, point 75). Such information and reports show organisational links between the parent company and its subsidiary and allow the parent company to monitor and control the activities of its subsidiary in order to take specific measures in relation to it.’*²⁹⁴⁸

²⁹⁴⁵ C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95.

²⁹⁴⁶ C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 76: ‘it is in no way necessary for the accumulation of posts within both the parent company and the subsidiary to concern more than one individual in order to constitute one indication among others of that capacity’. Compare C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 106: ‘[the subsidiary’s] sole director designated by [the parent] constituted, as a result of his consistent pattern of behaviour, a link between those two companies, by which the information concerning sales, production and financial results were communicated to [the parent]’.

²⁹⁴⁷ T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 121, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 73.

²⁹⁴⁸ T-682/14 *Mylan v Commission*, paragraph 351.

- 9.54. The provision by the subsidiary to the parent of information on *'the implementation stage of strategic and commercial plans'* is an indication that the parent *'exercised control'* over the decisions drawn up and executed by the subsidiary's executives.²⁹⁴⁹

The nature of the parent's business model

- 9.55. The nature of the parent's business model may be a relevant factor demonstrating its exercise of decisive influence over the subsidiary.
- 9.56. In particular, financial investors that actively engage with their portfolio companies to effect change are likely to exercise decisive influence over them. For example, in *Gigaset v Commission*, the EU General Court took into account the fact that the parent's commercial strategy relied on buying and restructuring companies in order to sell them for a higher price (typically on a three- to five-year timeframe), noting that it was difficult to see how this could be achieved without exercising decisive influence over its subsidiary.²⁹⁵⁰
- 9.57. The General Court has limited the concept of a *'pure financial investor'* (potentially lacking decisive influence) to *'the case of an investor who holds shares in a company in order to make a profit, but who refrains from any involvement in its management and in its control'*.²⁹⁵¹ There may be cases of pure financial investors; but any such finding can only be made on a case by case basis.
- 9.58. For example, in response to an industry parent company's attempt to rebut the *Akzo* presumption by arguing that its subsidiary was purchased for investment purposes, the General Court held that:

'the purchase by an investment company with a view to sale can also argue in favour of the existence of an economic entity between the investment company and the subsidiary in question. The fact that the investment company seeks to improve the subsidiary's results over the short term implies, as a rule, that the parent company must involve itself in the subsidiary's activities. An effective and strict system of

²⁹⁴⁹ C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraphs 104 to 107.

²⁹⁵⁰ T-395/09 *Gigaset AG v Commission*, EU:T:2014:23, paragraphs 37 to 38.

²⁹⁵¹ T-392/09 *1. garantovaná a.s. v Commission*, EU:T:2012:674, paragraph 52, citing the Opinion of Advocate General Kokott in C-97/08 *Akzo Nobel v Commission*, EU:C:2009:262.

monitoring may offer better guarantees for increased profitability than a policy of non-intervention'.²⁹⁵²

- 9.59. The courts, the European Commission and Member States' national competition authorities have, in a number of cases, held parent companies focused on financial investment to be liable for infringements committed by their portfolio companies. For example:
- a. In its *Gigaset* decision, the Commission found that Gigaset exercised decisive influence over its subsidiary SKW Holding, including during the period when its shareholding decreased from 100% to 57%, on the basis of factors including: overlapping roles on the Gigaset and SKW boards; veto rights over particular transactions; and Gigaset's involvement in the appointment, dismissal and terms of remuneration of SKW's key management. The General Court upheld the Commission's conclusions.²⁹⁵³
 - b. In its *Servier* decision, the European Commission attributed liability to Unichem Laboratories for the infringement committed by its subsidiary Niche Generics, including during the period when it owned 60% of its shares, on the basis that Unichem exercised decisive influence over Niche through its: '*prevailing presence on Niche's Board of Directors*', the majority of whom were appointed by Unichem (and which included the chairman of Unichem's board); rights under a shareholders' agreement; monitoring of Niche's financial performance and approval of its business plan.²⁹⁵⁴ The Commission dismissed Unichem's argument that it had been acting '*only as a passive investor in Niche much like a venture capitalist*', since these points showed that it had not refrained from any involvement in its subsidiary's management or control.²⁹⁵⁵ The Commission also found that Mylan Laboratories exercised decisive influence over its majority-owned subsidiary Matrix Laboratories, on the basis of factors including Mylan's: access to strategic information and leverage over Matrix's decision making processes; rights to be consulted and to veto strategic decisions; and personal links via Mylan employees serving on Matrix's board, '*on deputation from Mylan*' – ie seconded from Mylan.²⁹⁵⁶ The EU General Court upheld the

²⁹⁵² T-54/06 *Kendrion v Commission*, EU:T:2011:667, paragraph 66 (judgment only available in French and Dutch; English summary from the Opinion of Advocate General Sharpston in C-50/12 P *Kendrion v Commission*, EU:C:2013:350, paragraph 53).

²⁹⁵³ T-395/09 *Gigaset AG v Commission*, EU:T:2014:23.

²⁹⁵⁴ Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraphs 3017-3019.

²⁹⁵⁵ Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3016.

²⁹⁵⁶ Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraphs 3028-3036.

Commission's analysis of both cases in two separate appeals.²⁹⁵⁷ In relation to Mylan/Matrix, it found that *'the obligations as regards authorisation, consultation, reporting and consolidation of accounts as well as the cross-directorships between the subsidiary and its parent company'* were sufficient to establish decisive influence during the 20-month ownership period.²⁹⁵⁸

- c. In its *Lundbeck* decision, the European Commission found AL Industrier AS liable for the infringement committed by its subsidiary Alpharma – despite its shareholding of between 23 and 27.8% – on the basis that AL Industrier exercised decisive influence in particular via the personal links between parent and subsidiary, comprising (among other things): that the parent had the right to appoint six out of nine members of the subsidiary's board; and that individuals had overlapping roles between parent and subsidiary. In so doing the Commission expressly rejected the parent's argument that it was a mere financial investor.²⁹⁵⁹ This aspect of the decision was not appealed.²⁹⁶⁰
- d. In its *Power Cables* decision, the European Commission attributed liability to The Goldman Sachs Group, Inc. on the basis that it exercised decisive influence over its fund's portfolio company, Prysmian, for several years of the infringement period.²⁹⁶¹ During an initial period, Goldman Sachs held 100% of the voting rights in Prysmian, and the Commission applied the *Akzo* presumption as well as additional relevant factors including those referred to at paragraph 9.32 above. After Prysmian shares were sold off in a flotation, the Commission concluded that Goldman Sachs continued to exercise decisive influence via those factors. The General Court upheld the Commission's attribution of liability, noting that *'the exercise of voting rights regarding strategic decisions for the business conduct of the subsidiary, such as the appointment of top management and the approval of business and management plans, is evidence of a clear exercise of decisive influence rather than a purely temporary financial*

²⁹⁵⁷ T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89; and T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 344-361. Currently on appeal to the Court of Justice: C-166/19 P and C-197/19 P.

²⁹⁵⁸ T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 350 and 359.

²⁹⁵⁹ Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraphs 1274-1283.

²⁹⁶⁰ In Alpharma's appeal, T-471/13 *Xellia Pharmaceuticals and Alpharma v Commission*, EU:T:2016:460, the Court noted: *'the Commission held that A.L. Industrier, which controlled Alpharma Inc., formed with that company a single undertaking that also included Alpharma ApS. Moreover, the applicants do not dispute that those three companies formed a single undertaking at the time of the conclusion of the agreement at issue'* (paragraph 389).

²⁹⁶¹ In AT.39610 *Power Cables*, Commission Decision of 2 April 2014, the Competition Commissioner stated, *'I would like to highlight the responsibility of groups of companies, up to the highest level of the corporate structure, to make sure that they fully comply with competition rules. This responsibility is the same for investment companies, who should take a careful look at the compliance culture of the companies they invest in.'* Document PAD048, EU Commission: *'Introductory remarks on two cartel decisions: Power Cables and Steel Abrasives'*.

investment.²⁹⁶² The Court of Justice upheld the General Court in all respects.²⁹⁶³

- e. The Dutch national competition authority, the Authority for Consumers and Markets, found entities within two investment groups, Bencis Capital Partners and CVC Capital Partners, liable as successive parents of Meneba B.V., the legal entity that entered into a market sharing agreement. CVC was found to have exercised decisive influence over Meneba notwithstanding its minority share of 41%. It did not appeal. Bencis was found to have exercised decisive influence over Meneba via its powers to appoint board members (which it exercised, including by appointing one of its founders and managing partners as Meneba's chairman), cast deciding votes in relation to the supervisory board, and influence business plans. Bencis appealed to the District Court of Rotterdam, which upheld the Authority's decision, confirming that Bencis had exercised decisive influence over Meneba via these economic, organisational and legal links.²⁹⁶⁴

B. The CMA's assessment of undertakings and attribution of liability

- 9.60. For the reasons set out below, the CMA finds that the following legal entities formed part of the undertakings Auden/Actavis, Waymade and AMCo and are liable for the Infringements during the periods and on the basis indicated.

Table 9.1: Legal entities forming part of the undertakings over time and basis of liability

Infringement	Undertaking	Legal entity	Period of liability	Basis of liability
10mg Unfair Pricing Abuse	Auden/Actavis	Accord-UK	1 October 2008 – 31 August 2015	Economic successor of AM Pharma
			1 September 2015 – 31 July 2018	Direct participant
		Allergan	29 May 2015 – 1 August 2016	Parental liability: exercised decisive influence over direct participant
		Accord	9 January 2017 to 31	Parental liability: exercised decisive influence over direct

²⁹⁶² T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 180.

²⁹⁶³ C-595/18 P *Goldman Sachs v Commission*.

²⁹⁶⁴ Decisions 6306_20/217_OV (20 November 2014) and 6306_20/259 (11 September 2015); District Court of Rotterdam judgment of 26 January 2017, NL:RBROT:2017:588.

Infringement	Undertaking	Legal entity	Period of liability	Basis of liability
			July 2018	participant
		Intas	9 January 2017 to 31 July 2018	Parental liability: exercised decisive influence over direct participant
20mg Unfair Pricing Abuse	Auden/Actavis	Accord-UK	1 October 2008 – 31 August 2015	Economic successor of AM Pharma
			1 September 2015 – 8 January 2017	Direct participant
		Allergan	29 May 2015 – 1 August 2016	Parental liability: exercised decisive influence over direct participant
20mg Agreement	Auden	Accord-UK	11 July 2011 – 30 April 2015	Economic successor of AM Pharma
	Waymade	Waymade plc	11 July 2011 – 30 April 2015	Direct participant
10mg Agreement	Auden/Actavis	Accord-UK	23 October 2012 – 31 August 2015	Economic successor of AM Pharma
			1 September 2015 – 24 June 2016	Direct participant
		Allergan	29 May 2015 – 24 June 2016	Parental liability: exercised decisive influence over direct participant
	Waymade	Waymade plc	23 – 30 October 2012	Direct participant
		Amdipharm UK Limited	23 – 30 October 2012	Direct participant
	AMCo	Amdipharm UK Limited	31 October 2012 – 24 June 2016	Direct participant
		Amdipharm	1 January 2013 – 24	Direct participant

Infringement	Undertaking	Legal entity	Period of liability	Basis of liability
		Limited	June 2016	
		Advanz Pharma Services (UK) Limited	31 October 2012 – 24 June 2016	Direct participant
		Cinven MGP	31 October 2012 – 20 October 2015	Parental liability: exercised decisive influence over direct participant
		Luxco 1	31 October 2012 – 20 October 2015	Parental liability: exercised decisive influence over direct participant
		Cinven Partners	31 October 2012 – 20 October 2015	Parental liability: exercised decisive influence over direct participant
		Advanz	21 October 2015 – 24 June 2016	Parental liability: exercised decisive influence over direct participant

I. Auden/Actavis

9.61. The CMA finds that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition and the Chapter II prohibition, referred to as 'Auden', 'Actavis' or 'Auden/Actavis' as appropriate in context (see paragraph 1.3(a) above):

- a. from 1 October 2008 to 28 May 2015: AM Pharma;
- b. from 29 May 2015 to 1 August 2016: AM Pharma, Accord-UK and Allergan;
- c. from 2 August 2016 to 8 January 2017: Accord-UK; and
- d. from 9 January 2017 to 31 July 2018: Accord-UK, Accord and Intas.

9.62. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market (directly or through subsidiaries). During the time periods outlined above they formed part of the undertaking that supplied hydrocortisone tablets in

the UK at excessive and unfair prices and that entered into the 10mg and 20mg Agreements.

9.63. In summary, and as explained in the sections that follow:

- a. AM Pharma is the entity that sold hydrocortisone tablets from 1 October 2008 until 31 August 2015, and that entered into the Agreements.
[REDACTED].²⁹⁶⁵
- b. On 29 May 2015, AM Pharma was acquired by Allergan. Allergan also wholly owned Accord-UK (then known as Actavis UK Limited). AM Pharma's business and assets, including those relating to the sale of hydrocortisone tablets, were transferred under Allergan's 100% ownership to Accord-UK. Accord-UK took over the economic activity of selling hydrocortisone tablets, and supplying AMCo under the 10mg Agreement, with effect from 1 September 2015. Until 1 August 2016 AM Pharma and Accord-UK remained under common ownership and control by Allergan: the shares in each were indirectly wholly owned by Allergan.²⁹⁶⁶ The Akzo presumption therefore applied between Allergan and each of AM Pharma and Accord-UK and has not been rebutted (see section 9.B.I.b below), such that they formed a single undertaking.
- c. On 2 August 2016, Teva completed its acquisition of AM Pharma and Accord-UK. By this point AM Pharma had ceased the sale of hydrocortisone tablets in the UK. Teva did not exercise decisive influence over Accord-UK.
- d. On 9 January 2017 Accord acquired 100% of the share capital of Accord-UK. Accord is itself 100% owned by Intas. The Akzo presumption therefore applies between Intas, Accord and Accord-UK and has not been rebutted, such that they form a single undertaking from 9 January 2017 onwards.

9.64. The CMA attributes liability for the Infringements committed by Auden/Actavis to:

- a. Accord-UK, the legal person that directly participated in the Infringements from 1 September 2015 onwards and the economic successor of AM Pharma (the legal person that directly participated in the Infringements prior to 1 September 2015); and

²⁹⁶⁵ [REDACTED].

²⁹⁶⁶ Document 00733, response to question 11, AM Pharma/Accord-UK's response to the CMA's section 26 notice dated 18 October 2016.

- b. Allergan, Accord and Intas, as legal persons that exercised decisive influence over direct participants in the Infringements during their respective ownership periods, and are therefore jointly and severally liable with them.

a. Liability of Accord-UK

- 9.65. The CMA attributes liability to Accord-UK for AM Pharma's involvement in all the Infringements, for Accord-UK's direct involvement in the Unfair Pricing Abuses and the 10mg Agreement, and for the resulting financial penalties.
- 9.66. Specifically, Accord-UK is held liable:
 - a. for the 10mg Unfair Pricing Abuse, from 1 October 2008 until 31 July 2018;
 - b. for the 20mg Unfair Pricing Abuse, from 1 October 2008 until 8 January 2017;
 - c. for the 20mg Agreement, from 11 July 2011 until 30 April 2015; and
 - d. for the 10mg Agreement, from 23 October 2012 until 24 June 2016.
- 9.67. In relation to the period prior to 31 August 2015, this is because Accord-UK succeeded AM Pharma as economic actor on the relevant market(s) from 1 September 2015 and is therefore liable for AM Pharma's prior conduct in relation to the Infringements. From 1 September 2015, Accord-UK is liable as a direct participant in the Infringements.
 - i. 1 October 2008 until 31 August 2015**
- 9.68. Until 31 August 2015, hydrocortisone tablets were sold by AM Pharma. As described more fully in section 3.F.I above, AM Pharma acquired the MAs for hydrocortisone tablets from MSD in April 2008²⁹⁶⁷ and supplied hydrocortisone tablets in the UK under those MAs from that time until 31 August 2015.
- 9.69. Section 5 above explains the CMA's conclusion that Auden abused its dominant position by charging excessive and unfair prices for hydrocortisone tablets from 1 October 2008 onwards, contrary to the Chapter II prohibition.

²⁹⁶⁷ The MHRA approved the transfer on 3 June 2008, with authorisation number 17507/0097 and 17507/0098 for 10mg and 20mg hydrocortisone tablets respectively. AM Pharma also entered into manufacturing arrangements with Tiofarma for the supply of hydrocortisone tablets in April 2008 (Document 00452, response to question 4, Tiofarma's response to the CMA's section 26 notice dated 4 April 2016).

- 9.70. AM Pharma was the legal entity that initially entered into the Agreements with Waymade and later AMCo. Section 6 above provides a detailed description of these agreements and the CMA's findings that they infringed the Chapter I prohibition.
- 9.71. AM Pharma therefore directly participated in the Infringements until 31 August 2015.
- 9.72. From 1 September 2015, AM Pharma was succeeded as economic actor on the market(s) for hydrocortisone tablets and as participant in the Unfair Pricing Abuses and 10mg Agreement by Accord-UK (then known as Actavis UK Limited).
- 9.73. In summary, for the reasons set out below, the CMA considers that it is appropriate to apply the principle of economic continuity to hold Accord-UK liable for AM Pharma's participation in the Infringements prior to 31 August 2015, as economic successor to AM Pharma.

The legal test for applying the principle of economic continuity

- 9.74. Competition law applies to undertakings whose structure, method of financing, legal organisation and share ownership may vary over time. That fact, and the need to ensure the effective application of competition law to such changes, may justify accepting derogations from the principle of personal responsibility, particularly in cases in which the principle of economic continuity applies.²⁹⁶⁸
- 9.75. The conditions for applying the principle of economic continuity were set out by the Grand Chamber of the Court of Justice in Case C-280/06 *ETI v Commission*. They are that, where a business is transferred from one legal entity (the transferor) to another (the transferee):
- a. The transferee continued the transferor's economic activities on the market affected by the suspected infringement. In those circumstances, even though the transferor continues to exist as an economic operator on other markets, the transferee could be regarded – for the purposes of the procedure relating to the suspected infringement – as the 'economic successor' of the transferor,²⁹⁶⁹ and
 - d. those entities have been subject to control by the same person within the group and have therefore, given the close economic and

²⁹⁶⁸ See the Opinion of Advocate General Wathelet in Case C-434/13 P *Commission v Parker Hannifin Manufacturing Srl* EU:C:2014:2165, paragraph 35 (followed by the Court of Justice); see also Case C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 40, 41 and 44.

²⁹⁶⁹ C-280/06 *ETI v Commission* EU:C:2007:775, paragraph 45.

organisational links between them, carried out, in all material respects, the same commercial instructions.²⁹⁷⁰

The principle of economic continuity applies in this case

- 9.76. For the purposes of this case, Accord-UK can be regarded as the economic successor of AM Pharma. Following the sale of Auden Mckenzie Holdings Limited (the 100% owner of AM Pharma) to Allergan on 29 May 2015, AM Pharma's trading activities, including the business of selling hydrocortisone tablets, were transferred to Accord-UK.²⁹⁷¹ Accord-UK then took over the economic activity of selling hydrocortisone tablets, including supplying AMCo under the 10mg Agreement. Accord-UK has continued AM Pharma's economic activities on the market(s) affected by the Infringements. The first condition for the application of the principle of economic continuity is met.
- 9.77. Turning to the second condition, the Court of Justice has held that, for the purpose of establishing the existence of economic continuity, the relevant date for assessing whether the transfer of activities is within a group or between independent undertakings must be that of the transfer itself.²⁹⁷²
- 9.78. In the present case, the CMA considers that 1 September 2015 is the relevant date, since the transfer of the hydrocortisone tablets business took place with effect from that date.
- 9.79. The relevance of 1 September 2015 is confirmed by the following facts:
- a. AM Pharma's accounts for the year ending 31 December 2015 state that:

'With effect from 1 September 2015, the company transferred its activities to Actavis UK Limited [now Accord-UK], a fellow group company'.²⁹⁷³
 - b. Accord-UK wrote to AM Pharma's customers, including AMCo, to inform them that it would be taking over AM Pharma's sales to them from 1 September 2015 and that they should place orders with Accord-UK from that date.²⁹⁷⁴

²⁹⁷⁰ C-280/06 *ETI v Commission*, paragraph 49. These conditions were applied by the Court of Justice in C-601/18 P *Prysmian v Commission* (see paragraphs 87-90).

²⁹⁷¹ Document 00686, response to question 12, AM Pharma's response to the CMA's section 26 notice of 24 August 2016. See also AM Pharma's accounts for the year ending 31 December 2015.

²⁹⁷² C-434/13 P *Commission v Parker Hannifin*, paragraph 50.

²⁹⁷³ AM Pharma accounts for the year ending 31 December 2015, page 2.

²⁹⁷⁴ Document 205217, Auden/Actavis's RSSO, Annex 2 paragraph 1.5. See also Document 02329, email from [X] to [AMCo Employee] of AMCo dated 25 August 2015: 'I can confirm that Actavis will now be supplying future orders'.

- c. Accord-UK had purchased stock of hydrocortisone tablets from AM Pharma in July and August 2015 to enable itself to fulfil orders from 1 September 2015.²⁹⁷⁵
 - d. Accord-UK had made purchase orders with Tiofarma for supply of hydrocortisone tablets from August 2015 onwards, as part of its preparations for taking over that business.²⁹⁷⁶
 - e. Shortly after 1 September 2015, Accord-UK's commercial staff investigated the Second Written Agreement that they had acquired from AM Pharma and decided to continue that agreement on the existing terms.²⁹⁷⁷
 - f. From 3 September 2015 AMCo issued its purchase orders for the 12,000 monthly packs of 10mg hydrocortisone tablets supplied under the Second Written Agreement to Accord-UK. A purchase order issued in September 2015 stated: *'Actavis has taken over Auden & all the future orders would be supplied by Actavis'*.²⁹⁷⁸
- 9.80. On 1 September 2015 (and from 29 May 2015, when Allergan completed its acquisition, onwards), AM Pharma (as transferor) and Accord-UK (as transferee) were *'subject to control by the same person within the group'*.²⁹⁷⁹ both legal entities were indirectly wholly-owned by Allergan. In light of this, AM Pharma and Accord-UK constituted an economic entity, and it is permissible to impose a penalty on Accord-UK where (as here) both entities were under the control of Allergan and, given the close economic and organisational links between them, have carried out, in all material respects, the same commercial instructions.
- 9.81. The conditions for applying the principle of economic continuity are therefore met in this case.
- 9.82. The application of the principle is not affected by the subsequent sale by Allergan of Accord-UK and AM Pharma to Teva or the divestment of Accord-UK by Teva to Intas. The structural links between Accord-UK, AM Pharma and Allergan need not subsist after the transfer of the hydrocortisone tablets

²⁹⁷⁵ Document 205217, Auden/Actavis's RSSO, Annex 2 paragraph 1.5.

²⁹⁷⁶ Document 00412, minutes of a meeting with Tiofarma in August 2015.

²⁹⁷⁷ See, for example, Document 02311, emails between [Actavis Senior Employee 2] and [Actavis Senior Employee 1] dated 4 September 2015 (*'AmCo pay £1.78 for Hydrocortisone – you OK to continue selling at this price?' 'This is the contracted price so OK'*); Document 02329, emails between [Actavis Senior Employee 2] and [X] dated 4 and 7 September 2015.

²⁹⁷⁸ See, for example, purchase order numbers 4500010691 4500010692, and 4500010693 dated 3 September 2015; 4500010775 dated 11 September 2015; and 450001108 dated 4 November 2015.

²⁹⁷⁹ C-280/06 *ETI v Commission*, paragraph 49.

business.²⁹⁸⁰ The structural links also do not need to exist for any minimum period.²⁹⁸¹ The Court of Justice has held that '*The Court has never indicated that those links must subsist until the adoption of the decision penalising the infringement.*'²⁹⁸² To take a different stance would lead to arbitrary results, since the ability to attribute liability to the transferee would vary according to whether structural links with the transferor were maintained, or broken shortly before a decision.

9.83. Nor is the application of the principle affected by the fact that the 20mg Agreement ended on 30 April 2015, before Accord-UK began selling hydrocortisone tablets. It is well-established caselaw that the principle of economic continuity may apply where the transfer of the infringing business took place after the infringement had come to an end, provided that the structural links existed at the time of that transfer.²⁹⁸³ The principle does not require that the transferee continue the infringement²⁹⁸⁴ – though in fact, as explained above, Accord-UK continued the 10mg Agreement and the Unfair Pricing Abuses from 1 September 2015 onwards.²⁹⁸⁵

9.84. Nor does the principle require that AM Pharma has ceased to exist in law,²⁹⁸⁶ or ceased all economic activity.²⁹⁸⁷

It is appropriate to apply the principle of economic continuity in this case

9.85. The CMA has exercised its discretion²⁹⁸⁸ to apply the principle of economic continuity in this case in order to achieve its statutory objectives of imposing a penalty that reflects the seriousness of the infringements concerned and the desirability of deterring both the undertaking on whom the penalty is imposed and other undertakings.²⁹⁸⁹

²⁹⁸⁰ C-434/13 P *Commission v Parker Hannifin*, EU:C:2014:2456, paragraph 51.

²⁹⁸¹ C-434/13 P *Commission v Parker Hannifin*, paragraphs 51 to 52.

²⁹⁸² C-434/13 P *Commission v Parker Hannifin*, paragraph 49. This was recently confirmed in T-475/14 *Prysmian v Commission*, paragraphs 133-135.

²⁹⁸³ C-204/00 P *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraphs 59, 351, 356 and 357; and C-434/13 P *Commission v Parker Hannifin* EU:C:2014:2456, paragraph 49.

²⁹⁸⁴ C-204/00 P *Aalborg Portland and Others v Commission*, EU:C:2004:6, paragraphs 350 to 351, and 356 to 360.

²⁹⁸⁵ Compare T-134/94 *NMH Stahlwerke GmbH v Commission*, paragraphs 122-138.

²⁹⁸⁶ See C-204/00 P, C-205/00 P, C-211/00 P, C-217/00 P and C-219/00 P *Aalborg Portland v Commission* EU:C:2004:6, paragraphs 354 to 360; T-43/02 *Jungbunzlauer v Commission* EU:T:2006:270, paragraphs 132-133; C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 48 and 49.

²⁹⁸⁷ See, for example, T-43/02 *Jungbunzlauer v Commission* EU:T:2006:270, paragraphs 116 and 124 to 134. See also the Court of Justice's ruling in C-280/06 *ETI v Commission* EU:C:2007:775, paragraph 45.

²⁹⁸⁸ The General Court has recently confirmed that authorities have '*a wide margin of discretion to establish liability in cases of intra-group economic succession*' (T-531/15 *Coveris v Commission*, paragraph 45). See also T-161/05 *Hoechst v Commission*, paragraph 64: the doctrine of economic continuity is '*a power granted to the Commission, under certain circumstances, by the case-law, and not an obligation.*'

²⁹⁸⁹ Competition Act 1998, section 36(7A).

- 9.86. First, the CMA considers that any fine that could be imposed on AM Pharma would be an ineffective penalty. As explained in section 10 below, AM Pharma made a minimum financial benefit from the Unfair Pricing Abuses of around £92 million²⁹⁹⁰ during its time as monopoly seller of hydrocortisone tablets.²⁹⁹¹ Any fine that could be imposed on AM Pharma would be capped at 10% of its turnover for the year ending 31 December 2019: £1.7 million.²⁹⁹² This would be less than 2% of the minimum financial benefit AM Pharma accrued and would not reflect the seriousness of the infringements participated in by AM Pharma or effectively punish it for those infringements.²⁹⁹³
- 9.87. Second, the CMA considers that any penalty imposed on AM Pharma would not deter AM Pharma (or, given the points in the paragraph above, other undertakings):
- a. After the transfer of its business to Accord-UK, AM Pharma ceased any economic activity relating to hydrocortisone tablets.²⁹⁹⁴
 - b. AM Pharma's accounts for the year ending 31 December 2015 state that: *'Going forward, the company's activities will be limited to non-trading income, expenses and the holding of product licences for goods sold by other group entities'*.²⁹⁹⁵ Its income derives from other entities in the group headed by Teva, its current owner: intra-group loan repayments and revenue from trademarks and royalties for goods sold by other group entities. AM Pharma therefore continues to operate in all material respects solely on an intra-group basis. Its turnover for the year ended 31 December 2019 was £16.7 million. The senior team

²⁹⁹⁰ Around £87 million in relation to 10mg tablets, around £5 million in relation to 20mg. These figures give the financial benefit compared with the price level at which the CMA has prioritised investigating Auden/Actavis's prices (£20). As such, they represent the minimum financial benefit Auden made from selling hydrocortisone tablets at excessive and unfair prices.

²⁹⁹¹ Such gains have, moreover, not been invested in any assets currently controlled by AM Pharma. Instead, any assets acquired with sums not paid out in the form of dividends were transferred to Accord-UK.

²⁹⁹² AM Pharma would be entitled to its own 10% statutory cap if it were to be fined: *C-50/12 P Kendrion v Commission*, paragraph 57. Section 36(8) of the Act provides that no penalty fixed by the CMA for an infringement of the Act may exceed 10% of the turnover of the infringing undertaking. Article 3 of the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 provides that for these purposes the relevant turnover is *'the applicable turnover for the business year preceding the date on which the decision of the CMA is taken or, if figures are not available for that business year, the one immediately preceding it'*.

²⁹⁹³ The CMA's role in imposing a penalty is *'to punish the particular undertaking for the specific infringement and to deter it and other companies from further breaches of that kind'*: *Kier Group v OFT* [2011] CAT 3, paragraph 166. Compare *T-531/15 Coveris v Commission*, paragraph 49: the principle of economic continuity may be applied where *'necessary in order to punish [infringements] in a way that is proportionate to the fault and effectively'*. See also Opinion of AG Kokott in *C-280/06 ETI v Commission*, paragraph 81, and footnote 69: *'If an undertaking no longer has any significant turnover, it is no longer possible to impose an effective fine on it'*.

²⁹⁹⁴ Document 00686, response to question 12, AM Pharma's response to the CMA's section 26 notice of 24 August 2016. See also Document 00639, response to questions 1 and 8, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016: Accord-UK *'purchased closing stocks of Hydrocortisone tablets from Auden Mckenzie around the time sales transitioned across to Actavis'*.

²⁹⁹⁵ AM Pharma accounts for the year ending 31 December 2015, page 2.

involved in the Infringements have all left AM Pharma, which no longer has any employees. Its two directors receive no salary from AM Pharma: they are paid by other group entities that do not recharge AM Pharma. The company pays no dividends and files its accounts as a going concern on the basis of the continued financial support of other Teva group companies.²⁹⁹⁶

- c. AM Pharma therefore no longer trades at all, whether on the relevant market(s) or any market. Any fine imposed on AM Pharma would therefore have no deterrent effect.²⁹⁹⁷

- 9.88. Third, imposing a penalty on AM Pharma would in practice amount indirectly to imposing liability under the Act on Teva, its current owner, since AM Pharma is dependent on the Teva group for its continued existence as a going concern. Teva did not exercise decisive influence over the conduct of the infringing business (the sale of hydrocortisone tablets in the UK). Rather, Teva has only owned AM Pharma during the period after it ceased economic activity on the relevant market(s).²⁹⁹⁸
- 9.89. Any fine that could be imposed on AM Pharma for the Infringements would therefore neither effectively punish AM Pharma nor deter it and other undertakings from engaging in similar conduct in future.
- 9.90. By contrast, since 1 September 2015 Accord-UK has sold, and continues to sell, hydrocortisone tablets. It also continued the Unfair Pricing Abuses and 10mg Agreement after it succeeded AM Pharma as economic actor on the relevant market(s). It is therefore appropriate to impose a penalty on Accord-UK. Applying the principle of economic continuity to hold Accord-UK liable for the period prior to the transfer of the hydrocortisone tablets business (1 October 2008 until 31 August 2015) ensures that liability follows the infringing business and the gains from the Infringements and deters the entity on whom the penalty is imposed and other entities, so that the penalty is effective and proportionate to the Infringements.²⁹⁹⁹

²⁹⁹⁶ According to its latest available accounts (for the year ended 31 December 2019).

²⁹⁹⁷ The Court of Justice has stated that a '*penalty imposed on an undertaking that continues to exist in law, but has ceased economic activity, is likely to have no deterrent effect*': C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 40 to 41.

²⁹⁹⁸ In contrast to Allergan, which as explained in section 9.B.I.b below exercised decisive influence over AM Pharma and Accord-UK.

²⁹⁹⁹ Compare the Opinion of AG Kokott in C-280/06 *ETI v Commission*, paragraph 80: '*it is only by attributing the cartel offences to the new operator of the undertaking that one can ensure that on the one hand the person made responsible is the one who gains from any profits and increases in value of the undertaking in consequence of participation in the cartel, and on the other that the penalty as such is not ineffective. This is because it is only the economically active new operator who can have the undertaking conduct itself in future in compliance with competition law. A penalty would not have a comparable effect if it were imposed on the original operator of the*

The parties' representations on economic continuity

9.91. Auden/Actavis submitted that:

- a. The CMA had not met the legal test for applying the principle of economic continuity to Accord-UK; and
- b. In any event even if the principle could be applied, it should not be.³⁰⁰⁰

The legal test

- 9.92. Auden/Actavis submitted that the legal test requires '*the main part of those physical and human elements that were employed in [the infringing business]*' to be transferred at a time when transferor and transferee are part of the same undertaking.³⁰⁰¹
- 9.93. Applying this test, the parties stated that the main part of AM Pharma's hydrocortisone tablets business was not transferred to Accord-UK on 1 September 2015 but on 3 October 2016, pursuant to an asset purchase agreement (and in fact, certain elements such as AM Pharma's management and physical premises were never transferred). Since on 3 October 2016 Accord-UK was held separate by Teva pending divestment, this was '*a transfer between independent third parties*' and the conditions for applying the principle were not met.³⁰⁰²
- 9.94. The CMA disagrees with the parties' representations on this point. The parties' representations focus on whether there were structural links between AM Pharma and Accord-UK at the time of the CMA's Decision, whereas the caselaw clearly establishes (as set out above) that the relevant transfer is that of AM Pharma's business to Accord-UK. This point can be illustrated by the *Parker-Hannifin* case, where the Court of Justice found that the fact ITR Rubber had been transferred to new ownership was irrelevant – the relevant point was that prior to that transfer, ITR SpA's business had been transferred intra-group to ITR Rubber. The Court stated that: '*The Court has never*

undertaking who was no longer economically active. The general deterrent effect on other economic participants too would be at least less'.

³⁰⁰⁰ Document 205217, Auden/Actavis's RSSO, paragraphs 1.21-1.23, section 10 and Annex 2. Document 205212, Intas/Accord-UK's RSSO, Annex 1.

³⁰⁰¹ Document 205217, Auden/Actavis's RSSO, paragraphs 10.27-10.29, referring to T-134/94 *NMH Stahlwerke v Commission*, paragraph 133. Intas also cited as authority T-6/89 *Anic v Commission*, paragraph 237 (Document 205212, Intas/Accord-UK's RSSO, Annex 1 paragraph 3(iv)). However, the General Court's reference in that paragraph to the need to '*find the combination of physical and human elements which contributed to the commission of the infringement*' relates to the situation where the transferor had ceased to exist in law. That is not the situation here.

³⁰⁰² Document 205217, Auden/Actavis's RSSO, paragraphs 10.27-10.37; Document 205212, Intas/Accord-UK's RSSO, Annex 1, citing T-531/15 *Coveris v Commission*.

indicated that those links must subsist until the adoption of the decision penalising the infringement'.³⁰⁰³

9.95. The parties sought to distinguish the precedents on the basis of factors that do not detract from the central point for the application of the principle, namely whether the economic successor is part of the same undertaking as the transferor at the time the business is transferred.^{3004, 3005}

9.96. The General Court's statement in T-134/94 *NMH Stahlwerke v Commission* ('the main part of those physical and human elements...') is consistent with the test in *ETI*. In *NMH Stahlwerke*, the facts that the transferor and transferee 'were never run by the same persons'; that the transferee did not acquire all of the rights and obligations of the transferor; and that the transferee only took over 14% of the transferor's fixed assets (and did not, for example, acquire its land and buildings) did not preclude the application of the principle of economic continuity.³⁰⁰⁶ Notwithstanding these points, the General Court held that the transferee:

'took over the main part of those physical and human elements that were employed in the manufacture of beams and therefore contributed to the commission of the infringement in question'.³⁰⁰⁷

9.97. This meant that the transferee 'absorbed the main part of the economic activity concerned by the infringement'.³⁰⁰⁸ The parties' submissions that Accord-UK did not acquire the management of AM Pharma or its commercial premises are therefore irrelevant.³⁰⁰⁹

³⁰⁰³ C-434/13 P *Commission v Parker-Hannifin* EU:C:2014:2456, paragraph 49; see also T-475/14 *Prsymian v Commission* EU:T:2018:448, paragraph 135, upheld on appeal C-601/18 P *Prsymian v Commission* EU:C:2020:751.

³⁰⁰⁴ See eg Opinion of AG Kokott in C-280/06 *ETI v Commission*, paragraph 76. For example, Accord-UK argued that *Aalborg Portland* did not apply to this case because at the time of the CMA's Decision there is no structural link between AM Pharma and Accord-UK (Document 205217, Auden/Actavis's RSSO, paragraph 10.18). Accord-UK argued that *Parker-Hannifin* did not apply to this case because the transfer in that case was between a parent and a subsidiary (Document 205217, Auden/Actavis's RSSO, paragraphs 10.20-10.21). Accord-UK argued that *Jungbunzlauer* and *NMH Stahlwerke* did not apply because: (i) in *Jungbunzlauer* the transfers occurred while the infringement was ongoing, and (ii) in *NMH* the transferee was specifically set up to take over the transferor's activities (Document 205217, Auden/Actavis's RSSO, paragraph 10.24). None of these arguments is relevant. The points established in these cases are explained in section 9.A.II.a.i above.

³⁰⁰⁵ Accord-UK argued that *ETI* was 'of no relevance' to the present case, because: (i) '*the sale of Auden to Allergan was not a transfer made between undertakings both of which were under the control of the same parent entity*'; (ii) '*Accord-UK has again been transferred at arm's length to a further third party, Intas*'; and (iii) the case was essentially limited to its facts: to where two entities answer to the same public authority and continue to do so at the time of the infringement decision (Document 205217, Auden/Actavis's RSSO, paragraphs 10.16-10.23). The first two points are irrelevant: the relevant transfer is that of AM Pharma's business to Accord-UK, not the sale of AM Pharma to Allergan or the later sale of Accord-UK to Intas. The third point is wrong. The Court of Justice has confirmed that '*the scope of the judgment in ETI and Others is not limited ... to cases in which the entities concerned are controlled by a public authority*' (C-511/11 *Versalis v Commission*, paragraph 57).

³⁰⁰⁶ T-134/94 *NMH Stahlwerke v Commission*, paragraphs 106, 126 and 130.

³⁰⁰⁷ T-134/94 *NMH Stahlwerke v Commission*, paragraph 130 (emphasis added).

³⁰⁰⁸ T-134/94 *NMH Stahlwerke v Commission*, paragraph 133 (emphasis added).

³⁰⁰⁹ Document 205217, Auden/Actavis's RSSO, Annex 2 paragraphs 1.4-1.9.

- 9.98. For the same reasons, the CMA also rejects the parties' submission that the legal test requires the businesses of the transferor and the transferee to be '*identical*'.³⁰¹⁰
- 9.99. The parties went further, arguing that the businesses must be the same at the time of the transfer and at the time the penalty is imposed by the CMA's Decision.³⁰¹¹
- 9.100. These arguments are also without merit and have been rejected by the caselaw. As explained in section 9.A.II.a.i above, the businesses of transferor and transferee do not need to be identical in all respects: what is material is that the infringing business is transferred and that the transferee continues its economic activities on the relevant market. This means that, for the purposes of attributing liability for the infringement in question, 'the undertaking run by [the transferee after the transfer] is the same as that previously run by [the transferor]'.³⁰¹² For example, in *ETI* the Court of Justice held that the principle of economic continuity could apply where transferor and transferee were subject to the control of the same public authority, notwithstanding the referring court's observation that the transfer of activities '*made a clear break of continuity with the previous model of organisational management*'.³⁰¹³

The relevant date for applying the legal test

- 9.101. It is not in dispute that 1 September 2015 is the date on which Accord-UK took over from AM Pharma the economic activity of selling hydrocortisone tablets.³⁰¹⁴ As explained above, Accord-UK therefore succeeded AM Pharma as economic actor on the relevant market(s) from this date.
- 9.102. The CMA rejects the parties' representation that the relevant date for applying the legal test is 3 October 2016, rather than 1 September 2015.
- 9.103. The asset purchase agreement entered into between AM Pharma and Accord-UK on 3 October 2016 '*records the terms on which the Assets ... and associated rights under this Agreement transferred or were licensed on the Original Transfer Date [1 September 2015]*'.³⁰¹⁵ The agreement therefore

³⁰¹⁰ Document 205217, Auden/Actavis's RSSO, paragraphs 10.39-10.43 and Annex 2, paragraph 1.4, citing C-204/00 *Aalborg Portland v Commission*, paragraph 357.

³⁰¹¹ Document 205217, Auden/Actavis's RSSO, paragraph 10.43; Document 205212, Intas/Accord-UK's RSSO, Annex 1 paragraph 3(v).

³⁰¹² C-204/00 P *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraph 357.

³⁰¹³ C-280/06 *ETI v Commission* EU:C:2007:775, paragraphs 11 and 45 to 52.

³⁰¹⁴ From 1 September 2015, '*sales of Auden Mckenzie's products including Hydrocortisone tablets were made by Actavis [Accord-UK]*'. Document 00639, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016, page 2.

³⁰¹⁵ Document 205401, asset purchase agreement between AM Pharma and Accord-UK, introduction (emphasis added).

clearly sets out that the assets to which it relates were transferred beneficially on 1 September 2015. It states that Accord-UK acquired (among other things) the goodwill, stock, customer contracts and supplier contracts relating to hydrocortisone tablets from AM Pharma on 1 September 2015.³⁰¹⁶

- 9.104. Accord-UK's status as economic successor of AM Pharma did not depend on, and was not affected by, this agreement. Accord-UK had been selling hydrocortisone tablets since 1 September 2015. This agreement was put in place because Accord-UK was shortly to be divested to a third party pursuant to the commitments given by Allergan and Teva to the European Commission. The recitals explain that its purpose was to ensure that all the necessary legal rights to Allergan's UK generics business were held by Accord-UK ahead of that divestment.³⁰¹⁷
- 9.105. Economic continuity turns on the economic reality.³⁰¹⁸ This proposition has been confirmed by the Court of Justice in C-601/18 *Prysmian v Commission*. The Court held that the General Court was entitled to find that, even if the Commission had erred in considering PirelliCSE to be PirelliCS's legal successor, that finding would be irrelevant for the purposes of attributing liability to PirelliCSE for direct participation in the infringement, since the Commission was entitled to find that PirelliCSE was PirelliCS's economic successor.³⁰¹⁹
- 9.106. The CMA therefore maintains its finding that the relevant date for applying the principle is 1 September 2015, when Accord-UK took over the economic activity of selling hydrocortisone tablets.
- 9.107. The parties' reliance on T-531/15 *Coveris v Commission* is misplaced: that case involved an inter-group transfer of the infringing business and (unlike this case) not intra-group transfer.³⁰²⁰

³⁰¹⁶ Document 205401, asset purchase agreement between AM Pharma and Accord-UK, clause 2.1.

³⁰¹⁷ Document 205401, asset purchase agreement between AM Pharma and Accord-UK, recitals A to E. This is illustrated by the fact that the agreement for the sale of Accord-UK was signed two days later, on 5 October 2016. Document 205217, Auden/Actavis's RSSO, paragraph 10.4.9.

³⁰¹⁸ The CMA therefore rejects Accord-UK's argument that the transfer of the business can only be a legal transfer (Document 205217, Auden/Actavis's RSSO, paragraphs 10.27-10.28).

³⁰¹⁹ C-601/18 *Prysmian v Commission*, paragraph 91, upholding T-465/14 *Prysmian v Commission*, paragraph 140. See also paragraph 121 of the General Court judgment: the parties' argument that the transferee 'assumed neither the rights nor the obligations of [the transferor] and consequently it cannot be regarded as its legal successor' was rejected as irrelevant given that economic continuity was established; and paragraph 137: the General Court rejected the argument that the transferee could not be held liable 'until the complete transfer of the activities in the cable sector to [the transferee]'. In fact, the MAs for hydrocortisone tablets were not formally transferred into Accord-UK's name by the MHRA until July 2018 (Document 205217, Auden/Actavis's RSSO, Annex 2 footnote 690 to paragraph 1.7).

³⁰²⁰ T-531/15 *Coveris v Commission*, paragraph 44.

Whether the principle should be applied in this case

- 9.108. The CMA has carefully considered the parties' representations that even if the conditions for applying the principle of economic continuity are met, it should not be applied as a matter of discretion.
- 9.109. Accord-UK submitted, first of all, that it was illegitimate for the CMA to have regard to the level and effectiveness of a fine imposed on AM Pharma when deciding whether to apply the principle of economic continuity.³⁰²¹ The CMA rejects this submission. The statutory objectives in fixing a penalty are to reflect the seriousness of the infringement concerned and the desirability of deterring both the undertaking on whom the penalty is imposed and other undertakings.³⁰²² Neither objective would be achieved by seeking to impose a fine on AM Pharma that would be substantially less than the profits it had earned from the Unfair Pricing Abuses. As Advocate General Kokott noted in her Opinion in *ETI*: '*If an undertaking no longer has any significant turnover, it is no longer possible to impose an effective fine on it*'.³⁰²³
- 9.110. The parties nonetheless submitted that:
- a. the principle of economic continuity should only be applied to business transfers that were artificial manoeuvres in bad faith, designed to evade a fine;³⁰²⁴
 - b. by applying the principle of economic continuity to hold Accord-UK liable, the CMA was fining '*an undertaking which is completely removed from any wrongdoing*';³⁰²⁵
 - c. by applying the principle the CMA was infringing Accord-UK's rights of defence, since it had no access to information predating the transfer of the hydrocortisone tablets business;³⁰²⁶
 - d. fining Accord-UK for the 20mg Agreement, which had ended by the time Accord-UK took over sales of hydrocortisone tablets, would create an arbitrary risk for a purchaser and a dangerous precedent for a seller,

³⁰²¹ Document 205217, Auden/Actavis's RSSO, paragraph 10.26.

³⁰²² Competition Act 1998, section 36(7A).

³⁰²³ Opinion of AG Kokott in C-280/06 *ETI v Commission*, footnote 69.

³⁰²⁴ Document 205217, Auden/Actavis's RSSO, paragraph 10.22.

³⁰²⁵ Document 205212, Intas/Accord-UK's RSSO, Annex 1, paragraph 4. See also Document 205217, Auden/Actavis's RSSO, paragraph 10.47.2.

³⁰²⁶ Document 205212, Intas/Accord-UK's RSSO, Annex 1, paragraph 3(i).

by allowing companies to restructure and thus avoid liability.³⁰²⁷ This may in fact encourage infringers to on-sell their businesses;³⁰²⁸ and

- e. in any event, even if the CMA were entitled to hold Accord-UK liable as economic successor of AM Pharma, it should also hold AM Pharma liable jointly and severally with Accord-UK.³⁰²⁹

9.111. None of these submissions stands up to scrutiny. The CMA addresses each of them in turn below:

- a. The principle of economic continuity is not generally limited to business transfers in bad faith. This limitation only applies where the relevant business transfer is between third parties, not intra-group.³⁰³⁰ As explained above, that is not the situation here.
- b. Accord-UK is not ‘*an undertaking which is completely removed from any wrongdoing*’. In fact, Accord-UK continued the Unfair Pricing Abuses and the 10mg Agreement after taking over sales of hydrocortisone tablets on 1 September 2015. Indeed, it was under Accord-UK that the prices of hydrocortisone tablets reached their highest level of the entire relevant period, and it was Accord-UK’s management that attempted to extend the market exclusion achieved by the 10mg Agreement by buying off the entry of Alissa Healthcare in December 2015 (further confirming that the relevant date for applying the principle of economic continuity cannot be as late as 3 October 2016: Accord-UK was by this point the legal entity supplying hydrocortisone tablets and with the power to buy off competitors).
- c. Applying the principle of economic continuity does not infringe Accord-UK’s rights of defence, which have been respected in this case. Accord-UK has been given every procedural protection in the CMA’s Rules and procedural guidance. Accord-UK has been provided with all the evidence on which the CMA bases its decision to apply the principle and more generally with all the documents on the CMA’s file. Accord-UK instructed the same legal counsel as AM Pharma (in relation to the period prior to Intas’ acquisition of Accord-UK on 9 January 2017) and reviewed and endorsed AM Pharma’s representations on the SSO before they were submitted to the CMA, as well as making its own written representations on economic continuity. In any event, as

³⁰²⁷ Document 205217, Auden/Actavis’s RSSO, paragraph 10.47.1 and footnote 625.

³⁰²⁸ Document 205212, Intas/Accord-UK’s RSSO, Annex 1, paragraphs 3 and 5.

³⁰²⁹ Document 205212, Intas/Accord-UK’s RSSO, Annex 1, paragraph 6, citing T-405/06 *ArcelorMittal v Commission*.

³⁰³⁰ T-531/15 *Coveris v Commission*, paragraphs 50-51.

explained in section 9.B.I.b below, Accord-UK conducted extensive due diligence on AM Pharma's business prior to its acquisition by Allergan. Accord-UK therefore took over the hydrocortisone tablets business with its eyes open. Its own conduct after taking over sales of hydrocortisone tablets in September 2015 – for example, its staff investigated the terms of the Second Written Agreement and collated AM Pharma's Project Guardian materials for use in support of its own campaign to prevent off-label dispensing (see section 3.F.III.p above) – indicates that it knowingly chose to continue AM Pharma's strategy.³⁰³¹

- d. Accord-UK's liability for the 20mg Agreement is neither an arbitrary nor an unforeseeable risk. The Court of Justice has confirmed that economic continuity may apply where the transfer of the infringing business took place after the infringement had come to an end, provided that the structural links existed at the time of that transfer.³⁰³² The fact that the transferee may subsequently have passed into new ownership is irrelevant. Indeed, *'the attribution of liability must not depend upon the occurrence of an unforeseeable and uncertain event, such as a new organisational change decided on by the undertakings concerned.'*³⁰³³ In any event, as explained above, Accord-UK undertook extensive due diligence on the business of AM Pharma before acquiring it. Nor does the CMA consider that the application of the principle of economic continuity in the particular circumstances of this case means or implies that other undertakings would be encouraged to restructure or sell businesses in order to try to escape liability.
- e. The CMA has a discretion as to which legal entities to hold liable for an infringement, including in cases of economic succession. The fact that it chooses to hold one legal entity liable does not mean it is required to hold another liable.³⁰³⁴ In this case, the CMA's reasons for holding Accord-UK liable as economic successor of AM Pharma are also its reasons for not holding AM Pharma liable. The CMA has explained above that any penalty imposed on AM Pharma would be ineffective, would not achieve deterrence and would lead to liability under the Act

³⁰³¹ See also Document 202954, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2], [AMCo Senior Employee 6] and [AMCo Senior Employee 3] dated 20 May 2015: 'According to [Auden Senior Employee 1]] Actavis will continue his strategy'.

³⁰³² C-204/00 P *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraphs 59, 351, 356 and 357; and C-434/13 P *Commission v Parker Hannifin* EU:C:2014:2456, paragraph 49.

³⁰³³ C-434/13 P *Commission v Parker Hannifin* EU:C:2014:2456, paragraph 51.

³⁰³⁴ T-531/15 *Coveris v Commission*, paragraph 45; T-161/05 *Hoechst v Commission*, paragraph 64. See also T-204/08 *Team Relocations v Commission*, paragraph 156, upheld in C-444/11 P *Team Relocations v Commission*, paragraphs 159-161.

falling on Teva, its current owner, which never exercised decisive influence over the infringing business.³⁰³⁵

9.112. The CMA therefore holds Accord-UK liable for the Infringements until 31 August 2015 as economic successor to AM Pharma.

ii. 1 September 2015 onwards

9.113. Accord-UK was the legal entity within the Actavis undertaking that directly participated in the Infringements from 1 September 2015 onwards. Accord-UK is the legal entity that sold hydrocortisone tablets in the UK from 1 September 2015 onwards.³⁰³⁶ From that date, it therefore continued the Unfair Pricing Abuses. From that date, it also participated in the 10mg Agreement with AMCo: AMCo issued its purchase orders for the 12,000 monthly packs of 10mg hydrocortisone tablets to Accord-UK.³⁰³⁷

b. Liability of Allergan

9.114. The CMA attributes liability to Allergan for Auden/Actavis's involvement in the Infringements, and for the resulting financial penalties, jointly and severally with Accord-UK.

9.115. Specifically, Allergan is held liable:

- a. for the Unfair Pricing Abuses, from 29 May 2015 to 1 August 2016; and
- b. for the 10mg Agreement, from 29 May 2015 to 24 June 2016.

9.116. From 29 May 2015 until 1 August 2016, AM Pharma and Accord-UK were both ultimately wholly owned by Allergan.³⁰³⁸

9.117. Allergan therefore had the ability to exercise decisive influence over AM Pharma and Accord-UK. The CMA applies the *Akzo* presumption that Allergan did in fact exercise decisive influence over AM Pharma and Accord-

³⁰³⁵ Unlike in T-405/06 *ArcelorMittal v Commission*, in this case transferor (AM Pharma) and transferee (Accord-UK) no longer form part of the same undertaking at the time of the authority's decision.

³⁰³⁶ Document 00639, paragraph 6(c) and responses to questions 1 and 5, AM Pharma's response to the CMA's section 26 notice dated 18 March 2016; Document 00656, paragraph 14.2, AM Pharma's response to the CMA's section 26 notice dated 23 May 2016.

³⁰³⁷ See, for example, purchase order numbers 4500010691 4500010692, and 4500010693 dated 3 September 2015; 4500010775 dated 11 September 2015; and 450001108 dated 4 November 2015. Purchase order number 4500010693 dated 3 September 2015 specifically states: '*Actavis has taken over Auden & all the future orders would be supplied by Actavis*'.

³⁰³⁸ Document 00733, response to question 11, AM Pharma/Accord-UK's response to the CMA's section 26 notice dated 18 October 2016. See also Document 00686, response to question 11, AM Pharma's response to the CMA's section 26 notice dated 24 August 2016; and Document 00691, structure chart of the Allergan group. On 29 May 2015, Actavis Holdings UK Limited, a wholly-owned subsidiary in the Allergan group, acquired 100% of the shares in Auden Mckenzie Holdings Limited and thereby indirectly acquired 100% of the shares in AM Pharma, Auden Mckenzie Holdings Limited's 100% subsidiary. The shares were transferred on the same day to Chilcott UK Limited, another wholly-owned Allergan subsidiary, under a deed of assignment.

UK until their sale to Teva completed on 2 August 2016. Allergan, AM Pharma and Accord-UK therefore formed a single undertaking for the purpose of the Infringements.

- 9.118. Allergan accepted that it was capable of exercising decisive influence over AM Pharma and Accord-UK.³⁰³⁹ Moreover, Allergan properly accepted that the burden lay on it to produce evidence sufficient to rebut the *Akzo* presumption. Allergan's case was that it had managed to rebut the *Akzo* presumption.
- 9.119. For the reasons explained in this section, the CMA considers that Allergan has failed to rebut the *Akzo* presumption. Allergan is therefore liable for the Infringements committed by AM Pharma and Accord-UK during its ownership period.
- 9.120. It is important to be clear at the outset about the legal entities referred to in this section:
- a. The legal entity that directly acquired Auden Mckenzie Holdings Limited, AM Pharma's 100% parent, was Actavis Holdings UK Limited. Allergan was the ultimate 100% parent of Actavis Holdings UK Limited. The shares were transferred on the same day to Chilcott UK Limited, another wholly-owned Allergan subsidiary. Allergan therefore became the ultimate 100% parent of AM Pharma on 29 May 2015.
 - b. When it acquired AM Pharma, Allergan was known as Actavis plc. Shortly afterwards, in June 2015, it changed its name to Allergan plc. It is this legal entity formerly known as Actavis plc that the CMA means by 'Allergan'.
 - c. The company now called Accord-UK Limited was called Actavis UK Limited during the period of Allergan's ownership. It is this legal entity that the CMA means by 'Actavis UK' and 'Accord-UK'.
- 9.121. In its written representations and in its oral hearing on the SSO Allergan elided these legal entities. It referred to 'Actavis' as if it were separate from Allergan, without recognising that the legal entity Actavis plc had simply

³⁰³⁹ Document 205209, Allergan's RSSO, paragraph 15. Document 205514, transcript of Allergan's hearing on the SSO, page 30 lines 7-10. Allergan argued in its oral hearing that it was required to '*prove a negative*' and that rebutting the *Akzo* presumption '*imposes an impossible standard*' (Document 205514, transcript of Allergan's hearing on the SSO, page 29 lines 15-22). This is not the case: '*the fact that it is difficult to adduce the evidence necessary to rebut a presumption does not in itself mean that that presumption is in fact irrebuttable*' (C-521/09 P *Elf Aquitaine v Commission*, paragraphs 62, 66 and 70. See also C-611/18 P *Pirelli v Commission*, paragraph 73).

changed its name to Allergan plc.³⁰⁴⁰ It asserted that the CMA's provisional finding was that Allergan had in fact exercised decisive influence over AM Pharma through Actavis UK, which in turn exercised decisive influence over AM Pharma.³⁰⁴¹ Allergan described this as "*second order' influence over AM Pharma via the agency of Actavis UK*".³⁰⁴² However, this misstates the CMA's findings. The correct position is that AM Pharma and Actavis UK were sister companies under Allergan's 100% ownership. For the avoidance of doubt, the CMA's case has always been and remains that Allergan exercised decisive influence over the conduct of each of AM Pharma and Actavis UK.

- 9.122. On 10 March 2016 the European Commission announced that it had approved the proposed acquisition of Allergan's generics business by Teva, subject to conditions. One of those conditions was for Teva to divest a viable standalone business operation in the UK and Ireland based around the assets of the Actavis Generics business, including a portfolio of generic molecules (including hydrocortisone), Actavis's Barnstaple manufacturing plant, and the management and people to run the business units in the UK and Ireland (the '**Divestment Businesses**').³⁰⁴³ The Divestment Businesses included hydrocortisone tablets.
- 9.123. Pending completion of that divestment, Teva and Allergan committed to keep the Divestment Businesses separate from the businesses they were retaining (the '**Commitments**') and to appoint a hold-separate manager (the '**Hold Separate Manager**') to manage the Divestment Businesses.³⁰⁴⁴ Accord-UK was held separate under Allergan's 100% ownership between 10 March 2016 and 1 August 2016 (the '**Hold Separate Period**').
- 9.124. The CMA considers that Allergan continued to exercise decisive influence over Accord-UK during the Hold Separate Period, having regard to Allergan setting the strategic commercial behaviour of Accord-UK before and during the Hold Separate Period and the links between Allergan and Accord-UK

³⁰⁴⁰ For example, Allergan argued that the due diligence report prepared for the AM Pharma acquisition by PWC (referred to below) was '*commissioned, and Actavis UK's acquisition of AM Pharma was already initiated, before the Actavis/Allergan merger in March 2015*' (Document 205209, Allergan's RSSO, paragraph 13(e)). This is irrelevant: the Actavis/Allergan merger was an acquisition by Actavis plc of Allergan plc, after which it was decided to rename the newly formed group 'Allergan' and discontinue the 'Actavis' brand. This simply resulted, for the purposes of this case, in the legal entity Actavis plc changing its name to Allergan plc. It is this legal entity that acquired AM Pharma and that the CMA holds liable.

³⁰⁴¹ At its oral hearing Allergan's representative stated: '*Actavis UK ... itself owned Auden Mckenzie*', and '*Allergan is said to have exercised a decisive influence over Actavis UK and Actavis UK is then said to have exercised decisive influence over Auden Mckenzie*.' Document 205514, transcript of Allergan's hearing on the SSO, page 6 lines 22-24 and page 7 lines 14-16. These statements are not correct if by 'Actavis UK' Allergan's representative referred to Accord-UK.

³⁰⁴² Document 205209, Allergan's RSSO, paragraph 18(c)(2).

³⁰⁴³ http://europa.eu/rapid/press-release_IP-16-727_en.htm.

³⁰⁴⁴ Document 00743, Commitments, clause 37.

that persisted during the Hold Separate Period. While Allergan was precluded by the Commitments it had chosen to give from intervening in Accord-UK's day-to-day business, that business was conducted on the basis of a strategy set by Allergan and which the Hold Separate Manager was appointed to continue and did in fact continue. Allergan could at any point have withdrawn from the sale of Accord-UK, in which case the Commitments would have lapsed and Allergan would have resumed control of Accord-UK's day-to-day operations. In these circumstances, and as explained more fully below, the *Akzo* presumption is not rebutted by the Commitments.

i. 29 May 2015 to 9 March 2016

- 9.125. Between 29 May 2015 and 9 March 2016, the entire capital of AM Pharma and Accord-UK was owned by Allergan, such that Allergan was able to exercise decisive influence over their conduct and it is presumed that such influence was actually exercised. The application of the *Akzo* presumption is not conditional upon the production of additional indicia relating to the actual exercise of decisive influence by Allergan.³⁰⁴⁵
- 9.126. Furthermore, and in any event, the CMA finds that the *Akzo* presumption is corroborated by further evidence of the exercise of decisive influence. For example, under Allergan's ownership, AM Pharma's business was transferred to Accord-UK, which took over sales of hydrocortisone tablets from 1 September 2015 onwards (see section 9.B.I.a.i above).³⁰⁴⁶
- 9.127. Allergan submitted that the *Akzo* presumption was rebutted during this period because, notwithstanding the transfer of AM Pharma's activities to Accord-UK, Allergan did not intervene in the businesses of either subsidiary. In particular, Allergan submitted that:
- a. AM Pharma was '*both too small and too remote to be the subject of any direct oversight or control by Allergan in relation to the sale and pricing of hydrocortisone ... Allergan could not be expected to have, and there is no evidence to suggest that it did in fact have, any visibility of pricing or commercial arrangements in relation to one of AM Pharma's*

³⁰⁴⁵ C-595/18 P *Goldman Sachs v Commission* EU:C:2021:73, paragraph 33.

³⁰⁴⁶ Allergan submitted that: '*The CMA introduces no evidence in support of its assertion that Allergan plc, as opposed to Actavis UK, "transferred AM Pharma's business and assets" and instead seeks to attribute actions taken by Actavis UK to its ultimate parent company*' (Document 205209, Allergan's RSSO, paragraph 18(b)(1)). This argument illustrates the point made above about the importance of precise terminology. AM Pharma and Actavis UK were sister companies, both ultimately 100% owned by Allergan. It is unclear how a subsidiary such as Actavis UK could act to transfer the business and assets of its sister company without approval from their common 100% parent. Allergan equally did not adduce any evidence that this had in fact happened. At its oral hearing on the SSO Allergan conceded that the transfer was not '*rogue activity*' outside Allergan's authority (Document 205514, transcript of Allergan's hearing on the SSO, page 32 lines 4-9). The transfer of AM Pharma's business to Accord-UK is therefore attributable to Allergan.

products'.³⁰⁴⁷ Under Allergan's ownership AM Pharma simply continued to pursue its own pre-existing strategy. Once Accord-UK took over sales of hydrocortisone tablets from 1 September 2015, it continued to pursue that same strategy. Allergan did not know of or encourage AM Pharma's or Accord-UK's conduct.³⁰⁴⁸

- b. AM Pharma and Accord-UK were both part of Allergan's generics division, which was functionally and operationally distinct from the remainder of the Allergan group, subject to separate reporting lines, and already earmarked for sale at the time of the AM Pharma acquisition.³⁰⁴⁹

9.128. The CMA finds that these submissions are not well-founded for the following reasons.

9.129. The CMA notes, first of all, that Allergan has not identified a previous case in which these factors rebutted the *Akzo* presumption.³⁰⁵⁰

9.130. The CMA finds, secondly, that the factors relied on by Allergan do not rebut the *Akzo* presumption. In C-611/18 *Pirelli v Commission* the Court of Justice held that Pirelli's arguments that its subsidiary operated autonomously on the market and that Pirelli was no more than a financial holding company were '*clearly not sufficient to call into question the presumption of the exercise, by a parent company, of decisive influence on its subsidiaries*'.³⁰⁵¹ The Commission was therefore not required even to adopt a position on these matters in its decision, since they were clearly of no probative value in rebutting the presumption.³⁰⁵²

9.131. Pirelli also argued that '*it was in no way involved in the unlawful conduct of [its two subsidiaries], was not aware of the infringement in question and therefore could not take any action to stop it.*' The Court of Justice nonetheless upheld the General Court's finding that Pirelli had not rebutted the *Akzo* presumption, and specifically noted that:

*'none of the appellant's arguments ... has been capable of establishing that that presumption was not applicable in the present case.'*³⁰⁵³

³⁰⁴⁷ Document 205209, Allergan's RSSO, paragraph 14(c).

³⁰⁴⁸ Document 205209, Allergan's RSSO, paragraphs 14(a) and 16(c).

³⁰⁴⁹ Document 205209, Allergan's RSSO, paragraphs 14(b) and 16(a) and (b). See also Document 02261.A, Allergan's representations on the first Draft Penalties Statement, paragraph 6; and Document 01353, Allergan's submission to the CMA dated 5 December 2016, paragraphs 2.3 and 2.4.

³⁰⁵⁰ Document 205514, transcript of Allergan's hearing on the SSO, page 27 lines 17-25 and page 28 lines 1-18.

³⁰⁵¹ C-611/18 P *Pirelli v Commission*, paragraph 49 (CMA translation from the original French).

³⁰⁵² C-611/18 P *Pirelli v Commission*, paragraph 49.

³⁰⁵³ C-611/18 P *Pirelli v Commission*, paragraphs 59 and 83 (CMA translation from the original French).

- 9.132. The factors cited by Allergan are therefore incapable in principle of rebutting the *Akzo* presumption, even if established.
- 9.133. Thirdly, and in any event, the CMA finds that the contemporaneous evidence shows that these factors are not established on the facts. Allergan has not adduced any evidence to the CMA that calls into question the contemporaneous evidence.
- 9.134. Fourthly, the CMA considers that the points made by Allergan do not offset or counterbalance the evidence of actual exercise of decisive influence during this period.

Allergan's involvement in the strategy of AM Pharma and Accord-UK

- 9.135. While it is not legally necessary for the parent actually to intervene in the business of its subsidiary or to be involved in or even know of the subsidiary's infringing conduct to establish the parent's liability for the infringement,³⁰⁵⁴ the CMA (for completeness) demonstrates below that Allergan was involved in determining the commercial strategy of AM Pharma and Accord-UK, specifically in relation to hydrocortisone tablets.
- 9.136. Moreover, the continuation of that strategy by AM Pharma and Accord-UK under Allergan's ownership reflects not Allergan's lack of engagement in the businesses of its subsidiaries but Allergan's investment in and approval of the strategy of exploiting Auden/Actavis's monopoly position for hydrocortisone tablets.
- 9.137. Among the relevant items of evidence on this issue are the following.
- 9.138. A December 2014 briefing presentation in connection with the possible acquisition of AM Pharma bears the 'Actavis' logo (at the time, Allergan was known as Actavis plc – see paragraph 9.120 above). It was prepared for an audience that included Allergan's US management as well as Accord-UK management:

³⁰⁵⁴ The Court of Justice has made clear that '*the fact that a parent company and its subsidiary constitute a single undertaking ... enables the Commission to address a decision imposing fines to the parent company, without having to establish the personal involvement of the latter in the infringement*' (C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 58 to 59); and that: '*what counts is not whether the parent company encouraged its subsidiary to commit an infringement ..., or whether it was directly involved in the infringement committed by its subsidiary, but the fact that those two companies constitute a single economic unit and thus a single undertaking ... which enables the Commission to impose a fine on the parent company*' (C-90/09 P *General Química SA v Commission*, EU:C:2011:21, paragraph 102. See also C-97/08 *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 59 and 77). Where a parent formed part of the economic entity that breached competition law, it is itself '*deemed to have committed the infringement*' (C-50/12 P *Kendrion v Commission* EU:C:2013:771, paragraph 55. See also T-372/10 *Bolloré v Commission* EU:T:2012:325, paragraphs 51-52).

- a. Monetary figures are given mainly in US dollars. For example, AM Pharma's revenue and EBITDA figures are given in US dollars. US dollar figures are also given for Allergan's bid for the company and base case for its value, with a note explaining the exchange rate to pounds. Dates are also given in US format.³⁰⁵⁵
 - b. The transaction's closing is described as '*subject to UK review*'. The presentation mentions risks such as '*Tax penalty from UK (HMRC) investigation*'.³⁰⁵⁶
 - c. The '*external message*' to be given for the rationale behind the transaction is: '*Investing where we are strong, our 2nd largest market. We know the UK market very well*'.³⁰⁵⁷
 - d. The presentation distinguishes between '*Actavis*' and '*Actavis UK*'. For example, AM Pharma is described as '*what Actavis UK would call – "CrownJewel-Co", comprised of MAs that UK BD would like to acquire*'. One slide entitled '*Actavis UK – Current Footprint*' explains the UK business, with figures presented in US dollars.³⁰⁵⁸ Although '*All ACT ELT [Actavis Executive Leadership Team] functional groups engaged in diligence process*', '*In depth commercial diligence*' was done '*by ACT UK team*'.³⁰⁵⁹
- 9.139. The presentation shows that Allergan paid close attention to the strategic direction of AM Pharma's business. It states that Allergan would acquire AM Pharma in order to benefit from its successful strategy of exploiting niche generic drugs, which Allergan viewed as aligned with its own existing strategy:
- 'The Auden portfolio and pipeline is well aligned with our existing Gx strategy – specialized, niche, low competition products'*.³⁰⁶⁰
- 9.140. The presentation indicates that Allergan's intention was to integrate AM Pharma swiftly into its existing business. Describing the anticipated acquisition as a '*Good example of the type of tuck-in deals we would consider*', it states: '*It will be a straight-forward, quick integration ... the Auden products will drop right into our existing robust UK Commercial*

³⁰⁵⁵ Document 00679, Project Apple presentation dated December 2014, slide 2.

³⁰⁵⁶ Document 00679, Project Apple presentation dated December 2014, slide 9.

³⁰⁵⁷ Document 00679, Project Apple presentation dated December 2014, slide 3.

³⁰⁵⁸ Document 00679, Project Apple presentation dated December 2014, slides 11 and 13.

³⁰⁵⁹ Document 00679, Project Apple presentation dated December 2014, slide 8.

³⁰⁶⁰ Document 00679, Project Apple presentation dated December 2014, slide 3.

infrastructure'.³⁰⁶¹ This statement is consistent with Allergan's intention to assimilate AM Pharma into Allergan's commercial structure.

- 9.141. Whether or not the presentation was prepared for Allergan as opposed to Accord-UK, these statements are consistent with the public statements of Allergan's most senior US management. On 26 January 2015, when Allergan's acquisition of AM Pharma was announced, [REDACTED] [Allergan Senior Employee 1] gave an interview with Fox News about the acquisition. [Allergan Senior Employee 1] stated:

'the deal today is really a bolt-on. It was really something we've been looking at for a while to really add to our strength in the UK where we were the number two generic company. Now we're number one in generics and number three overall. And it really fits beautifully right into our UK operation and our global generics business'.³⁰⁶²

- 9.142. Together these statements and the briefing presentation are not consistent with Allergan's subsequent portrayal of AM Pharma as being '*both too small and too remote*' to register with its management. On the contrary, [Allergan Senior Employee 1]' statement indicates that Allergan's senior management spent considerable time evaluating the merit of the acquisition and the strategic intention was clear: to integrate AM Pharma into its existing generics business.

- 9.143. This reality is further demonstrated by the publicly available materials prepared for Allergan's 2015 investor day. The slides presented by [Allergan Senior Employee 1] referred to AM Pharma's '*Portfolio of exclusive and semi-exclusive generic products*' and identified '*Auden McKenzie Acquisition*' as one of the '*Key assumptions*' driving the 2015 revenue forecast.[REDACTED] [Allergan Senior Employee 2] referred to Allergan's plan for AM Pharma to be subject to a '*Quick, low risk integration*'.³⁰⁶³

- 9.144. Moreover, the evidence also shows that Allergan paid particular attention specifically to hydrocortisone tablets as the main component of AM Pharma's value. This contradicts Allergan's assertion during the administrative procedure that: '*Allergan could not be expected to have, and there is no evidence to suggest that it did in fact have, any visibility of pricing or commercial arrangements in relation to one of AM Pharma's products*'.³⁰⁶⁴

³⁰⁶¹ Document 00679, Project Apple presentation dated December 2014, slide 3.

³⁰⁶² [REDACTED].

³⁰⁶³ [REDACTED].

³⁰⁶⁴ Document 205209, Allergan's RSSO, paragraph 14(c).

- 9.145. The due diligence report prepared by PWC on AM Pharma noted that *‘The hydrocortisone product has been the foundation of the business and supported the development and acquisition of other niche products’*, and that *‘significant price increases have been achieved in Hydrocortisone largely due to the orphan status that it holds in the UK and the current lack of competition’*.³⁰⁶⁵
- 9.146. Allergan submitted that this report was prepared for Accord-UK and that there was no evidence that any Allergan staff saw it.³⁰⁶⁶ It is implausible that Allergan’s management would not have reviewed the due diligence report prepared for this significant acquisition. In fact, the evidence indicates that Allergan management did review it. For example, the presentation discussed above states: *‘Reviewed: Finance & Tax draft DD reports received from PWC’*;³⁰⁶⁷ that *‘All ACT ELT [Actavis Executive Leadership Team] functional groups engaged in diligence process’*; and *‘several detailed Q&A sessions conducted with ACT Management from UK and NJ [New Jersey]’*.³⁰⁶⁸
- 9.147. In any event, whether or not Allergan management reviewed the PWC due diligence report, the evidence shows that Allergan conducted extensive due diligence on AM Pharma’s strategy for hydrocortisone tablets and that Allergan significantly modified the terms of the AM Pharma acquisition as a result of what it discovered about the hydrocortisone tablets business.
- 9.148. The December 2014 briefing presentation provides a detailed explanation of the contribution of hydrocortisone tablets to the AM Pharma business:
- ‘Gx Hydrocortisone tablets comprise 40% of sales today to due [sic] a unique orphan drug exclusivity – expected to erode in the near term; hydrocortisone erosion is factored into current Bid*
- Near term cash cow with the remainder of the business is growing [sic] with a significant pipeline’*³⁰⁶⁹
- 9.149. It also explains the nature of the protection provided by the orphan designation, stating, *‘Significant IP investigation on protection from orphan indication on Hydrocortisone completed’*, and modelling erosion of AM Pharma’s market share and prices on the assumption that competitors launched in 2015 with skinny label tablets dispensed off-label.³⁰⁷⁰

³⁰⁶⁵ Document 00681, Project Apple due diligence report dated 11 December 2014, pages 7 and 17.

³⁰⁶⁶ Document 205209, Allergan’s RSSO, paragraph 13(e).

³⁰⁶⁷ Document 00679, Project Apple presentation dated December 2014, slide 16.

³⁰⁶⁸ Document 00679, Project Apple presentation dated December 2014, slide 8.

³⁰⁶⁹ Document 00679, Project Apple presentation dated December 2014, slide 2.

³⁰⁷⁰ Document 00679, Project Apple presentation dated December 2014, slides 4-7 and 16.

9.150. In fact, Allergan paid such close attention to the prospect of off-label supply of hydrocortisone tablets and the issue of whether the orphan designation effectively protected AM Pharma's position that it negotiated a £220 million discount to its initial bid for AM Pharma. The '*Significant IP investigation*' that led to this was carried out by Allergan's US staff.

9.151. On 20 November 2014 a meeting took place between Auden, Allergan and Accord-UK staff. [Auden Senior Employee 1] explained in an internal email:

'The reason for moving the base enterprise value substantially from £520 million to £300,000 million [sic] + an earnout on Hydrocortisone is as briefly set out below.

During our meeting on 20th November 2014, to discuss Auden's product portfolio and in particular our top 5 products there was a long discussion around Hydrocortisone. The discussion centred around the Orphan [sic] drug status granted to Viropharma SPRL (which has now been acquired by Shire) for Plenadren (Hydrocortisone) for the treatment of adrenal insufficiency in adults, which was activated on 03/11/2011 upon grant of their marketing authorisation and the subsequent protection the Auden product would benefit from.

In this meeting [X] [Allergan Senior Employee 3] ... established the point to all present in the meeting that Auden's product did actually not have complete protection.

[Allergan Senior Employee 3] also expressed his opinion that the regulatory authority has no grounds to stop the grant of further Hydrocortisone licenses for other indications apart from "treatment of adrenal insufficiency in adults".³⁰⁷¹

9.152. [Auden Senior Employee 1] went on to explain that the MHRA's grant of an MA to Orion in November 2014 '*resulted in the Executive board of Actavis raising concerns over the proposed deal to acquire Auden ... Actavis were seriously concerned about the new Orion license been [sic] used "Off label" and the impact this would have on their investment if they acquired Auden.*'

9.153. Following this meeting, Allergan asked detailed questions about the nature and scope of the orphan designation and the 10mg supply agreement with AMCo, including whether the orphan designation would prevent AMCo's skinny label product from competing with Auden's full label product, and

³⁰⁷¹ Document 302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015 (emphasis added).

querying the assertions in AM Pharma's correspondence with the MHRA about legal implications of off-label sales.³⁰⁷²

- 9.154. According to the internal Auden email these enquiries led to a new structure for the deal:

'This resulted in a meeting on 6th January 2015 in Marlow where a concept was floated and subsequently accepted by [Allergan Senior Employee 2] [sic] on 9th January ... The deal agreed was as £300,000,000 + Hydrocortisone earnout ... This deal represents a total and complete de risking of Hydrocortisone for Actavis and only an earnout depending on their success to market Hydrocortisone tablets.'

³⁰⁷³

- 9.155. [Auden Senior Employee 1]'s email and Allergan's due diligence questions demonstrate that Allergan's concern about the risks off-label supply of hydrocortisone tablets posed for Auden's monopoly position was the reason it reduced the purchase price of AM Pharma by £220 million. The concern was driven by Allergan's staff. [Allergan Senior Employee 3], whose expertise underpinned the price reduction, was Allergan's [REDACTED].³⁰⁷⁴ [Allergan Senior Employee 3]'s in-depth knowledge of the orphan designation and its implications for hydrocortisone tablets is demonstrated by the letter he wrote in February 2014, asking Plenadren's owner for consent to the grant of a full-label MA for Actavis and arguing that refusal would be a breach of Articles 101 and/or 102 TFEU.³⁰⁷⁵ [Allergan Senior Employee 2], who ultimately accepted the new AM Pharma deal structure, was Allergan's [REDACTED].³⁰⁷⁶ As explained in paragraph 9.143 above, it was [Allergan Senior Employee 2] who during Allergan's 2015 investor day ([REDACTED]) referred to Allergan's plan for AM Pharma to be subject to a 'Quick, low risk integration'.³⁰⁷⁷

- 9.156. The earnout arrangement was recorded in the agreement for the sale and purchase of Auden Mckenzie Holdings Limited by Actavis Holdings UK Limited. While the obligation to make payments under the earnout fell on Actavis Holdings UK Limited in the first instance, Allergan (then known as Actavis plc) was party to the agreement, and as ultimate parent company of Actavis Holdings UK Limited guaranteed performance of its obligations as purchaser (including committing to perform those obligations if the purchaser

³⁰⁷² See, for example, Document 00213, Project Apple third IP due diligence Q&A dated 1 December 2014, questions 4 and 5. See also Document 00228, answers provided by AM Pharma.

³⁰⁷³ Document 302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015 (emphasis added).

³⁰⁷⁴ [REDACTED].

³⁰⁷⁵ Document 200321, letter from [Allergan Senior Employee 3] to ViroPharma SPRL dated 26 February 2014.

³⁰⁷⁶ [REDACTED].

³⁰⁷⁷ [REDACTED].

defaulted and indemnifying the sellers of Auden Mckenzie Holdings Limited for any failure by Actavis Holdings UK Limited to perform those obligations).³⁰⁷⁸ Allergan was therefore ‘on the hook’ for the earnout.

- 9.157. Following the acquisition of AM Pharma, this earnout arrangement gave Allergan every reason to continue paying close attention to AM Pharma’s business and in particular its strategy in relation to hydrocortisone tablets. Allergan’s 2016 SEC filings disclose that as part of the AM Pharma acquisition, Allergan was ‘*required to pay royalties based on the sales of hydrocortisone*’, amounting to contingent consideration of \$17.3 million.³⁰⁷⁹ Allergan’s advisers prepared detailed statements on the value of the earn-out payments for each quarter, [REDACTED].³⁰⁸⁰ The evidence shows that Allergan did pay close attention to hydrocortisone tablets. A 2015/16 budget presentation on slides bearing the Allergan logo and presented to [Allergan Senior Employee 2] and [Allergan Senior Employee 4],³⁰⁸¹ referred to ‘*Earn out on Hydrocortisone reclassified as Purchase price adjustment*’, noted ‘*Auden’s strong performance on Hydrocortisone increasing overall GX margin %*’, and, on a slide headed ‘*Auden McKenzie*’:

‘Product margin \$42.7 Million ahead of deal model driven by delayed competition on Hydrocortisone – deal model assumed 60% share loss vs AOP 25%-33%

*... Deal model assumed earn out to impact P&L, final deal structure included this in purchase price*³⁰⁸²

- 9.158. The evidence therefore shows that Allergan paid close attention to AM Pharma’s strategy in relation to hydrocortisone tablets prior to and after the acquisition of that company. Allergan did not provide any evidence to the CMA that cast doubt on the contemporaneous evidence cited above. The CMA therefore rejects Allergan’s description of AM Pharma as a ‘*subsidiary we – to the extent we even knew it existed, we barely knew it existed*’.³⁰⁸³ The continuation of AM Pharma’s strategy in relation to hydrocortisone tablets under Allergan’s ownership reflects Allergan’s endorsement of that strategy.

³⁰⁷⁸ Document 302385, agreement for the sale and purchase of Auden Mckenzie Holdings Limited dated 23 January 2015, clause 10. The earnout arrangement was documented in Schedule 9.

³⁰⁷⁹ www.sec.gov/Archives/edgar/data/1578845/000156459017002433/agn-10k_20161231.htm, page F-38.

³⁰⁸⁰ See, for example, Document 302362, email from [REDACTED] to [Auden Senior Employee 1] dated 29 January 2016.

³⁰⁸¹ [REDACTED].

³⁰⁸² Document 02315, Allergan ‘2015 Update and 2016 Budget’ presentation dated October 2015, attached to Document 02314, email from [Actavis Senior Employee 4] entitled ‘*copies of the presentations given at Budget meetings with [Allergan Senior Employee 4]/[Allergan Senior Employee 2]*’ dated 20 October 2015, slide 38. See also slides 3, 5, 9 and 39.

³⁰⁸³ Document 205514, transcript of Allergan’s hearing on the SSO, page 43 lines 7-8.

Allergan's generics division

- 9.159. Allergan submitted that its generics division was functionally and operationally distinct from the remainder of the Allergan group and subject to separate reporting lines. In particular, its UK generics business reported to an executive in Switzerland [X], whereas its branded business reported to an executive in the UK.³⁰⁸⁴
- 9.160. Allergan also submitted that its generics division was already earmarked for sale at the time of the AM Pharma acquisition.³⁰⁸⁵
- 9.161. In principle, neither of these submissions, even if established on the facts, is capable of rebutting the *Akzo* presumption.
- 9.162. The General Court has held that:
- ‘the exercise of a decisive influence by a parent company over its subsidiary is not incompatible with a decision by the former to dispose of its shareholding in the latter at some point in the future. Certainly, once that shareholding has been disposed of, the decisive influence of the parent company over its former subsidiary will come to an end. However, until that disposal takes place, nothing prevents the parent company from exercising a decisive influence over its subsidiary.’³⁰⁸⁶*
- 9.163. The General Court rejected the appellant’s argument that it did not exercise decisive influence over its subsidiary because that subsidiary was held in a separate division of the parent’s group, with different management and resources from the parent’s main division. The appellant’s argument that *‘since it was informed from the outset that its shareholding in [the subsidiary] would be short-term, it did not strive ... to integrate that company in its group’* was also rejected.³⁰⁸⁷
- 9.164. It is therefore clear that the absence of integration of a subsidiary into a parent company’s ‘main’ business division, including in circumstances where the parent company intends from the outset to sell the subsidiary, does not rebut the *Akzo* presumption.
- 9.165. In any event, the CMA finds that neither of Allergan’s submissions is established on the facts.

³⁰⁸⁴ Document 205209, Allergan’s RSSO, paragraph 13(f).

³⁰⁸⁵ Document 205209, Allergan’s RSSO, paragraphs 8(a) and 14(b).

³⁰⁸⁶ T-399/09 *Holding Slovenske v Commission* EU:T:2013:647, paragraph 51.

³⁰⁸⁷ T-399/09 *Holding Slovenske v Commission* EU:T:2013:647, paragraphs 42 and 47 to 54.

9.166. Whether Allergan's branded and generics businesses were managed separately from one another is not relevant to the question of whether Allergan exercised decisive influence over AM Pharma and Accord-UK, both of which were within its generics business. In relation to that question, it is well-established that the exercise of decisive influence must be assessed in light of the economic, organisational and legal links between the companies, rather than confining itself solely to commercial policy in the narrower sense.³⁰⁸⁸ In any event, the evidence shows that Allergan did in fact have oversight of both subsidiaries' commercial strategy, including in relation to hydrocortisone tablets. In addition to the evidence discussed above:

- a. Allergan stated that '*In functional terms the, [X] [Actavis Senior Employee 4] ... reported to [X] for her responsibilities in relation to Actavis UK and Auden Mckenzie. Actual decisions on pricing, product launches, account management, and commercial operations for the generics business including Actavis UK and Auden Mckenzie*' were made by a team reporting to [X].³⁰⁸⁹ [X] was [X], reporting to [Allergan Senior Employee 2], whose role in the AM Pharma acquisition is discussed above.³⁰⁹⁰
- b. Allergan's SEC filings from the time of the Actavis/Allergan merger refer to its "'one company" philosophy' and state that its generics and branded divisions together comprised a single '*International Commercial Organization*', administered by regional presidents responsible for both branded and generic drugs in their regions.³⁰⁹¹ Ultimately, all management, including the executives at the head of the generics and branded divisions, reported to [Allergan Senior Employee 1], [X].

9.167. While Allergan went through significant changes during 2015 and 2016 as a result of Actavis plc acquiring Allergan plc and the group then changing its name to Allergan and deciding to divest its generics business to Teva, the contemporaneous evidence does not indicate that the generics business was earmarked for sale when AM Pharma was acquired.

³⁰⁸⁸ C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:356, paragraphs 72 to 74. The fact that responsibility for setting the prices of hydrocortisone tablets lay at the subsidiary level – initially with AM Pharma, and subsequently Accord-UK – therefore does not preclude Allergan from having exercised decisive influence over both those companies, as Allergan submitted (Document 02261.A, Allergan's representations on the first Draft Penalties Statement, paragraph 6. See also Document 01353, Allergan's submission to the CMA dated 5 December 2016, paragraphs 2.3 and 2.4).

³⁰⁸⁹ Document 01353, Allergan's submission to the CMA dated 5 December 2016, paragraphs 2.3 and 2.4.

³⁰⁹⁰ [X].

³⁰⁹¹ www.sec.gov/Archives/edgar/data/850693/000119312515029969/d864235d425.htm. See also www.sec.gov/Archives/edgar/data/850693/000119312515041804/d870080d425.htm.

- 9.168. As explained above, the contemporaneous documents clearly show that when Allergan acquired AM Pharma its intention was to integrate it with its existing business and thereby to improve its position in the UK generics market. Shortly after the transaction completed, on 1 June 2015 [Allergan Senior Employee 2], [REDACTED], stated: *'Auden Mckenzie's expertise in the development and commercialization of high value, technically demanding formulations as well as specialized and niche opportunities is complementary to and expands Actavis' UK business focus ... The opportunity to combine this profitable and growing company into the Actavis UK business demonstrates our commitment to invest in and expand strategically in our global generics business'*. Allergan's [REDACTED] [Allergan Senior Employee 1] stated, *'The acquisition of Auden Mckenzie is a strategic combination that makes Actavis the number one generic company in the UK and aligns with our strategy to establish a leading position in all of our markets'*.³⁰⁹²
- 9.169. The sale of Actavis Generics to Teva was announced on 27 July 2015. Contemporary press reports described this as *'something of a surprise move'*, stating that *'Allergan has committed to selling its generics business to Israeli generics giant Teva ... despite having no prior plans to sell'*. [Allergan Senior Employee 1] stated, *'While we were not actively seeking a buyer for our generics business, Teva presented an offer at a very compelling valuation'*. Press coverage noted that *'The transaction has surprised many analysts'*.³⁰⁹³ In an internal email, [Allergan Senior Employee 1] described the sale as *'something that I didn't expect to happen'*, stating that *'up until about two weeks ago – we had every intention of running the new Allergan with both a strong brand business and an equally strong generic business'*.³⁰⁹⁴
- 9.170. Further, the evidence shows that notwithstanding its intention to divest its generics division (whenever that intention arose), Allergan continued to monitor the entry of competitors and revenues from hydrocortisone tablets closely – as it would be expected to given the materiality of the earnout arrangement to which it had agreed. For example:
- a. When news of Waymade's launch of its 20mg product was circulated within Accord-UK in July 2015, [Actavis Senior Employee 2], [REDACTED] noted:

³⁰⁹² [REDACTED].

³⁰⁹³ www.chemistryworld.com/news/allergan-steps-away-from-generics-with-sale-to-teva/8807.article.

³⁰⁹⁴ Document 00680, email from [Allergan Senior Employee 1] to Allergan staff dated 27 July 2015.

'I will inform [Allergan Senior Employee 3] [X] – the Orphan Designation still stands so this will be interesting'.³⁰⁹⁵

- b. On 20 October 2015, [Actavis Senior Employee 4] circulated an Allergan budget presentation to individuals including Allergan's [X], [X], [X], and [X] (they each have @allergan.com email addresses, in contrast to the @actavis addresses of Accord-UK staff).³⁰⁹⁶ The subject line of her email was *'copies of the presentations given at Budget meetings with [Allergan Senior Employee 4]/[Allergan Senior Employee 2]'. [X]*. The presentation, on slides bearing the Allergan logo, listed Hydrocortisone as the *'Top UK Gx Product'* by revenue in 2015, and the top product by revenue for 2016, and noted: *'Auden significantly ahead of deal model with delayed competitor entry on Hydrocortisone'* and *'Hydrocortisone 10mg competitor launched in October versus deal model assumption of March'*. The slides also noted that AMCo was being supplied with a *'Market Share – 10mg'* of 15% at a *'% off Tariff'* of *'97.9%'*.³⁰⁹⁷

9.171. Contrary to Allergan's submission that *'all the relevant evidence points in the other direction'* to it exercising decisive influence over AM Pharma and Accord-UK,³⁰⁹⁸ the CMA therefore finds that the evidence reinforces the Akzo presumption that Allergan actually exercised decisive influence over AM Pharma and Accord-UK.

ii. 10 March 2016 to 1 August 2016 (the Hold Separate Period)

Allergan's submission that it did not exercise decisive influence over Accord-UK

9.172. Allergan submitted that it did not exercise decisive influence over Accord-UK (and that therefore the Akzo presumption was rebutted) during the Hold Separate Period. It submitted that the Commitments prevented Allergan from making any material intervention in the business of Accord-UK (and therefore from exercising decisive influence over it). According to Allergan, the Hold Separate Manager had autonomy to run the business as she saw

³⁰⁹⁵ Document 02306, email from [Actavis Senior Employee 2] to [Actavis Senior Employee 3] dated 24 July 2015. Allergan submitted that this email chain did not support the case for decisive influence, since it could equally have sought legal advice from a third-party law firm (Document 02983, Allergan's representations on the March 2018 Letter of Facts, paragraph 10). In context, however, the CMA considers that this email shows Allergan's continued appraisal of developments in relation to hydrocortisone tablets, which is relevant to its exercise of decisive influence.

³⁰⁹⁶ Document 02314, email from [Actavis Senior Employee 4] to multiple recipients dated 20 October 2015.

³⁰⁹⁷ Document 02314, email from [Actavis Senior Employee 4] to multiple recipients dated 20 October 2015, attaching Document 02315, Allergan *'2015 Update and 2016 Budget'* presentation dated October 2015, slides 5, 16, 35 and 40. See also slide 39.

³⁰⁹⁸ Document 205209, Allergan's RSSO, paragraph 15.

fit, without oversight from Allergan.³⁰⁹⁹ At its oral hearing Allergan put it in these terms: *'the divestment business has control over its actions'*.³¹⁰⁰

The proper approach to assessing whether Allergan exercised decisive influence during the Hold Separate Period

- 9.173. In order to ascertain whether Accord-UK determined its conduct on the market independently of Allergan during the Hold Separate Period, account must be taken not only of Allergan's influence over Accord-UK's commercial policy, but also of all the relevant factors relating to economic, organisational and legal links which tied those companies together. The CMA must take into account all the evidence before it, including the application of the Commitments.
- 9.174. The impact of hold-separate commitments given by a 100% shareholder on its ability, pre-completion, to exercise decisive influence over the business that is held separate depends on how those commitments affect the legal, economic and organisational links between the seller and the divestment business. This requires a case-by-case assessment.
- 9.175. In principle, the exercise of decisive influence over Accord-UK may be established even if Allergan did not interfere in the day-to-day business of Accord-UK under the Commitments. A parent exercises decisive influence where it *'retains only the power to define or approve certain strategic commercial decisions, where appropriate by its representatives in the bodies of the subsidiaries, while the power to define the commercial policy stricto sensu of the subsidiary is delegated to the managers responsible for its operational management, chosen by the parent company and representing and promoting the parent company's commercial interests'*.³¹⁰¹ For example, in C-293/13 P *Del Monte v Commission* the Court of Justice held that Del Monte exercised decisive influence over its joint venture partnership Weichert notwithstanding Del Monte's argument that *'it was excluded, as a matter of German law, from any management function and had no means of making decisions as to who managed Weichert'* and retained veto rights under the partnership agreement only over measures outside the ordinary course of business.³¹⁰² The Court of Justice held that:

'the fact that Del Monte was legally precluded from involvement in the management of Weichert's day-to-day business and that its veto rights

³⁰⁹⁹ Document 205209, Allergan's RSSO, paragraph 35. Compare Document 02261.A, Allergan's representations on the first Draft Penalties Statement, paragraph 11(b) and (c).

³¹⁰⁰ Document 205514, transcript of Allergan's hearing on the SSO, page 26 line 2.

³¹⁰¹ T-543/08 *RWE v Commission* EU:T:2014:627, paragraphs 31-32 and the case law cited.

³¹⁰² C-293/13 P *Del Monte v Commission*, paragraphs 60-61.

*did not allow it, inter alia, to impose a particular budget does not mean that Del Monte was precluded altogether from being able to exert decisive influence over Weichert's conduct on the relevant market.*³¹⁰³

- 9.176. The Court of Justice held that the rights enjoyed by Del Monte under the partnership agreement; the capital links between Del Monte and Weichert and Del Monte's rights and obligations under a distribution agreement with Weichert enabled Del Monte to exercise decisive influence over Weichert.³¹⁰⁴

Allergan exercised decisive influence over Accord-UK during the Hold Separate Period

- 9.177. In this case, the submissions put forward by Allergan are not such as to cast doubt on Allergan's ongoing exercise of decisive influence over Accord-UK, having regard, in particular, to the economic, organisational and legal links between those companies.
- 9.178. The CMA notes at the outset that the purpose of the Commitments was to render the acquisition by Teva of the global generic pharmaceuticals business of Allergan compatible with the EU Merger Regulation.³¹⁰⁵ In particular, the Commitments sought to preserve the economic viability, marketability and competitiveness of the Divestment Businesses until the closing date. The CMA notes, however, that the sale of Allergan's generic business to Teva was not final until the closing of the transaction. Consequently, Allergan, as the sole owner of Accord-UK, had the power to withdraw from the sale at any time before closing.³¹⁰⁶ This is an indication of the fact that Allergan continued to exercise decisive influence over Accord-UK during the Hold Separate Period.
- 9.179. The Commitments maintained the links between Allergan and Accord-UK that existed during the period prior to the Hold Separate Period (see section 9.B.I.b.i above). While the Commitments prevented Allergan from intervening in Accord-UK's day-to-day operations, Accord-UK's business was conducted on the basis of a strategy determined by Allergan and which Accord-UK's Hold Separate Manager was appointed to continue and did in fact continue. The Commitments therefore did not prevent Allergan from continuing to exercise decisive influence over Accord-UK: Allergan had no need to seek to

³¹⁰³ C-293/13 P *Del Monte v Commission*, paragraph 88.

³¹⁰⁴ C-293/13 P *Del Monte v Commission*, paragraphs 79-86.

³¹⁰⁵ Document 00743, recital 1, Commitments.

³¹⁰⁶ See, similarly, T-146/09 *RENV Parker Hannifin v Commission*, paragraph 66.

intervene in its day-to-day operations given that it had set in place its strategic course.

9.180. On 10 March 2016, Allergan and Teva committed:

- a. To '*preserve or procure the preservation of the economic viability, marketability and competitiveness of the Divestment Businesses*' and to '*minimise as far as possible any risk of loss of competitive potential of the Divestment Businesses*',³¹⁰⁷ and in particular:
- b. '*not to carry out any action that might have a significant adverse impact on the value, management or competitiveness of the Divestment Businesses or that might alter the nature and scope of activity, or the industrial or commercial strategy or the investment policy of the Divestment Businesses*'; and
- c. '*to make available, or procure to make available, sufficient resources for the development of the Divestment Businesses, on the basis and continuation of the existing business plans*'.³¹⁰⁸

9.181. Under the terms of the Commitments, the Hold Separate Manager was required to manage the Divestment Businesses independently and in the best interests of the business '*with a view to ensuring its continued economic viability, marketability and competitiveness*' and in cooperation with the monitoring trustee, who was required to oversee the management of the Divestment Businesses, also with a view to ensuring its continued economic viability, marketability and competitiveness.³¹⁰⁹

9.182. [Actavis Senior Employee 4] [X] – who, as explained above, had been responsible for decisions on pricing and commercial operations for the generics business prior to the Hold Separate Period, reporting to Allergan's [X]³¹¹⁰ – was appointed as the Hold Separate Manager by an amendment to her employment contract with Accord-UK effective from 10 March 2016.³¹¹¹ [Actavis Senior Employee 4] would have been well-acquainted with the existing business plans, given her role to date prior to being appointed as Hold Separate Manager. She was also well-acquainted with Allergan's, AM Pharma's and Accord-UK's strategy in relation to hydrocortisone tablets, the orphan designation and competition. For example, prior to Allergan's acquisition of AM Pharma she was involved in negotiating the earn-out

³¹⁰⁷ Document 00743, clause 36, Commitments.

³¹⁰⁸ Document 00743, clauses 36(a) and (b) of the Commitments (emphasis added).

³¹⁰⁹ Document 00743, clauses 38 and 57 of the Commitments.

³¹¹⁰ Document 01353, Allergan's submission to the CMA dated 5 December 2016, paragraphs 2.3 and 2.4.

³¹¹¹ Document 00733, response to question 13, AM Pharma/Accord-UK's response to the CMA's section 26 notice dated 18 October 2016.

clause on hydrocortisone tablets discussed at paragraphs 9.154 to 9.157 above; and after that acquisition she monitored the potential for competitor entry and its potential impact on the business.³¹¹² As explained above, Allergan referred to her in submissions to the CMA as *'the UK country manager for Allergan'*.³¹¹³

- 9.183. While the Commitments required Allergan to have no involvement in the day-to-day business of the Divestment Businesses during the Hold Separate Period, this does not mean that Accord-UK functioned independently on the market. The role of the Hold Separate Manager was clearly defined by the amendment to her employment contract as follows:

'Under the Commitments Teva is committed to divesting certain assets specified in the Commitments, and in consultation with the Monitoring Trustee has agreed to appoint (inter alia) a Hold Separate Manager ("HSM") to manage and oversee the business and operations of such products which comprise Divestment Businesses in Ireland and the United Kingdom to ensure the commercial efforts dedicated to their promotion and commercialization remain substantially unaltered until they have been fully transferred to relevant purchasers ("HSM Divestment UK/Ireland")'.

*This amendment confirms the appointment of the Employee [[Actavis Senior Employee 4]] as "HSM Divestment UK/Ireland" effective from 10th March 2016*³¹¹⁴

- 9.184. The amendment to [Actavis Senior Employee 4]'s employment contract continued:

³¹¹² Document 00263, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015: *'I have just had a telecon with [Actavis Senior Employee 4] regarding the Hydrocortisone earn out, to ensure it reflects a more balanced agreement and addresses our current concerns'*. Once the acquisition had taken place, in September 2015 [Actavis Senior Employee 4] commented on a summary of market conditions and potential budget models based on various potential scenarios for competitor entry in relation to hydrocortisone tablets, noting that the *'set volume at a set price'* of the Second Written Agreement *'creates a dynamic for the uk pack'* once competition arrived (Document 02312, email from [Actavis Senior Employee 4] to [REDACTED] dated 28 September 2015). Just before the Hold Separate Period, in February 2016, she modelled risks and opportunities for the business including assumptions relating to hydrocortisone tablets (Document 02307, email from [Actavis Senior Employee 4] to [REDACTED] dated 3 February 2016). On 2 March 2016, she chaired a management meeting, at which the nature of the Commitments was discussed and it was noted: *'Hydrocortisone competitive intensity increasing, Bristol & Alissa MAs granted, further developments noted – AMCO contract expires in June 22nd, review as part of 2 + 10 forecast the commercial impact'* (Document 02802, Actavis management meeting minutes 2 March 2016, items 2 and 6). During the Hold Separate Period, in May 2016, she was involved, in conjunction with [REDACTED], in preparing a response to a *Times* story about AM Pharma's pricing of drugs including hydrocortisone tablets (Document 02301, email from [Actavis Senior Employee 4] to [Actavis Senior Employee 1] dated 31 May 2016).

³¹¹³ Document 01353, Allergan's submission to the CMA dated 5 December 2016, paragraphs 2.3 and 2.4.

³¹¹⁴ Document 00744, letter appointing the Hold Separate Manager, paragraph 1.1.

*'The cost of this role will be borne by [Accord-UK] (as part of Allergan PLC) pre-close ... For the avoidance of doubt, in case the Agreement [for the sale of Allergan's generics business to Teva] will not be consummated and not close the Employee will resume her prior role and responsibilities as the Regional President for United Kingdom & Ireland.'*³¹¹⁵

- 9.185. The Hold Separate Manager was therefore appointed (at Allergan's ultimate expense) to ensure that the business of Accord-UK, and especially its approach to commercialising its products, remained substantially unaltered until the divestment completed. If the sale of Allergan's generics division did not complete, she would cease to be Hold Separate Manager and revert to her existing role at Accord-UK under Allergan's continued ownership.
- 9.186. In the circumstances the CMA considers that Allergan continued to exercise decisive influence over Accord-UK during the Hold Separate Period. The commercial strategy of Accord-UK was set under Allergan's decisive influence in the previous nine months, during which Allergan also acted to transfer AM Pharma's business to Accord-UK. This preceding period, when Allergan exercised decisive influence over AM Pharma and Accord-UK unencumbered by the Commitments, is vital context for the Hold Separate Period. The Court of Justice has recently reiterated in *Goldman Sachs* that an authority may have regard to factors from a prior period as demonstrating the exercise of decisive influence during a later period, provided it can show their continued relevance.³¹¹⁶ In this case, by the time the Commitments came into force on 10 March 2016, Accord-UK's strategy in relation to hydrocortisone tablets was well-established under Allergan's decisive influence. The Hold Separate Period cemented the status quo ante:
- a. By 29 May 2015, when Allergan acquired AM Pharma, it had been charging excessive and unfair, and regularly increasing, prices for hydrocortisone tablets for almost seven years (see section 5 above). AM Pharma had also been buying off its competitors Waymade and AMCo for several years (see section 6 above). The commercial policy of Auden, in particular insofar as it concerned the Infringements, was well-established by this point.
 - b. Accord-UK (then known as Actavis UK Limited) took over sales of hydrocortisone tablets from 1 September 2015 and continued the

³¹¹⁵ Document 00744, Annex 11 to AM Pharma/Accord-UK's response to the CMA's section 26 notice dated 18 October 2016.

³¹¹⁶ C-595/18 P *Goldman Sachs v Commission*, paragraph 68. See also C-155/14 P *Evonik Degussa v Commission*, paragraph 34.

Unfair Pricing Abuses and the 10mg Agreement under Allergan's 100% ownership, as explained above.

- c. The Hold Separate Manager was appointed to ensure the Divestment Businesses continued on the strategic course on which they were then set, on the basis of the existing business plans. That strategic course and business plan were set under the decisive influence of Allergan, before the Hold Separate Period commenced. The Hold Separate Manager did in fact continue on that strategic course. Accord-UK continued its pricing practices and its attempts to preserve its dominant position during the Hold Separate Period. For example, as explained in section 3.F.III.p above, it continued the 'communications plan' designed to emphasise the superiority of Accord-UK's hydrocortisone tablets to those of new entrants, drawing on the Project Guardian materials prepared by AM Pharma.³¹¹⁷

9.187. The CMA therefore concludes that during the Hold Separate Period, Accord-UK did not decide independently upon its conduct on the market but carried out the instructions given to it under the commercial strategy that was in place prior to the Hold Separate Period and which the Hold Separate Manager was appointed to maintain.

9.188. Allergan portrayed this as a proposition that '*a parent company remains liable for the conduct of its subsidiary after the parent company has ceased to be able to exercise decisive influence over it*', and claimed that this would mean that liability could extend beyond the date on which a subsidiary changes ownership. Allergan also submitted that the CMA found that '*Allergan exercised decisive influence over the divestment business during a different period, a prior period. So, as a result, it is going to be deemed to exercise a decisive influence over the subsidiary in this period.*'³¹¹⁸ However, the CMA's findings are that Allergan continued to exercise decisive influence over Accord-UK during the Hold Separate Period and should therefore be held liable for its involvement in the Infringements.

9.189. The CMA considers, moreover, that it is right to hold Allergan liable during this period. Holding Allergan liable ensures that liability follows the implementation of the strategy set under Allergan's decisive influence and the profits from the Infringement. The Commitments did not preclude Allergan from continuing to extract profits from Accord-UK, provided this did not affect the viability and competitiveness of the business. Allergan was

³¹¹⁷ See, for example, Document 02342, Actavis UK Key Product Summaries, May 2016, slide 3.

³¹¹⁸ Document 205209, Allergan's RSSO, paragraph 34. See also Document 205514, transcript of Allergan's hearing on the SSO, page 24 lines 23-25 and page 25 lines 1-15.

therefore able to continue benefitting from Accord-UK's sales of hydrocortisone tablets, notwithstanding the Commitments.

Analogies with the Parker-Hannifin case

9.190. In support of its assessment of the Hold Separate Period, the CMA notes that the General Court has adopted a similar approach to the attribution of liability in circumstances that are analogous to the Commitments.

9.191. In *Parker-Hannifin v Commission*, one of the issues was whether Parker ITR could be held liable for the conduct of its predecessor, ITR. In particular, it was argued that a sale and purchase agreement between Parker-Hannifin Corp (Parker ITR's parent) and Saiag precluded ITR (and Saiag) from exercising decisive influence over ITR Rubber (which had been involved in cartel activity).³¹¹⁹ The General Court held that the obligation that ITR undertook in the purchase and sale agreement to ensure that the subsidiary ITR Rubber would operate and be managed in the ordinary course of business constituted an indication of the fact that ITR Rubber did not function independently on the market.³¹²⁰ The Court continued:

*'Although, in that period known as the 'interim' period, ITR Rubber cannot be considered to have been controlled by Parker-Hannifin, neither can it be considered an independent entity, which was capable of deciding on its activities in a completely independent way, since ITR ensured that ITR Rubber did not deviate, in particular with respect to its commercial policy, from the ordinary course of business. Consequently, on account of the undertaking of its parent company, ITR Rubber could not have unilaterally decided, for example, to alter its commercial policy or to cease its activities, which would have been possible had ITR Rubber been a completely independent entity.'*³¹²¹

9.192. The General Court also emphasised that, until the closing of the transaction, the sale of ITR Rubber to Parker-Hannifin was not final.³¹²² Consequently, during what was known as the interim period, ITR, as the sole owner of ITR Rubber, had the power to withdraw from the sale, albeit by running the risk of having to compensate the prospective purchaser in particular under the compensation mechanisms provided for in the agreement itself. In light of this, the General Court held that the evidence put forward by Parker could not be regarded as sufficient to prove that, during the interim period, ITR Rubber acted independently on the market. It followed that Parker had not

³¹¹⁹ T-146/09 RENV *Parker-Hannifin v Commission*, paragraph 59.

³¹²⁰ T-146/09 RENV *Parker-Hannifin v Commission*, paragraph 63.

³¹²¹ T-146/09 RENV *Parker-Hannifin v Commission*, paragraph 64.

³¹²² T-146/09 RENV *Parker-Hannifin v Commission*, paragraph 66.

rebutted the presumption that ITR actually exercised decisive influence over its wholly-owned subsidiary ITR Rubber.³¹²³

9.193. The CMA considers that there are analogies between the facts of the *Parker-Hannifin* case and the present case and, therefore, that the General Court's reasoning is applicable. In particular:

- a. The obligations under the sale and purchase agreement in *Parker-Hannifin* and the Commitments in this case were both designed to preserve the economic viability of the businesses to be divested.
- b. The obligations under the sale and purchase agreement in *Parker-Hannifin* and the Commitments in this case were both voluntarily assumed by, respectively, Parker-Hannifin Corp and Allergan.
- c. The proposed sales in *Parker-Hannifin* and in the present case were not final; they could have lapsed at any point had the vendor chosen to abandon the relevant sale (albeit potentially incurring termination fees under its sale agreement). If they had done so, the sellers would have been free to alter the commercial strategy of their subsidiaries as they saw fit.^{3124, 3125}

9.194. In light of the similarities between the *Parker-Hannifin* case and the present case, the CMA considers that the judgment of the General Court supports its conclusion that Accord-UK did not function independently on the market during the Hold Separate Period.

Conclusion

9.195. In light of all the foregoing, the CMA therefore finds that the Commitments do not rebut the *Akzo* presumption during the Hold Separate Period.³¹²⁶ To

³¹²³ T-146/09 RENV *Parker-Hannifin v Commission*, paragraph 72.

³¹²⁴ Compare T-399/09 *Holding Slovenske v Commission* EU:T:2013:647, paragraph 51: 'the exercise of a decisive influence by a parent company over its subsidiary is not incompatible with a decision by the former to dispose of its shareholding in the latter at some point in the future. Certainly, once that shareholding has been disposed of, the decisive influence of the parent company over its former subsidiary will come to an end. However, until that disposal takes place, nothing prevents the parent company from exercising a decisive influence over its subsidiary'.

³¹²⁵ Allergan submitted that *Parker-Hannifin* was not relevant because in that case the subsidiary was the subject of contractual arrangements rather than commitments given to the Commission (Document 205209, Allergan's RSSO, paragraph 24). This factual difference does not mean the case is irrelevant. It is relevant by analogy to the situation under discussion.

³¹²⁶ Between 2 August 2016 and 8 January 2017, Accord-UK was wholly owned by Teva. The CMA has exercised its discretion not to attribute liability to Teva: the reasons outlined above for holding Allergan liable are also reasons for treating Allergan and Teva, as successive parents of the Divestment Businesses, differently. Teva never meaningfully owned Accord-UK. In fact, the Commitments ensured that Teva could never exercise influence over the Divestment Businesses, as the Allergan/Teva clearance was conditional on the parties fully complying with the Commitments. By contrast, Allergan was able to exercise decisive influence over the business plan that was adopted before the Hold Separate Period and which the Hold Separate Manager was appointed to

refrain from holding Allergan liable in these circumstances would amount to allowing a parent company to contract out of antitrust liability by setting a strategy for its subsidiary which is then maintained under a set of contractual commitments to sell a business, and then disclaim responsibility for that business. That would undermine the effectiveness of competition law.

c. Liability of Accord and Intas

- 9.196. The CMA attributes liability to Accord and Intas for Accord-UK's involvement in the 10mg Unfair Pricing Abuse from 9 January 2017 until 31 July 2018, and for the resulting financial penalties, jointly and severally with Accord-UK.
- 9.197. Since 9 January 2017, Accord-UK has been wholly owned by Accord, which is in turn wholly owned by Intas.³¹²⁷
- 9.198. Each of Accord and Intas therefore had the ability to exercise decisive influence over Accord-UK during this period. The CMA applies the *Akzo* presumption that Accord and Intas each did actually exercise decisive influence over Accord-UK during this period.³¹²⁸
- 9.199. Accord and Intas did not dispute that they exercised decisive influence over Accord-UK. They submitted that the CMA should nonetheless not hold them liable because:
- a. Whether to attribute liability to parent companies is in the CMA's discretion and '*the CMA's practice has not been to hold parent companies jointly and severally responsible in all circumstances and as a default approach*'; and
 - b. Finding Intas and Accord liable '*would not serve any policy objective*', in particular since they have not '*somehow encouraged, facilitated or overseen the relevant conduct*.' There is also no need to fine Intas and

continue, and if the Allergan/Teva transaction had been abandoned, the Divestment Businesses would remain under Allergan's control. These considerations do not apply to Teva, which was at all times prevented from exercising influence over the Divestment Businesses. Teva was itself required to divest Accord-UK to a suitable purchaser; and from 2 August 2016, when the sale to Teva completed, until 9 January 2017, when it was sold to Intas, Accord-UK continued to be held separate from the Teva business. The CMA therefore rejects Allergan's submission that '*There is no coherent reason for treating the two successive parent companies of the Divestment Business [Allergan and Teva] differently*' (Document 02261.A, Allergan's representations on the first Draft Penalties Statement, paragraph 11(a)).

³¹²⁷ Companies House filings.

³¹²⁸ In the case of Intas, the CMA presumes the actual exercise of decisive influence over Accord, the interposed wholly-owned holding company, and through Accord over Accord-UK.

Accord since a fine imposed on Accord-UK alone would sufficiently penalise it and exceed its gains under Intas/Accord's ownership.³¹²⁹

- 9.200. The CMA continues to consider it appropriate to exercise its discretion to hold Intas and Accord jointly and severally liable with Accord-UK for their ownership period. This does not mean that the CMA will hold parent companies liable *'in all circumstances and as a default approach'*. The CMA has chosen to do so in the circumstances of the present case. The CMA is not bound by its previous decisions; each assessment is made on a case-by-case basis.
- 9.201. The Court of Justice has recently confirmed that the essential aim of imposing fines on parent companies jointly and severally with subsidiaries is not solely to avoid the risk that the fine will not be paid if levied on the subsidiary alone, but *'to punish the illegal acts of the companies concerned as well as to dissuade both the companies in question and other economic operators from violating, in the future, the rules of Union competition law'*. There is no 'priority' between subsidiary and parent as regards the deterrent effect that a fine pursues, since where a parent exercises decisive influence over a directly participating subsidiary both companies form part of the economic entity that infringed the law and are liable on the same basis. That an authority has a discretion, not an obligation, to hold the parent liable is irrelevant in this regard.³¹³⁰
- 9.202. Further, Intas and Accord did *'encourage, facilitate or oversee'* the 10mg Unfair Pricing Abuse during their ownership period:
- a. Although the *Akzo* presumption is sufficient to hold Intas and Accord jointly and severally liable with Accord-UK for their ownership period and no direct involvement in or knowledge of the Unfair Pricing Abuses is required, it is relevant that Intas and Accord were made aware of the CMA's investigation, including that this involved a potential abuse of dominance by way of charging excessive and unfair prices for hydrocortisone tablets, prior to acquiring Accord-UK.³¹³¹ By the time of Intas/Accord's acquisition of Accord-UK, the pricing of this drug had been under investigation by the CMA for almost a year; [Actavis Senior Employee 1] had attended State of Play meetings on behalf of Accord-UK at which the CMA outlined its concerns on two separate

³¹²⁹ Document 205212, Intas/Accord-UK's RSSO, Annex 1 paragraphs 9-11 (emphasis in original). See also Document 02001.B, Intas/Accord-UK's RSO1, paragraphs 175 to 180; and Document 02977, Intas/Accord-UK's representations on the first Draft Penalties Statement, section 3.

³¹³⁰ C-611/18 P *Pirelli v Commission*, paragraphs 95-99 (CMA translation from the original French).

³¹³¹ Document 03006, transcript of oral hearing with Intas/Accord-UK on 15 December 2017, page 57 lines 14-20.

occasions;³¹³² and a Statement of Objections outlining the CMA's provisional conclusions that the drug was excessively and unfairly priced had been issued.

- b. [Actavis Senior Employee 1] [X].³¹³³ [X]. As [X] it was ultimately his responsibility to sign off on Accord-UK's overall monthly trade price list, including the prices it would charge for hydrocortisone tablets each month.³¹³⁴ [X].³¹³⁵ He remained [X] of Accord-UK and was succeeded as [X] by [Actavis Senior Employee 3], another individual who like [Actavis Senior Employee 1] had been closely involved in Accord-UK's strategy in relation to hydrocortisone tablets prior to the Intas/Accord acquisition.³¹³⁶
- c. In the circumstances it is reasonable to expect that the price Accord-UK was charging for hydrocortisone tablets, and any changes, would be carefully considered after Intas and Accord acquired the business. Indeed, this was the case even prior to the CMA's investigation being launched. [Actavis Senior Employee 1] stated in interview that after Accord-UK took over sales of hydrocortisone tablets in September 2015 they were treated as *'a key important product. So, it would have got a lot more focus than others.'*³¹³⁷
- d. Intas and Accord therefore acquired Accord-UK in the knowledge that its pricing of hydrocortisone tablets was alleged to be excessive and unfair; were in a position to bring that abusive conduct to an end; and did not act to do so despite Actavis's special responsibility as a dominant undertaking. Their submission that *'market forces were*

³¹³² Document 00746, note of state of play meeting on 12 May 2016; Document 00747, note of state of play meeting on 7 September 2016 (at this meeting the CMA provided a detailed slide presentation with its provisional views on the case – see Document 00748).

³¹³³ [Actavis Senior Employee 1] stated in interview that he was [X] from 2014 onwards, with *'full responsibility for all of the commercial efforts for our generic sales resources'*. Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 8 lines 2-5.

³¹³⁴ Document 02238, Intas/Accord-UK's response to the CMA's section 26 notice dated 20 December 2017, response to question 1.

³¹³⁵ Document 02238, response to question 1, Intas/Accord-UK's response to the CMA's section 26 notice dated 20 December 2017.

³¹³⁶ Document 02238, Intas/Accord-UK's response to the CMA's section 26 notice dated 20 December 2017, response to question 1. For example, in March 2016 [Actavis Senior Employee 3] circulated to staff including [Actavis Senior Employee 1] a set of assumptions about market developments for 10mg hydrocortisone tablets, including pricing, noting: *'ASP from April reflects new tariff and price for Q2 worked on that, plus Amco supply plus some erosion. ASP then uplift post Amco supply'*: Document 02327, email from [Actavis Senior Employee 3] to [X] dated 18 March 2016. [Actavis Senior Employee 3] also briefed Accord-UK's field teams on the differences between Accord-UK's product and skinny label competitors in anticipation of Alissa's entry (Document 02337, email from [Actavis Senior Employee 3] to [Auden Senior Employee 4] dated 16 October 2015). Until August 2017 [Actavis Senior Employee 3] also chaired Accord-UK's monthly Generics Commercial Meetings, which set Accord-UK's pricing strategy for the following month (Document 02238, response to question 1, Intas/Accord-UK's response to the CMA's section 26 notice dated 20 December 2017).

³¹³⁷ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 13, lines 13-16.

*demonstrably already producing lower prices*³¹³⁸ under their ownership belies the point that Intas/Accord could at any point have intervened to reduce Accord-UK's prices more quickly.³¹³⁹

- 9.203. The CMA therefore holds Accord and Intas jointly and severally liable with Accord-UK for the 10mg Unfair Pricing Abuse during their ownership period.

II. Waymade

- 9.204. The CMA concludes that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition, referred to as 'Waymade':

- a. From 11 July 2011 to 30 October 2012: Waymade plc and Amdipharm UK Limited; and
- b. From 31 October 2012 to 30 April 2015: Waymade plc.

- 9.205. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market. During the time periods outlined above these entities formed part of the undertaking that entered into the 20mg and 10mg Agreements.

- 9.206. In summary, and as explained in the sections that follow:

- a. Waymade plc is the entity that entered into the 20mg Agreement. During October 2012, both Waymade plc and Amdipharm UK Limited played a role in negotiating and implementing the 10mg Agreement, in particular through their respective employees [Waymade Senior Employee 1] and [Amdipharm Senior Employee].
- b. Until 30 October 2012, Waymade plc and Amdipharm UK Limited were both indirectly wholly owned by Waymade Group Holdings Limited, itself ultimately wholly owned by Verdot Limited, a Jersey company [REDACTED].³¹⁴⁰ The Akzo presumption therefore applied between Verdot Limited and each of Waymade plc and Amdipharm UK Limited and has not been rebutted, such that they formed a single undertaking.

³¹³⁸ Document 02977, Intas/Accord-UK's representations on the first Draft Penalties Statement, paragraph 47.

³¹³⁹ Indeed, Intas/Accord-UK wrote to the DHSC in December 2017 to suggest that '*The use of all or at least most suppliers' and/or wholesalers' prices as input in the formation of the Drug Tariff price for hydrocortisone tablets would quickly lower the latter and reinforce the competitive process*' (Document 02194, letter from Intas/Accord-UK to the DHSC dated 7 December 2017) – a suggestion that recognises the limited constraint imposed on Accord-UK by the Drug Tariff (see sections 4.C.II.c.ii and 5.D.II.b.ii above) but fails to recognise that Accord-UK has always been free to lower its own prices.

³¹⁴⁰ Amdipharm Limited was also indirectly wholly owned by Waymade Group Holdings Limited and ultimately Verdot Limited until this date. On 31 October 2012 it became part of the AMCo undertaking. Document 302243, Annex 1.1(a) to Waymade's response to the CMA's section 26 notice dated 8 October 2018.

- c. On 31 October 2012 Waymade Group Holdings Limited was sold to the Fifth Cinven Fund. Amdipharm UK Limited became part of the AMCo undertaking on that date and continued to participate in the 10mg Agreement as part of the AMCo undertaking thereafter. Between 31 October 2012 and 30 December 2012, Waymade plc, although also majority owned by the Fifth Cinven Fund, was part of an ‘excluded group’ pending the exercise of a put and call option and remained subject to the management of [X].³¹⁴¹ On 31 December 2012 that option was exercised and Waymade plc was ‘spun’ back into their ownership (via Verdot Limited).³¹⁴²
 - d. Waymade plc continued to be wholly owned by Verdot Limited, [X] and continued to participate in the 20mg Agreement until 30 April 2015. Verdot Limited has since been dissolved.³¹⁴³
- 9.207. The CMA attributes liability for the Infringements committed by Waymade to Waymade plc and Amdipharm UK Limited, as legal persons that directly participated in the Agreements.
- 9.208. Since Amdipharm UK Limited formed part of the AMCo undertaking and continued to participate in the 10mg Agreement from 31 October 2012 onwards, its liability is addressed in a single section below.
- a. Liability of Waymade plc**
- 9.209. The CMA attributes liability for Waymade’s participation in the Agreements, and for the resulting financial penalties, to Waymade plc.
- 9.210. Specifically, Waymade plc is held liable:
- a. for the 20mg Agreement, from 11 July 2011 to 30 April 2015; and
 - b. for the 10mg Agreement, from 23 October 2012 to 30 October 2012.
- 9.211. This is because, as set out below, Waymade plc directly participated in the Agreements during those periods.

³¹⁴¹ Document 200471, Cinven’s response to the CMA’s section 26 notice dated 7 November 2016, paragraph 1.7). Document 200003, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016, paragraphs 10-11. Document 200476, Amdipharm SPA, Schedule 15 paragraphs 1, 2.1, 2.6 and 2.7.

³¹⁴² Document 200003, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016, paragraphs 10-11.

³¹⁴³ Document 302244, Annex 1.1(b) to Waymade’s response to the CMA’s section 26 notice dated 8 October 2018. Verdot Limited was liquidated later in 2015: Document 200003, Waymade’s response to the CMA’s section 26 notice dated 5 May 2016, paragraph 6; and JFSC Companies Registry records.

i. Waymade plc's liability for the 20mg Agreement

9.212. Throughout the duration of the 20mg Agreement, Waymade plc was the legal entity within the Waymade undertaking that:

- a. received the payments from Auden under the 20mg Agreement;
- b. held Waymade's 20mg MA;
- c. engaged with Aesica on the manufacture of 20mg hydrocortisone tablets; and
- d. sold 20mg hydrocortisone tablets.³¹⁴⁴

9.213. Further, Waymade plc played a prominent role in the negotiation and implementation of the 20mg Agreement, via its employees [Waymade Senior Employee 4], [Waymade Employee] and [Waymade Senior Employee 3] and especially [X] [Waymade Senior Employee 1] (see section 6.D.II.c.i above).³¹⁴⁵

ii. Waymade plc's liability for the 10mg Agreement

9.214. Waymade plc was the legal entity that initially held Waymade's 10mg MA when it was granted on 27 September 2012.³¹⁴⁶ It remained the legal owner

³¹⁴⁴ Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, response to question 2.

³¹⁴⁵ Each of these individuals was employed by Waymade plc: Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, response to question 3. Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, in which the Commission held companies liable on the basis of their employees playing a prominent role in negotiation and implementation of the infringing agreements: paragraphs 1256-1257, 1272 and 1288-1290. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril* (Servier): Les Laboratoires Servier was liable 'through the participation ... in the negotiation of the agreement' (paragraph 3006); Teva Pharmaceuticals BV was held liable 'through the involvement of top management ... in the preparations for the conclusion of the Teva Settlement Agreement', and Teva Pharmaceutical Industries Limited was liable through its involvement 'in the preparations for the conclusion of the Teva Settlement Agreement' (paragraph 3047). See also Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, in which the Commission attributed liability to the subsidiaries that actually signed the agreement or played a prominent role in its negotiation or implementation (recital 444). The CAT has confirmed that an employee 'will typically be part of the undertaking that employs him or her': *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 358. See also *Tesco v OFT* [2012] CAT 31, paragraphs 62-63: 'since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking'. The General Court has held that: '[T]he position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole' (T-705/14 *Unichem v Commission*, paragraph 77). See also T-77/92 *Parker Pen v Commission*, paragraphs 78-82 and C-100/80 *Musique Diffusion v Commission*, paragraph 97: action by principal managers of an undertaking is not required, but where present is a strong factor establishing liability of the undertaking they manage.

³¹⁴⁶ Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, response to question 2.

of the 10mg MA until the change of ownership to Amdipharm UK Limited was registered on 9 May 2013.³¹⁴⁷

- 9.215. As explained in sections 3.F.III.d and e above, the beneficial interest in Waymade's 10mg MA passed from Waymade plc to Amdipharm UK Limited on 13 October 2012. Amdipharm UK Limited remained part of the Waymade undertaking until 31 October 2012, when the sale of the Amdipharm group completed.³¹⁴⁸ Notwithstanding the transfer to Amdipharm UK Limited, in the period prior to completion on 31 October 2012 Waymade plc was directly involved in the negotiation and implementation of the 10mg Agreement.
- 9.216. As explained in section 3.F.III.d and paragraphs 6.588 to 6.589 above, the first order under the 10mg Agreement was sent to Auden by Waymade plc staff, on the instructions of [Waymade Senior Employee 1] and following a discussion between [Waymade Senior Employee 1] and [Auden Senior Employee 1]. It was submitted on an urgent basis and its fulfilment was closely monitored by [Waymade Senior Employee 1]. Once it was fulfilled, Waymade plc's Head of Sales was immediately instructed to sell the packs:
- a. On 23 October 2012 [Waymade Senior Employee 1] sent an email to [Waymade Senior Employee 4]. [Waymade Senior Employee 1] wrote:

*'2000 hydrocort 10 mg p/o at full price . plse send bu [sic] midday if possible'*³¹⁴⁹
 - b. The body of the email contained only the email address of [Auden Senior Employee 1]: '[✂]'.
 - c. [Waymade Senior Employee 1] sent his email at 11.51 am. He gave [Waymade Senior Employee 4] nine minutes to send the purchase order.
 - d. At 12.56 pm, [Waymade Senior Employee 4] sent the order to [Auden Senior Employee 1], blind copying [Waymade Senior Employee 1], stating:

³¹⁴⁷ See eg, www.mhra.gov.uk/home/groups/par/documents/websitesresources/con364162.pdf, page 2.

³¹⁴⁸ From July 2011 until 30 October 2012, each of Waymade plc, Amdipharm Limited and Amdipharm UK Limited was indirectly wholly owned by Waymade Holdings S.à.r.l., which was itself indirectly wholly owned by Waymade Group Holdings Limited and ultimately by Verdot Limited. [✂]. Document 302243, Annex 1.1(a) to Waymade's response to the CMA's section 26 notice dated 8 October 2018; Document 302242, paragraph 1.4, Waymade's response to the CMA's section 26 notice dated 8 October 2018. The Akzo presumption therefore applied between Verdot Limited and each of Waymade plc, Amdipharm Limited and Amdipharm UK Limited and has not been rebutted, such that they formed a single undertaking during this period.

³¹⁴⁹ Document 300320, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 4] dated 23 October 2012.

Please find attached PO for the 2,000 x Hydrocortisone 10mg 30's that are required on URGENT delivery as per [Waymade Senior Employee 1]'s request'.³¹⁵⁰

- e. [Waymade Senior Employee 4] attached a purchase order on Waymade plc headed paper, for 2,000 10mg hydrocortisone tablets.³¹⁵¹
- f. The price listed on the purchase order was £34.50.³¹⁵² However, as explained in section 3.F.III.d and paragraphs 6.588 to 6.589 above, on the corresponding invoice for these 2,000 packs, issued by Auden on the same day, the £34.50 was circled and a handwritten note added: *'Await credit note [Waymade Senior Employee 4]'* – indicating that Waymade understood that it would receive a rebate to reduce the net price.³¹⁵³ As explained in section 6.D.II.c.ii above, the CMA concludes that the 10mg Agreement was in place at the latest by 23 October 2012.
- g. [Auden Senior Employee 1] responded within ten minutes of [Waymade Senior Employee 4]'s email: *'I have forwarded the order to sales and stock will be with you tomorrow'*. [Waymade Senior Employee 4] forwarded his response to [Waymade Senior Employee 1] within two minutes.³¹⁵⁴
- h. Three days later, on 26 October 2012, [Waymade Senior Employee 4] emailed [Waymade Senior Employee 1] with the subject, *'Hydrocortisone 10mg': 'Confirm they have arrived. [Auden Senior Employee 2] called to check as well'*.³¹⁵⁵ [Waymade Senior Employee 1] replied to thank him within seven minutes.³¹⁵⁶

³¹⁵⁰ Document 300321, email from [Waymade Senior Employee 4] to [Auden Senior Employee 1] dated 23 October 2012.

³¹⁵¹ Document 300322, purchase order attached to Document 300321. The header on the purchase order specified 'Waymade Healthcare plc'. As explained in section 3.A.I above, Waymade plc was named Waymade Healthcare plc until 12 October 2012. The header on its purchase orders had yet to be adjusted (there was no other entity named Waymade Healthcare plc at the time).

³¹⁵² Document 200010, data on Waymade's purchases of hydrocortisone tablets.

³¹⁵³ Document 300645, invoice dated 23 October 2012.

³¹⁵⁴ Document 300326, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 1] dated 23 October 2012.

³¹⁵⁵ Document 300329, email from [Waymade Senior Employee 4] to [Waymade Senior Employee 1] dated 26 October 2012.

³¹⁵⁶ Document 300329, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 4] dated 26 October 2012.

- i. Within a minute of his email to [Waymade Senior Employee 1], [Waymade Senior Employee 4] emailed [X], with the subject, *'Hydrocortisone 10mg 30's': 'Extra 2000 available now'*.³¹⁵⁷

- 9.217. It is clear from these email exchanges that [Waymade Senior Employee 1] had spoken to [Auden Senior Employee 1] around 23 October 2012 and that they had agreed that Auden would supply Waymade plc with these packs (*'as per [Waymade Senior Employee 1]'s request'*). [Waymade Senior Employee 1] was therefore actively involved in the negotiation and implementation of the 10mg Agreement on or around 23 October 2012. [Waymade Senior Employee 4]'s annotation on the invoice sent to Waymade plc, *'Await credit note'*, also indicates that although [Waymade Senior Employee 1] had instructed him to submit the order *'at full price'*, the common understanding of Waymade plc and Auden was that the order would be substantially discounted through a rebate.
- 9.218. [Waymade Senior Employee 1]'s (and [Waymade Senior Employee 4]'s) actions in negotiating and implementing the 10mg Agreement are attributable to Waymade plc.
- 9.219. Both [Waymade Senior Employee 1] and [Waymade Senior Employee 4] were employed by Waymade plc.³¹⁵⁸ The CAT has confirmed that an employee *'will typically be part of the undertaking that employs him or her'*.³¹⁵⁹ An employee's actions are attributable to his employer.³¹⁶⁰ This is the case even where he or she is acting without the knowledge of the employer's principal managers or specific authority to make the company party to an anticompetitive agreement. All that is required is that he is authorised generally to act on his employer's behalf – ie that he act within the powers given to him by his employment.³¹⁶¹
- 9.220. In this case, [Waymade Senior Employee 4] was acting not only with the knowledge of [Waymade Senior Employee 1], but on his express instruction.

³¹⁵⁷ Document 300328, email from [Waymade Senior Employee 4] to [X] dated 26 October 2012. [X]. Document 300302, email from [X] to [Waymade Senior Employee 1] dated 28 September 2012 (as explained above, Waymade plc was named Waymade Healthcare plc until 12 October 2012).

³¹⁵⁸ Document 302242, Waymade's response to the CMA's section 26 notice dated 8 October 2018, paragraphs 3.2 and 3.5.

³¹⁵⁹ *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 358.

³¹⁶⁰ *Tesco v OFT* [2012] CAT 31, paragraph 62 and the cases cited: *'Since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking'*. For example, in *Paroxetine* the CMA found that GUK had participated in the agreement with GSK through the involvement of its employees in negotiating and implementing that agreement. *Paroxetine* decision, paragraph 9.19.

³¹⁶¹ See e.g. C-100/80 *Musique Diffusion v Commission*, paragraphs 97-98; C-40/73 *Suiker Unie v Commission*, paragraph 539; C-68/12 *Slovenska sporitelna v Commission*, paragraph 25; T-588/08 *Dole v Commission*, paragraphs 581-582; T-56/99 *Marlines v Commission*, paragraph 60.

[X].³¹⁶² *'[T]he position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole'*.³¹⁶³ The Court of Justice has held that action by a person authorised to act on behalf of an undertaking – such as a principal manager – suffices to attribute liability to that undertaking.³¹⁶⁴

- 9.221. Waymade submitted that [Waymade Senior Employee 1]'s actions were not attributable to Waymade plc – [X]. [Waymade Senior Employee 1] was just as much an Amdipharm UK Limited staff member as a Waymade plc staff member.³¹⁶⁵
- 9.222. Whether [Waymade Senior Employee 1]'s employment by Waymade plc was [X] does not change the fact that his actions are attributable to Waymade plc – if anything it reflects his role [X] of the undertaking that included Waymade plc.
- 9.223. The fact that [Waymade Senior Employee 1] was just as connected to Amdipharm UK Limited as to Waymade plc only emphasises the importance of focusing on the Waymade undertaking, which includes both companies during October 2012 – and the importance of holding both companies liable for the 10mg Agreement during that month.³¹⁶⁶ It was the Waymade undertaking that Auden regarded during October 2012 as a competitor with which it was necessary to reach a market exclusion agreement.³¹⁶⁷ It would be artificial to distinguish between the actions of Waymade plc and Amdipharm UK Limited as part of that undertaking during October 2012. [X] with regard to 10mg hydrocortisone tablets.³¹⁶⁸
- 9.224. Waymade plc – through [Waymade Senior Employee 1] and [Waymade Senior Employee 4] – therefore played a prominent role in the negotiation

³¹⁶² Waymade plc's articles of association state that *'the directors are responsible for the management of the company's business, for which purpose they may exercise all the powers of the company'*. [X].

³¹⁶³ T-705/14 *Unichem v Commission*, paragraph 77. In T-77/92 *Parker Pen v Commission*, the actions of Parker's director in signing the anticompetitive agreement sufficed to establish that Parker had committed the infringement intentionally, even where he was acting contrary to company policy and the board, once it became aware, immediately rescinded the agreement (paragraphs 78-82).

³¹⁶⁴ C-68/12 *Slovenská sporiteľňa*, EU:C:2013:71, paragraph 25; and Joined cases C-100/80 to 103/80 *Musique Diffusion française and Others v Commission*, EU:C:1983:158, paragraph 97: *'it is not necessary for there to have been action by, or even knowledge on the part of, the partners or principal managers of the undertaking concerned; action by a person who is authorized on behalf of the undertaking suffices'* (see also T-588/08 *Dole v Commission*, EU:T:2013:130, paragraph 581). Although action by principal managers is therefore not required, where it is present this is a strong factor establishing liability of the undertaking they manage.

³¹⁶⁵ Document 204903, Waymade's RSSO, paragraph 8.63.

³¹⁶⁶ Compare the Commission's *Lundbeck* decision, paragraphs 1256 and 1265-1266.

³¹⁶⁷ Compare T-56/99 *Marlines v Commission*, paragraph 60.

³¹⁶⁸ Waymade's representations on the 10mg Agreement relied principally on ignoring the CMA's definition of the Waymade undertaking, which during October 2012 included both Waymade plc and Amdipharm UK Limited, sister companies both owned by [Waymade Senior Employee 1].

and implementation of the 10mg Agreement and should be held liable for it.³¹⁶⁹

- 9.225. Further, as explained above, the first order under the 10mg Agreement was placed on Waymade plc headed paper and the corresponding invoice was issued to Waymade plc.³¹⁷⁰ [X] was immediately instructed to sell the packs once the order was fulfilled – confirming that Waymade plc was involved in implementing this first order.
- 9.226. Waymade plc submitted that since on 13 October 2012 Waymade plc transferred the beneficial interest in its 10mg MA to Amdipharm UK Limited under the intra-group transfer agreement, *‘Any action in relation to 10mg tablets undertaken by Waymade [plc] was thereafter, by the terms of that agreement, exclusively at the direction of and for the benefit of Amdipharm [UK Limited]’*.³¹⁷¹ Waymade submitted that: *‘From 13 October 2012 onwards transferring products, including 10mg hydrocortisone, were sold by Waymade [plc] entirely for the benefit of Amdipharm [UK Limited]. In accordance with clause 5.4 of the [intra-group transfer agreement], from 13 October 2012 Waymade [plc] would have purchased and sold 10mg hydrocortisone, including the 10mg Supplies [under the 10mg Agreement], only as agent for, and at the direction of, Amdipharm [UK Limited].’* From 13 October 2012, therefore, *‘while the mechanics of the purchase and distribution of 10mg hydrocortisone may have been similar, Waymade [plc] acted as agent for Amdipharm [UK Limited] until the 10mg MA could be formally transferred into Amdipharm [UK Limited]’s name.’*³¹⁷²
- 9.227. Waymade plc therefore submitted that it did not profit from the 10mg Agreement. [X].³¹⁷³ Waymade plc submitted that it did not receive any financial benefit – direct or indirect – from the 10mg Agreement.³¹⁷⁴
- 9.228. Waymade plc’s role as agent for Amdipharm UK Limited in implementing the 10mg Agreement could in itself suffice to attribute liability to Waymade plc for that agreement.³¹⁷⁵

³¹⁶⁹ Compare the Commission’s *Servier* decision, paragraph 3006(c).

³¹⁷⁰ Compare C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, in which the fact that most of the documents found during the Commission’s inspections were on the letterhead of Knauf Gips KG, with its address and details, was one relevant factor in the Court’s finding that Knauf Gips KG should be liable for the infringement (paragraphs 104 to 106).

³¹⁷¹ Document 204903, Waymade’s RSSO, paragraph 2.38. See also paragraph 8.44.

³¹⁷² Document 302242, paragraphs 5.7 and 5.9, Waymade’s response to the CMA’s section 26 notice dated 8 October 2018.

³¹⁷³ Document 204903, Waymade’s RSSO, paragraphs 2.42 and 8.64.

³¹⁷⁴ Document 204903, Waymade’s RSSO, paragraphs 8.4(b) and 8.45.

³¹⁷⁵ Where agents can *‘be regarded as auxiliary organs forming an integral part of the principal’s undertaking’*, agent and principal form a single economic unit (C-40/73 *Suiker Unie v Commission*, paragraphs 538-541. See

9.229. However, the more credible reading of the evidence discussed above of [Waymade Senior Employee 1]'s instigation and supervision of the first order under the 10mg Agreement is that Waymade plc did not in fact pass on the benefit of this order to Amdipharm UK Limited. The urgency with which Waymade plc staff pursued the first order (*'required on URGENT delivery as per [Waymade Senior Employee 1]'s request'*), and the speed with which they passed on confirmation that they had received it (within a minute of receiving confirmation, [Waymade Senior Employee 4] had instructed [✂] that an 'Extra 2000' packs were *'available now'*), indicate that Messrs [Waymade Senior Employee 1] and [Waymade Senior Employee 4] expected that the 2,000 packs would be sold by Waymade plc in addition to the 10mg hydrocortisone tablets it already sold (*'Extra'*) and that the benefit from selling those packs in the market would remain with Waymade plc. This reading of the evidence is consistent with [Waymade Senior Employee 1]'s statement in interview in relation to this purchase order, which directly contradicts Waymade's representations:

[Waymade Senior Employee 4] has ordered one on my request; it was the only supply we were going to get in for our benefit commercially. Afterwards, seven days later, the business was sold, so it would not be for our benefit. It's commercial reason ... 30 October the business was sold and from then on, it would not be in our benefit or commercial interest'.³¹⁷⁶

9.230. In any event, whether or not Waymade plc in fact retained the benefit of the first order, it is clear that Waymade plc played a prominent role in the negotiation and implementation of that order, as explained above. This is sufficient to attribute liability to Waymade plc for the 10mg Agreement.

9.231. As explained in section 3.F.III.e above, on 31 October 2012 the benefit of the 10mg Agreement passed to the AMCo undertaking with the Amdipharm group.

also T-56/99 *Marlines v Commission*, paragraph 60). In C-294/98 *Metsa-Serla v Commission* the trade association Finnboard, which acted as *'alter ego'* and agent for its members, invoicing customers on their behalf and passing profits on to them, was held liable for the infringement along with its members despite having no economic interest of its own in taking part in the infringement. See in particular paragraphs 26-28 of the Court of Justice's judgment and paragraphs 44 and 57-59 of the General Court's judgment. Compare also *Crest Nicholson v OFT* [2011] CAT 10, paragraphs 24-36, in which ISG Pearce was held liable as principal since the infringing subsidiary Pearce (which was also held liable) was operating as its undisclosed agent.

³¹⁷⁶ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 148 lines 22-25 and page 149 lines 3-4 (emphasis added).

III. **AMCo**

9.232. The CMA concludes that the following legal entities formed part of an undertaking for the purposes of the Chapter I prohibition, referred to as 'AMCo':

- a. From 31 October 2012 to 20 October 2015:
 - i. Amdipharm UK Limited; Amdipharm Limited; and Advanz Pharma Services (UK) Limited (together defined at paragraph 1.1 above as the Amdipharm Companies); and
 - ii. Cinven Capital Management (V) General Partner Limited; Cinven (Luxco 1) S.A.; and Cinven Partners LLP (together defined at paragraph 1.1 as the Cinven Entities).
- b. From 21 October 2015 to 24 June 2016, the Amdipharm Companies and Advanz.

9.233. Throughout these periods, each of these entities was engaged in economic activities, including the sale of pharmaceutical products on the market (directly or through subsidiaries). During the time periods outlined above these entities formed part of the AMCo undertaking that entered into the 10mg Agreement.

9.234. In summary, and as explained in the sections that follow:

- a. Each of the Amdipharm Companies directly participated in the 10mg Agreement. From 31 October 2012 until 20 October 2015, the Amdipharm Companies were majority owned by the Fifth Cinven Fund. The *Akzo* presumption does not apply. However, for the reasons explained in section 9.B.III.d below, the CMA concludes that each of the Cinven Entities exercised decisive influence over the Amdipharm Companies during this period, such that the Amdipharm Companies and the Cinven Entities formed a single undertaking.
- b. From 21 October 2015 until 24 June 2016, the Amdipharm Companies were wholly owned by Advanz. The *Akzo* presumption therefore applied between Advanz and each of the Amdipharm Companies and has not been rebutted, such that they formed a single undertaking.

9.235. The CMA attributes liability for AMCo's participation in the 10mg Agreement to:

- a. the Amdipharm Companies, the legal persons that directly participated in the 10mg Agreement; and
- b. the Cinven Entities and Advanz, as legal persons that exercised decisive influence over the Amdipharm Companies during their ownership periods, and are therefore jointly and severally liable with them.

a. Liability of Amdipharm UK Limited

- 9.236. The CMA attributes liability for the 10mg Agreement to Amdipharm UK Limited, and for the resulting financial penalty, from 23 October 2012 to 24 June 2016.
- 9.237. This is because Amdipharm UK Limited directly participated in the 10mg Agreement during that period.³¹⁷⁷
- 9.238. Amdipharm UK Limited employed [Amdipharm Senior Employee], the principal negotiator and custodian of the 10mg Agreement, prior to the beginning of the 10mg Agreement³¹⁷⁸ and until he left the AMCo group's employment in May 2014 (though he continued to be involved as a consultant thereafter).³¹⁷⁹
- 9.239. As explained in section 6.D.II.c.ii above, [Amdipharm Senior Employee] appears extensively in the documentary evidence of the 10mg Agreement, negotiating and implementing it.
- 9.240. [Waymade Senior Employee 1] [X].³¹⁸⁰ As explained in section 6.D.II.c.ii above, [Waymade Senior Employee 1] also appears extensively in the documentary evidence of the 10mg Agreement. The first order under the 10mg Agreement was placed on his instructions.
- 9.241. Amdipharm UK Limited therefore played a prominent role in the negotiation and implementation of the 10mg Agreement, via [X] [Amdipharm Senior Employee] and [X] [Waymade Senior Employee 1].³¹⁸¹

³¹⁷⁷ As explained above, Amdipharm UK Limited formed part of the Waymade undertaking until 30 October 2012.

³¹⁷⁸ Document 302242, paragraph 3.1, Waymade's response to the CMA's section 26 notice dated 8 October 2018. [Amdipharm Senior Employee] was employed by Amdipharm UK Limited from at least January 2011 until May 2014.

³¹⁷⁹ Document 00444, AMCo's response to the CMA's section 26 notice dated 15 April 2016, footnote 1. For [Amdipharm Senior Employee]'s consultancy role see, for example, Document LIO4933, emails from [Amdipharm Senior Employee] dated 29 June 2015.

³¹⁸⁰ [X].

³¹⁸¹ Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, in which the Commission held companies liable on the basis of their employees playing a prominent role in negotiation and implementation of the infringing agreements: paragraphs 1256-1257, 1272 and 1288-1290. Compare Commission decision of 9 July

- 9.242. Further, as explained in section 3.F.III.d above, on 13 October 2012 Amdipharm UK Limited acquired the beneficial interest in Waymade's 10mg MA and the beneficial entitlement to associated sales of 10mg hydrocortisone tablets, following an intra-group transfer in preparation for the sale of the Amdipharm group.
- 9.243. This meant that from 13 October 2012 onwards Amdipharm UK Limited not only held the beneficial interest in the 10mg MA, but was also entitled to the benefit of the value derived from that MA via the threat of independent entry it represented and the resulting payments from Auden under the 10mg Agreement. Amdipharm UK Limited also fulfilled the counter-performance for those payments (non-entry).
- 9.244. In addition to the beneficial title, from 9 May 2013 until the end of the 10mg Agreement Amdipharm UK Limited also held the legal title to AMCo's 10mg MA.³¹⁸² Amdipharm UK Limited was one of the 'Affiliate' entities on whose behalf Amdipharm Limited entered into the First and Second Written Agreements.^{3183, 3184}

2014 in Case 39.612 *Perindopril (Servier)*: Les Laboratoires Servier was liable '*through the participation ... in the negotiation of the agreement*' (paragraph 3006); Teva Pharmaceuticals BV was held liable '*through the involvement of top management ... in the preparations for the conclusion of the Teva Settlement Agreement*', and Teva Pharmaceutical Industries Limited was liable through its involvement '*in the preparations for the conclusion of the Teva Settlement Agreement*' (paragraph 3047). See also Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, in which the Commission attributed liability to the subsidiaries that actually signed the agreement or played a prominent role in its negotiation or implementation (recital 444). The CAT has confirmed that an employee '*will typically be part of the undertaking that employs him or her*': *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 358. See also *Tesco v OFT* [2012] CAT 31, paragraphs 62-63: '*since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking*'. The General Court has held that: '*[T]he position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole*' (T-705/14 *Unichem v Commission*, paragraph 77). See also T-77/92 *Parker Pen v Commission*, paragraphs 78-82.

³¹⁸² Document 200258, response to question 6, AMCo's response to the CMA's section 26 notice dated 23 August 2016.

³¹⁸³ Document 00445 and Document 00446, First and Second Written Agreements, clauses 1.1, 1.4 and 1.5 from which it follows that Amdipharm Limited (the entity entering into the contracts) entered into these written contracts '*on behalf of itself and its Group*'; '*Group*' was defined as Amdipharm Limited '*and all its Affiliates*'; '*Affiliates*' was defined as all companies subject to a common owner of 50% or more of their shares; and throughout this period, Amdipharm UK Limited and Amdipharm Limited were '*Affiliates*': they were both indirectly 100% owned by Amdipharm Mercury Limited (see, for example, Document 200480, structure chart of the Amdipharm group as at 31 October 2012 (Amdipharm Mercury Limited was at the time known as CCM Pharma Limited); Document 200481, structure chart of the Amdipharm Mercury combined group; and Document 202007, '*Annex 2: Updated structure chart*', attachment to Document 202009, Concordia's response to the CMA's section 26 notice dated 21 August 2017). Further, the Second Written Agreement purported to bind not only Amdipharm Limited, but also its Affiliates. For example, clause 2.2 provided that Amdipharm Limited '*shall not and shall procure that none of its Affiliates shall*' manufacture or supply competing hydrocortisone products '*under a licence granted to it or any of its Affiliates*' without giving Auden three months' written notice.

³¹⁸⁴ Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*: each of the two subsidiaries that signed the relevant agreement '*accepted the commitments in the agreement "on its own behalf and on behalf of all associated and related entities"*'. One of the reasons for the Commission attributing liability to Arrow Group ApS was that '*the United Kingdom agreement was concluded on behalf of the Arrow group of companies*' (paragraphs 1256 and 1260).

b. Liability of Amdipharm Limited

9.245. The CMA attributes liability for the 10mg Agreement to Amdipharm Limited, and for the resulting financial penalty, from 1 January 2013 to 24 June 2016.

9.246. This is because Amdipharm Limited directly participated in the 10mg Agreement during that period.³¹⁸⁵ Amdipharm Limited was the legal entity that entered into the First and Second Written Agreements on behalf of AMCo, which between them cover the period 1 January 2013 to 24 June 2016 and served as the vehicles for the payments from Auden/Actavis to AMCo in exchange for which AMCo agreed not to enter the market independently with its own 10mg hydrocortisone tablets.³¹⁸⁶

c. Liability of Advanz Pharma Services (UK) Limited

9.247. The CMA attributes liability for the 10mg Agreement to Advanz Pharma Services (UK) Limited, and for the resulting financial penalty, from 31 October 2012 to 24 June 2016.³¹⁸⁷

9.248. This is because Advanz Pharma Services (UK) Limited directly participated in the 10mg Agreement during that period.

9.249. Advanz Pharma Services (UK) Limited was the management services company of the AMCo group in the UK throughout this period.³¹⁸⁸ As such, Advanz Pharma Services (UK) Limited was the employing entity for AMCo's senior UK staff. Key AMCo senior management involved in determining the group's UK strategy and directing its commercial operations, including negotiating with Auden regarding the supply of 10mg hydrocortisone tablets – including [AMCo Senior Employee 1] [REDACTED], [AMCo Senior Employee 2] [REDACTED], and [AMCo Senior Employee 8] [REDACTED], all of whom appear extensively in the documentary evidence of the 10mg Agreement in section 6.D.II.c.ii above, negotiating and implementing it – were all employed by and acted for Advanz Pharma Services (UK) Limited.³¹⁸⁹

³¹⁸⁵ As explained above, Amdipharm Limited formed part of the Waymade undertaking until 30 October 2012.

³¹⁸⁶ Document 00445 and Document 00446, First and Second Written Agreements. Compare T-705/14 *Unichem v Commission*, EU:T:2018:985, paragraph 105, in which the Commission's attribution of liability to the legal entity that signed the relevant agreement in its *Servier* decision was upheld.

³¹⁸⁷ Advanz Pharma Services (UK) Limited was originally part of the Mercury Pharma group, and so did not form part of the same undertaking as Amdipharm UK Limited and Amdipharm Limited until 31 October 2012.

³¹⁸⁸ Financial statements for Amdipharm Mercury Company Limited, 2013 to 2016. Further, in the context of this investigation, all replies of entities within the AMCo group have been made by, and on behalf of, Advanz Pharma Services (UK) Limited. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3008.

³¹⁸⁹ [REDACTED] attended board meetings of the ultimate holding company of the AMCo group, Amdipharm Mercury Limited, as representatives of Advanz Pharma Services (UK) Limited (then known as Amdipharm Mercury Company Limited): see eg Document 200496, minutes of Amdipharm Mercury Limited board meeting dated 29

- 9.250. The individuals responsible for managing AMCo's relationship with Aesica – including [AMCo Employee], [AMCo Senior Employee 7], [AMCo Employee] and [AMCo Employee], all of whom also appear in the documentary evidence of the 10mg Agreement in section 6.D.II.c.ii above – were also all employed by Advanz Pharma Services (UK) Limited.³¹⁹⁰
- 9.251. Advanz Pharma Services (UK) Limited therefore played a prominent role in the negotiation and implementation of the 10mg Agreement, via its employees and [X] [AMCo Senior Employee 1].³¹⁹¹
- 9.252. Advanz Pharma Services (UK) Limited was also one of the 'Affiliates' on whose behalf AMCo entered into the First and Second Written Agreements, for the same reasons as outlined for Amdipharm UK Limited above.

d. Liability of the Cinven Entities

- 9.253. From 31 October 2012 until 20 October 2015 (the '**Cinven Period**') each of the Amdipharm Companies was indirectly majority owned by the Cinven private equity house ('**Cinven**'):
 - a. The Amdipharm Companies were wholly owned by Amdipharm Mercury Limited ('**AML**') (formerly known as CCM Pharma Limited).

April 2013; Document 200497, minutes of Amdipharm Mercury Limited board meeting dated 30 October 2013; Document 200498, minutes of Amdipharm Mercury Limited board meeting dated 29 January 2014; Document 200500, minutes of Amdipharm Mercury Limited board meeting dated 31 July 2014; Document 200501, minutes of Amdipharm Mercury Limited board meeting dated 5 November 2014; Document 200501, minutes of Amdipharm Mercury Limited board meeting dated 27 January 2015; Document 200502, minutes of Amdipharm Mercury Limited board meeting dated 24 April 2015; Document 200503, minutes of Amdipharm Mercury Limited board meeting dated 22 July 2015.

³¹⁹⁰ Document 200258, response to question 8, AMCo's response to the CMA's section 26 notice dated 23 August 2016.

³¹⁹¹ Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, in which the Commission held companies liable on the basis of their employees playing a prominent role in negotiation and implementation of the infringing agreements: paragraphs 1256-1257, 1272 and 1288-1290. See also Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*: Les Laboratoires Servier was liable 'through the participation ... in the negotiation of the agreement' (paragraph 3006); Teva Pharmaceuticals BV was held liable 'through the involvement of top management ... in the preparations for the conclusion of the Teva Settlement Agreement', and Teva Pharmaceutical Industries Limited was liable through its involvement 'in the preparations for the conclusion of the Teva Settlement Agreement' (paragraph 3047). See also Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*, in which the Commission attributed liability to the subsidiaries that actually signed the agreement or played a prominent role in its negotiation or implementation (recital 444). The CAT has confirmed that an employee 'will typically be part of the undertaking that employs him or her': *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 358. See also *Tesco v OFT* [2012] CAT 31, paragraphs 62-63: 'since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking'. The General Court has held that: '[T]he position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole' (T-705/14 *Unichem v Commission*, paragraph 77). See also T-77/92 *Parker Pen v Commission*, paragraphs 78-82 and C-100/80 *Musique Diffusion v Commission*, paragraph 97: action by principal managers of an undertaking is not required, but where present is a strong factor establishing liability of the undertaking they manage.

- b. Cinven held more than 55% of the shares in AML (and therefore the Amdipharm Companies) but less than 100%.
- 9.254. For the reasons set out in this section, the CMA concludes that as a result of the economic, organisational and legal links between the Cinven Entities and the Amdipharm Companies, the Cinven Entities each exercised decisive influence over each of the Amdipharm Companies throughout the Cinven Period.³¹⁹² Throughout the Cinven Period, the Cinven Entities and the Amdipharm Companies therefore formed an economic unit for the purpose of the 10mg Agreement.
- 9.255. The CMA therefore holds each of the Cinven Entities liable, jointly and severally with the Amdipharm Companies, for AMCo's participation in the 10mg Agreement, and for the resulting financial penalty, during the Cinven Period.
- 9.256. Before setting out the detail of the CMA's findings it is important to provide some context in order to explain why the CMA considers it appropriate to hold entities associated with Cinven liable and why the CMA has chosen the Cinven Entities (of the myriad legal entities associated with Cinven).
- 9.257. The CMA has structured its analysis of the decisive influence each Cinven Entity exercised in sections 9.B.III.d.i to vi below to reflect the multiple and cumulative links between the Cinven Entities and the AMCo group (in this section, the CMA uses the phrase '**the AMCo group**' to mean AML and all its wholly-owned subsidiaries during the Cinven Period (including the Amdipharm Companies)). This analysis is necessarily detailed because of the complex way Cinven structured its investment in the AMCo group.
- 9.258. This should not, however, detract from the simple points explained below: that Cinven publicly described its approach as one of making '*control investments*' and acting as '*a catalyst for change*';³¹⁹³ that Cinven publicly described its investment in the AMCo group as '*transformative*';³¹⁹⁴ and that in achieving that transformation, three key Cinven Entities and in particular a

³¹⁹² Cinven submitted that '*The CMA is not entitled to rely on links between the Cinven [Entities], which merely show that they are part of the same corporate group, for the purposes of attributing parental liability. To do so would expose all entities within a 'corporate group' (even those which are not affiliated to one another) to potential liability for the conduct of separate entities over which they have no influence*' (Document 204970, Cinven RSO in Case 50395, paragraph 12.2 (in responding to the SSO in this case Cinven referred the CMA to its representations in other cases). This mischaracterises the CMA's findings. The links between the Cinven Entities are relevant (in showing, among other things, the alignment of their interests) but the CMA's findings relate to the economic, organisational and legal links between each Cinven Entity and the Amdipharm Companies, which demonstrate the exercise of decisive influence by each Cinven Entity.

³¹⁹³ Document LIO7765, Cinven 2011 annual review, page 22.

³¹⁹⁴ Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*'.

handful of key Cinven individuals were involved, following what Cinven publicly described as ‘a “one-team” approach’.³¹⁹⁵

9.259. In the sections that follow, the CMA first explains the approach Cinven takes to its investments, demonstrating that Cinven’s approach generally, and specifically to its investment and management of the AMCo group, was centred around obtaining control and using that control to actively manage the portfolio business. The CMA goes on to explain the role the Cinven Entities played in Cinven’s approach, following which the CMA explains why each of the Cinven Entities exercised decisive influence over the Amdipharm Companies during the Cinven Period and is therefore jointly and severally liable with them for the 10mg Agreement.

i. Cinven’s approach to investment and creation of the AMCo group

9.260. This section explains Cinven’s approach to investment generally and specifically how that approach was implemented in relation to the AMCo group, drawing on Cinven’s own published and internal documents. It shows that to exercise decisive influence (or in Cinven’s words, to ‘*leverage control ownership positions*’³¹⁹⁶) by buying, restructuring, adding to, making profitable and then divesting companies is the essence of Cinven’s business model, and it is the strategy it successfully applied to this investment. It is for these reasons that the CMA considers it appropriate to hold entities associated with Cinven liable.

9.261. Cinven’s own descriptions of its approach to investments confirm that it is not a ‘*pure financial investor*’.³¹⁹⁷ Its public documents describe it as ‘*an active and engaged investor in companies*’³¹⁹⁸ and explain ‘*The Cinven approach*’ to investment as follows:

‘Cinven creates value by making control investments in leading European companies and accelerating growth through the application of our sector expertise, global reach and active ownership model

...

³¹⁹⁵ Document LIO7766, ‘Cinven Annual Review 2012’, page 7.

³¹⁹⁶ Document LIO7766, ‘Cinven Annual Review 2012’, page 26.

³¹⁹⁷ See section 9.A.II.b.ii above.

³¹⁹⁸ Document PAD156, Cinven: ‘Annual Review 2014’, page 120. In this document, the term ‘Cinven’ ‘means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006), and/or funds managed or advised by any of the foregoing’. See page 1.

*We act as a catalyst for change; driving revenue, EBITDA and margin growth through active engagement with our portfolio companies and their management.*³¹⁹⁹

...

*We seek to improve all aspects of the companies we invest in, for the full duration of our ownership.*³²⁰⁰

*'A key differentiating factor in the Cinven offer is ... the active investor model that we pursue with all our investments.*³²⁰¹

9.262. One of the 'Investment criteria for a typical Cinven company' was 'Control positions, a path to control, or a significant influence over the strategy and management'.³²⁰² Cinven's approach is, in its own words, to 'acquire control positions in market-leading, cash-generative companies with attractive market dynamics'.³²⁰³

9.263. Cinven emphasised that its active ownership continued throughout the lifetime of an investment:

*'The Sector, Portfolio and Financing teams come together to evaluate opportunities, through the development of an investment case and strategy, from initial acquisition, through the ownership period and finally to ultimate exit.'*³²⁰⁴

9.264. In this case, Cinven pursued its active investor model when acquiring the Amdipharm and Mercury Pharma groups, combining them to create the AMCo group, and ultimately divesting that group. The contemporaneous documents demonstrate these aspects of Cinven's active ownership with respect to the AMCo group, as further discussed below:

- a. When developing the '*investment case and strategy*';
- b. '*Through the ownership period*'; and
- c. When preparing for '*the ultimate exit*'.

³¹⁹⁹ LIO7765, Cinven 2011 annual review, page 22 (emphasis added).

³²⁰⁰ Document PAD156, Cinven: 'Annual Review 2014', page 22 (emphasis added). As above, the term 'Cinven' 'means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006), and/or funds managed or advised by any of the foregoing' (page 1).

³²⁰¹ Document LIO7765, 'Cinven Annual Review 2011', page 18 (emphasis added).

³²⁰² Document LIO7767, 'Cinven Annual Review 2013', page 25.

³²⁰³ Document LIO7766, 'Cinven Annual Review 2012', page 23. See also page 26: '*We leverage control ownership positions*'.

³²⁰⁴ Document LIO7766, 'Cinven Annual Review 2012', page 7 (emphasis added).

Developing the 'investment case and strategy'

9.265. Cinven's investment case and strategy for the AMCo group was to combine the Mercury Pharma and Amdipharm groups and bring them under single management, and to adopt for the combined group a strategy and business plan focussed on what it called '*off-patent, niche pharmaceuticals*' (see below).

9.266. Cinven stated publicly in relation to these investments:

'Creating a global force in niche pharmaceuticals

In 2012, Cinven acquired and brought together Mercury Pharma and Amdipharm, two complementary niche pharmaceutical companies, to create an international player of scale and a platform for continued consolidation in this fragmented market. The combined business is now called Amdipharm Mercury Company Limited (AMCo).

...

*Our Healthcare sector team identified off-patent, niche pharmaceuticals as a particularly attractive sub-sector. It is insulated from the patent expiry issues which affect the broader pharmaceutical industry, has high entry barriers, and is a relatively fragmented market, offering opportunities for significant value creation through consolidation.'*³²⁰⁵

9.267. In publicising its investments, Cinven therefore emphasised both its industry expertise and its understanding of the way niche generic drugs could be exploited for profit. Cinven's knowledge of the reimbursement system for generic drugs – in particular, the free pricing regime, which could be exploited where effective competition failed to materialise – was a key factor in its decision to invest in the Mercury Pharma and Amdipharm groups.

9.268. Cinven's Healthcare sector team was led by two Cinven Partners: [Cinven Senior Employee 1], [REDACTED], and [Cinven Senior Employee 4], [REDACTED].³²⁰⁶ Both were appointed to the boards of AMCo group companies during the Cinven Period. [Cinven Senior Employee 1] was quoted in the press when the investment in the Amdipharm group was announced, explaining the rationale for the investment. The *Financial Times* wrote:

'Amdipharm buys up the rights to what Cinven calls "unloved generics" – legacy drugs that still have a solid base of patients in spite of being

³²⁰⁵ Document LIO7766, 'Cinven Annual Review 2012', page 8.

³²⁰⁶ Document LIO7767, 'Cinven Annual Review 2013', page 109.

superseded by newer versions that have slightly different effects. Cinven is hoping to exploit the stable growth of these cheap off-patent medicines that are sold in low volumes and with limited risk of price competition.

*These relatively neglected drugs, which Cinven partner [Cinven Senior Employee 1] dubbed “little jewellery boxes”, can still attract strong sales. Amdipharm generates annual revenues of more than £110m.*³²⁰⁷

9.269. [REDACTED].³²⁰⁸ [REDACTED].

9.270. The investment recommendation for Cinven's acquisition of the Mercury Pharma group stated:

'Approximately 40% of the generics market in the UK is unbranded

- The pricing of these unbranded products is not regulated because competition suppresses pricing across the market as a whole*
- However, for smaller, niche formulations, the competitive forces may not work to suppress prices as efficiently as for larger volume products and create room for price growth*

...

Mercury therefore operates below the radar and capitalises on opportunities to achieve volume and pricing growth even in such a heavily regulated market'

...

Reimbursement for drug manufacturers is controlled by a small group within the DoH ... The focus is on high volume drugs (patent and off-patent) as this is where the absolute quantum of savings is higher: niche products are typically below the radar'³²⁰⁹

9.271. The 'investment attraction' of the Mercury Pharma group was therefore its ability to exploit the absence of effective regulation for niche generic drugs and increase prices while remaining 'below the radar' of authorities.

³²⁰⁷ [REDACTED].

³²⁰⁸ Document 204971, Cinven RSSO in Case 50395, footnote 558.

³²⁰⁹ Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012', pages 6 and 8 (emphasis added).

9.272. [REDACTED]. The investment recommendation for Cinven's acquisition of the Amdipharm group stated:

*'The primary growth levers for Amdipharm [REDACTED]'*³²¹⁰

9.273. [REDACTED].³²¹¹

9.274. As these documents make clear, the investment thesis and business plan for the combined AMCo group were a continuation and expansion of the same strategy that the existing management of the Mercury Pharma group had already pursued – in particular under [AMCo Senior Employee 1]. Cinven has publicly stated that it cultivates an early relationship with portfolio company management so that *'when the time comes we already have a strong affinity with the management team and are able to move quickly'*.³²¹² In its internal documents, Cinven noted that *'the levers [AMCo Senior Employee 1] has pulled on pricing etc. would be applicable to Amdipharm'*.³²¹³ The final recommendation for Cinven to acquire the Mercury Pharma and Amdipharm groups again emphasised that the *'Mercury-Amdipharm combination investment thesis'* was to:

'Drive growth in UK through optimisation of the Amdipharm UK portfolio in an identical manner to what Mercury have done in the last 2 years – a low risk value lever which we believe can deliver in excess of £20m of additional EBITDA under our ownership

...

*... It should be noted that this is the same strategy that [AMCo Senior Employee 1] and the team have successfully executed at Mercury. [emphasis in original]'*³²¹⁴

9.275. On 13 November 2012 [AMCo Senior Employee 1] and [AMCo Senior Employee 2] gave a presentation to investors at a healthcare conference run by the Jefferies financial group. The presentation stated that a *'key strategic element'* of the merger between Amdipharm and Mercury was that their *'Portfolio comprises low-cost, off-patent products which are not the main focus of healthcare cost reduction initiatives'*. It went on to note: *'Pharmaceutical reimbursement contributed c.10% to the total NHS budget*

³²¹⁰ Document LIO6490.4, 'Annex 2.2 - memorandum to the IC titled 'Amdipharm - initial investment recommendation' dated 9 July 2012', page 4.

³²¹¹ Document LIO0250, 'Ampule Confidential Information Memorandum_Draft_v08.pdf.pdf', page 14.

³²¹² Document PAD156, Cinven: 'Annual Review 2014', page 21 (emphasis added).

³²¹³ Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012', page 2.

³²¹⁴ Document LIO6491.1, 'Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012', pages 5 (emphasis added) and 36 (emphasis in original).

in 2012, so is not as material to overall healthcare spending as actual service provision, which is the primary focus of healthcare reform'.³²¹⁵

- 9.276. Both Cinven and AMCo group senior management therefore shared a common strategy from the outset of Cinven's investment. In simple terms, this was to increase the prices of certain off-patent drugs where AMCo faced no or ineffective competition, and whose markets were small enough to avoid attention from the DHSC.
- 9.277. Cinven's investment case and strategy for the AMCo group therefore involved two key elements that, if implemented, would each amount to the exercise of decisive influence:
- a. The combining into a single group of two previously independent groups of companies, including installing a single management team at the top of that combined group which answered to Cinven. Only through exercising decisive influence over the Mercury Pharma and Amdipharm groups could this be achieved; and
 - b. The adoption for the combined AMCo group of a business plan to be carried out by that management team, focussed on generating profit from the AMCo group's portfolio of '*off-patent, niche pharmaceuticals*'. Again, only through exercising decisive influence over the AMCo group could Cinven have achieved this.

'Through the ownership period'

- 9.278. Throughout the period in which Cinven owns a portfolio company, it ensures that its investment strategy is implemented, including through operational input, appointing senior managers, and regular reporting. Cinven's public documents state: '*we do guarantee our operational input, which is targeted, systematic and on-going throughout the entire period of our ownership*'.³²¹⁶
- 9.279. This was the case for the AMCo group during the Cinven Period. Cinven's investment strategy was implemented immediately and throughout the Cinven Period through ongoing and systematic strategic and operational oversight.

³²¹⁵ Document 202401, AMCo conference presentation dated 13 November 2012, slides 11 and 14.

³²¹⁶ Document PAD156, Cinven: '*Annual Review 2014*', page 24. As above, the term 'Cinven' '*means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006), and/or funds managed or advised by any of the foregoing*'.

- 9.280. Once the Mercury Pharma and Amdipharm acquisitions were complete, Cinven's strategy was put into effect without delay. As explained in the sections that follow, Cinven immediately:
- a. appointed two 'Investor Directors' to the board of AML to exercise its rights as majority shareholder in the AMCo group and to oversee implementation of its strategy (see paragraphs 9.347 to 9.349 below);
 - b. appointed key individuals to positions on the boards of numerous other AMCo group companies to further entrench its influence (see paragraphs 9.351 to 9.356 below); and
 - c. put in place reporting lines to ensure the regular provision of strategic and operational information about the AMCo group's performance, and used that information to direct the AMCo group's conduct (see paragraphs 9.370 to 9.386 below).
- 9.281. Immediately after acquiring the two groups, Cinven put in place a '*100 day action plan*' which included integrating them and optimising senior management under a single team led by [AMCo Senior Employee 1], to oversee '*UK portfolio optimisation: Price increases, De-branding, Cross-selling*'.³²¹⁷ Such a 100 day action plan was what Cinven generally put in place when it made an investment, as its 2012 annual review explained: the plan '*involves our Investment and Portfolio teams working closely with a company's management team and expert consultancies to develop our strategy into a detailed business plan*'.³²¹⁸ This immediate, in-depth oversight of the AMCo group's integration, management and strategy demonstrates that Cinven exercised decisive influence over its investment from the outset, in order to ensure its goals were achieved.
- 9.282. The combined AMCo group prepared consolidated management accounts from January 2013 onwards, which were presented to Cinven by [AMCo Senior Employee 1].³²¹⁹
- 9.283. Once Cinven has invested, every portfolio company also develops a longer-term '*Value Creation Plan*' in conjunction with Cinven, looking at '*all aspects of operational improvement, with a specific emphasis on Cinven's areas of*


³²¹⁷ Document LIO6537.69, '*Review of investments and Valuations at 31 December 2012*', page 5.

³²¹⁸ Document LIO7766, Cinven 2012 annual review, page 28 (emphasis added). Pages 28-29 provide a case study of the activities of the Portfolio team in relation to another investment, CPA Global, including reorganising sales and marketing functions; developing technical plans for its software to reduce customer churn; and '*instituting a formal and robust long-term strategic planning process*'.

³²¹⁹ See, for example, Document 200057, AMCo group January 2013 management accounts and CEO's report.


functional expertise'.³²²⁰ Such a plan was also put in place for AMCo. In 2014, Cinven noted that:

*'AMCo continued to execute its Value Creation Plan, characterised by international expansion and strong growth ... The size and geographic presence of the combined business has allowed Cinven and AMCo's leadership team, to build a truly international platform in line with Cinven's buy and build and internationalisation strategies ... Cinven's deep experience of executing complex mergers, operational improvement and acquisitive growth, has created a new force in the global pharmaceuticals industry'*³²²¹

- 9.284. Throughout the Cinven Period, in addition to the 'follow-on' acquisitions (acquisitions by the AMCo group, financed in part by Cinven) that formed part of Cinven's *'buy and build'* strategy during the Cinven Period, under Cinven's ownership the AMCo group also implemented Cinven's strategy by leveraging the absence of competition and weak regulation of niche generic drugs to increase prices. Cinven oversaw this.³²²² In fact, the *'buy and build'* strategy went hand in hand with the strategy of exploiting niche generics. For example, slides for an AMCo group investor presentation noted that AMCo was looking *'to replicate UK success'* overseas, stating: '[

³²²⁰ Document PAD156, Cinven: 'Annual Review 2014', page 24.

³²²¹ Document PAD156, Cinven: 'Annual Review 2014', page 25. As above, the term 'Cinven' *'means, as the context requires, Cinven Group Limited, Cinven Partners LLP, Cinven (Luxco 1) S.A., Cinven Limited, Cinven Capital Management (V) General Partner Limited and their respective Associates (as defined in the Companies Act 2006), and/or funds managed or advised by any of the foregoing'*.

³²²² For example, on 5 August 2014 [Cinven Senior Employee 1] provided guidance to [AMCo Senior Employee 1] and [AMCo Senior Employee 6], ['AMCo core competence' *'Driving value from portfolio of niche drugs'*, [Cinven Senior Employee 1] commented: *'Whilst AMCo core competence is identifying and making the most of these niche products, clearly the most important thing is we have them in the first place'*. The slides went on to note: *'UK is a free priced market for generics, allows for price increases for the right products if you can spot the opportunity'*. Document 202716, 'AMCo overview' slide pack August 2014, attached to Document 202715, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 1] and [AMCo Senior Employee 6] dated 5 August 2014, slides 2 and 3. Document 202715, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 1] and [AMCo Senior Employee 6] dated 5 August 2014.

³²²³ Document 202716, 'AMCo overview' slide pack August 2014, attached to Document 202715, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 1] and [AMCo Senior Employee 6] dated 5 August 2014, slide 2.

Preparing for the 'ultimate exit'

9.286. Finally, Cinven's divestment of the AMCo group and its strategy and decisions in the run-up to that divestment demonstrate that it continued to explore and implement initiatives that continued its investment strategy for the AMCo group. Statements made by Cinven and AMCo group management when the divestment was announced demonstrate that the investment in the AMCo group had been successful and that Cinven had played a decisive role in that success.

9.287. Cinven's 'AMCo exit paper', prepared in February 2015, stated:

'We have worked with [X] to help to define AMCo's strategy ... We have also identified the weaker areas of AMCo's business and are working to address these

...

While M&A would allow us to address these matters more quickly, given it involves external parties, it remains somewhat outside of our control

...

We have a Cinven friendly SHA [shareholders' agreement] in place, where we retain full control in exit (including information rights and controlling access to bidders)

Management's interests are largely aligned with ours, although a later sale would likely be the preferred option by most of the management as it would increase their likely capital gain ... We are aware of management's incentivisation and are continuing to monitor it closely. We have allowed the management team to meet a number of private equity funds'.³²²⁴

9.288. The exit paper made clear that Cinven:

- a. Was able to 'define AMCo's strategy';
- b. Considered that internal initiatives (not involving third parties) were subject to its 'control';

³²²⁴ Document LIO6494.3, 'AMCo Exit Paper' dated 27 February 2015', pages 3, 11 and 13 (emphasis added). Compare to Document LIO6494.2, 'Q4 PRC Paper on Amco dated December 2014', page 2: 'During Q4, we and management worked with McKinsey to help to define AMCo's strategy and ensure the company is fully prepared to articulate the equity story for the next buyer.'

- c. Retained '*full control in exit*'; and
- d. Was aligned with AMCo group management on exit strategy (but need not be: it was Cinven that made the call on when divestment would take place).

9.289. The paper also noted, under '*Strategic initiatives*', that:

'In order to improve the attractiveness of AMCo on exit we are working on a number of business initiatives. [X]'.³²²⁵

9.290. The exit paper therefore also made clear that the strategic business initiatives devised at the time of disposing of the AMCo group were [X].

9.291. Cinven succeeded in using its expertise to increase significantly the value of the AMCo group. Cinven bought the Mercury Pharma group for £465 million and the Amdipharm group for £367 million,³²²⁶ and sold the combined AMCo group three years later for £2.3 billion,³²²⁷ making a profit of £1.5 billion. Its (approximately three-year) investment '*returned cash proceeds of 3.5x cost*'.³²²⁸ In its own press release announcing the sale to Concordia International (now Advanz), Cinven described the combination of the two businesses as '*transformative*' and emphasised its role in engineering it:

'Cinven created AMCo, which focuses on the sale of niche prescription off-patent products, in 2012 through the transformative merger of Mercury Pharma ('Mercury') and Amdipharm, both of which were acquired in bilateral transactions, in August and October 2012 respectively'.

9.292. [Cinven Senior Employee 1] commented:

'Cinven successfully created AMCo – through the combination of two businesses – as a result of bilateral transactions and our strong healthcare sector focus and track record. We saw an opportunity to create significant value through the consolidation of the relatively fragmented, off-patent, niche pharmaceuticals market and AMCo has certainly achieved that. We have worked closely with the highly capable management at AMCo, led by [AMCo Senior Employee 1], in further strengthening the senior team, internationalising the business,

³²²⁵ Document LIO6494.3, '*AMCo Exit Paper*' dated 27 February 2015', page 11 (emphasis added).

³²²⁶ Document LIO7766, '*Cinven Annual Review 2012*', page 9.

³²²⁷ Concordia paid USD1.2 billion in cash, USD700 million in shares and USD220 million in additional payments relating to the AMCo group's future performance, as well as assuming its debt. See Document PAD087, FT: '*Cinven to sell AMCo to Concordia in £2.3bn deal*'.

³²²⁸ See Document PAD096, Cinven: '*Annual Review 2015*', page 4.

executing and integrating several acquisitions as part of our “buy and build” strategy, and optimising AMCo’s capital structure in order to most effectively achieve growth’.

9.293. [AMCo Senior Employee 1] stated:

*‘Cinven has been instrumental in the growth and success of the AMCo business, starting with the initial combination of Mercury Pharma with Amdipharm which made us a truly international player. Subsequently, they have provided considerable assistance in areas including international expansion, through their Portfolio team in Asia and Europe; and expertise in M&A, and integration to ensure we generated the most upside quickly from the acquisitions we made. They have been first class in their understanding of the healthcare sector and the dynamics and drivers of our business’.*³²²⁹

9.294. The *Times* wrote:

‘A private equity firm has made about £1.5 billion from buying and selling generic drug companies that exploit NHS rules to impose huge increases in the price of medicines

...

*The combined strategy generated a massive profit for the private equity company when it sold AMCo last October in a deal valued at £2.3 billion, including almost £1 billion debt – five times the value of its original investment. [Cinven Senior Employee 1], a partner in Cinven, said it was one of his most successful deals.*³²³⁰

9.295. Cinven submitted that [X].³²³¹ However, as explained in paragraphs 9.57 to 9.59 above, the European courts have limited the concept of a ‘*pure financial investor*’ (potentially lacking decisive influence) to ‘*the case of an investor who holds shares in a company in order to make a profit, but who refrains from any involvement in its management and in its control*’.³²³² This was not the case with Cinven, as the documents discussed in this section demonstrate. In particular, case law shows that financial investors that actively engage with their portfolio companies to effect change – as Cinven

³²²⁹ Document PAD066, Cinven: ‘AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp’ (emphasis added).

³²³⁰ Document PAD157, The *Times*: ‘Firm’s £1.5bn drug profit is bitter pill for taxpayer’, June 2016 (emphasis added).

³²³¹ Document 204970, Cinven RSO in Case 50395, paragraphs 12.1(b)(iv) and 12.79-12.85.

³²³² T-392/09 1. *garantovaná a.s. v Commission*, EU:T:2012:674, paragraph 52, citing the Opinion of Advocate General Kokott in C-97/08 *Akzo Nobel v Commission*, EU:C:2009:262.

did – are likely to exercise decisive influence over them.³²³³ For this reason the courts, the Commission and Member States' national competition authorities have held parent companies focused on financial investment liable for infringements committed by their portfolio companies in numerous cases.³²³⁴

9.296. In this case, Cinven's '*active*' and '*engaged*' ownership,³²³⁵ its '*targeted, systematic and on-going*' operational input,³²³⁶ its instigation of '*the transformative merger*'³²³⁷ of two corporate groups; its success in generating a very substantial profit drawing on its knowledge of the pharmaceutical sector and in particular its understanding of the opportunities presented by the '*little jewellery boxes*' of '*unloved*' niche generic drugs,³²³⁸ demonstrate that it was no pure financial investor in the AMCo group. In the Cinven Period Cinven combined the Mercury Pharma and Amdipharm groups and placed them under a single management team; it put in place a strategy and business plan and ensured these were implemented and regularly reported on; and its investment in the AMCo group was successful, with this success being attributable according to both [Cinven Senior Employee 1] and [AMCo Senior Employee 1] to Cinven's active management of the AMCo group.

9.297. For all these reasons, the CMA considers it appropriate to hold entities associated with Cinven liable for the 10mg Agreement during the Cinven Period and rejects Cinven's submission that '[X]'.³²³⁹

ii. The roles of the Cinven Entities

9.298. It is therefore clear that Cinven exercised decisive influence over the AMCo group.

9.299. The law requires that liability for the infringement committed by the Amdipharm Companies is attributed to legal persons on whom fines may be

³²³³ For example, T-395/09 *Gigaset AG v Commission*, EU:T:2014:23, paragraphs 37-38.

³²³⁴ See, for example, T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, upheld in C-595/18 P *Goldman Sachs v Commission*; Commission decision in *Lundbeck*, upheld in T-471/13 *Xellia Pharmaceuticals and Alpharma v Commission*, EU:T:2016:460; Commission decision in *Servier*, upheld in T-705/14 *Unichem v Commission*, EU:T:2018:915 and T-682/14 *Mylan v Commission*, EU:T:2018:907; T-395/09 *Gigaset AG v Commission*, EU:T:2014:23; Dutch AGCM decisions in *Meneba*, Decisions 6306_20/217_OV (20 November 2014) and 6306_20/259 (11 September 2015); District Court of Rotterdam judgment of 26 January 2017, NL:RBROT:2017:588.

³²³⁵ Document PAD156, Cinven: '*Annual Review 2014*', page 120. Document LIO7765, '*Cinven Annual Review 2011*', page 18.

³²³⁶ Document PAD156, Cinven: '*Annual Review 2014*', page 24.

³²³⁷ Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*'.

³²³⁸ Document PAD067, FT: '*Cinven accelerates into UK healthcare*'.

³²³⁹ Document 204970, Cinven RSO in Case 50395, paragraphs 12.3 and 12.86.

imposed.³²⁴⁰ The CMA must therefore identify the legal entities within Cinven to which liability for the 10mg Agreement can be attributed.³²⁴¹

9.300. Cinven bought the Amdipharm and Mercury Pharma groups, and sold the combined AMCo group, through the Fifth Cinven Fund. [REDACTED].³²⁴² [REDACTED].

9.301. [REDACTED].

Figure 9.2: [REDACTED]

[REDACTED].

9.302. As this diagram shows, the structure of the fund was complex. Despite this complexity, however, for the purposes of this case there are three core entities and a handful of core individuals through which Cinven exercised decisive influence over the Amdipharm Companies:

a. [REDACTED].³²⁴³ [REDACTED];

b. [REDACTED]

c. [REDACTED].

9.303. Cinven MGP, Luxco 1 and Cinven Partners are together defined at paragraph 1.1 above as the **Cinven Entities**.

9.304. Notwithstanding the complexity of the Fifth Cinven Fund, the Cinven Entities were structurally and – most importantly – personally connected:

a. [REDACTED].³²⁴⁴

b. [REDACTED].³²⁴⁵ [REDACTED].

³²⁴⁰ C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 54 to 57.

³²⁴¹ Cinven submitted that '[REDACTED]' (Document 204971, Cinven RSSO in Case 50395, paragraph 10.19. See also Document 204970, Cinven RSO in Case 50395, paragraph 12.40(f)). The CMA rejects this submission. It is clear from the contemporaneous evidence cited in the sections above that the Cinven private equity house exercised decisive influence over the Amdipharm Companies. In the following sections, the CMA has set out how that decisive influence was exercised through specific legal entities, as the law requires.

³²⁴² Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraph 9.7. See also Document 200512, limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership, clause 4.1.3: '[REDACTED]'..

³²⁴³ [REDACTED]. Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraphs 9.4-9.5. See also Document 200512, limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership (annex 37 to Document 200471), recital (1), definitions and clauses 4.1.1 and 4.2.

³²⁴⁴ Document LIO6497.1, Cinven Partners LLP Partnership Agreement dated 17 February 2012, clause 8. [REDACTED].

³²⁴⁵ Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraph 9.12.

c. [REDACTED].³²⁴⁶ [REDACTED].

d. [REDACTED].³²⁴⁷

e. [REDACTED].

9.305. These connections ensured that the Cinven Entities acted as one in relation to the AMCo group investment.

9.306. Cinven publicly emphasised that its ‘*active ownership approach*’ was ‘*underpinned*’ by a ‘*complete alignment*’ between the interests of its Partners, fund entities such as Cinven MGP and Luxco 1 and portfolio companies such as the Amdipharm Companies. [REDACTED] during the Cinven Period stated:

‘there is a clear alignment of interests between investors, owners and portfolio companies, focused on creating value through growing sales and EBITDA

...

Partnership alignment:

Cinven is a collegial partnership ... Our incentives and remuneration are directly linked to the performance of our portfolio companies and funds. This complete alignment with our investing interests underpins our active ownership approach’.³²⁴⁸

9.307. Cinven described this as a “*one team*” approach’ that it followed throughout the lifetime of an investment:

This integrated, one team culture of trust and partnership lies at the heart of Cinven’s success.

...

Cinven is wholly owned by its 25 Partners. A widely-spread, single pot incentive structure reinforces the one team ethos. Incentives are directly aligned with the performance of our Portfolio companies and the returns to our investors’³²⁴⁹

³²⁴⁶ Document 200471, Cinven’s response to the CMA’s section 26 notice dated 20 October 2016, paragraph 9.12.

³²⁴⁷ Document 200471, Cinven’s response to the CMA’s section 26 notice dated 20 October 2016, paragraph 9.14.

³²⁴⁸ Document LIO7765, ‘*Cinven Annual Review 2011*’, pages 4 and 7 (emphasis added).

³²⁴⁹ Document LIO7765, ‘*Cinven Annual Review 2011*’, page 25 (emphasis added).

*'Ours is a 'one-team' approach.'*³²⁵⁰

- 9.308. Cinven submitted that [REDACTED].³²⁵¹ However, the CMA finds that the evidence shows that pursuant to this "*one-team' approach*", the interests of each of the Cinven Entities and the Amdipharm Companies were aligned in pursuit of their common strategy of exploiting the profit opportunities presented by niche generic drugs.
- 9.309. Each of the Cinven Entities played a specific role in the AMCo group investment, and was able to and did actually exercise decisive influence over the Amdipharm Companies as will be explained in the sections that follow:
- a. [REDACTED];
 - b. [REDACTED];
 - c. [REDACTED].
- 9.310. [REDACTED].³²⁵² [REDACTED].

iii. The legal test for attributing liability to the Cinven Entities

- 9.311. Before explaining the CMA's legal analysis of the decisive influence exercised by each of the Cinven Entities, the CMA here responds to Cinven's representations on the legal test.
- 9.312. Cinven submitted that [REDACTED].³²⁵³
- 9.313. [REDACTED].³²⁵⁴
- 9.314. This submission is misdirected.
- 9.315. The phrase '*a specific economic aim on a long-term basis*' derives from the EU General Court's description of an undertaking:

'Article [101] of the Treaty is aimed at economic units which consist of a unitary organisation of personal, tangible and intangible elements,

³²⁵⁰ Document LIO7766, 'Cinven Annual Review 2012', page 7 (emphasis added). See also page 30: '*Our interests are directly aligned with our Limited Partner investors and our portfolio companies, building value*' (emphasis added).

³²⁵¹ Document 204971, Cinven RSSO in Case 50395, paragraph 10.14(g). In responding to the SSO in this case Cinven referred to the CMA to its representations in Case 50395.

³²⁵² Document 205931, Cinven's response to the CMA's section 26 notice dated 2 December 2020.

³²⁵³ Document 204970, Cinven RSO in Case 50395, paragraph 12.1(a). Cinven repeated this argument in Document 204971, Cinven RSSO in Case 50395, paragraphs 10.4-10.8. In responding to the SSO in this case Cinven also referred to its representations in cases 50511-1 and 50511-2. These did not add new points to its arguments in documents 204970 and 204971.

³²⁵⁴ Document 204970, Cinven RSO in Case 50395, paragraphs 12.7-12.9. See also Document 203736, Cinven's RSO, paragraphs 12.7-12.15.

*which pursue a specific economic aim on a long-term basis and can contribute to the commission of an infringement of the kind referred to in that provision.*³²⁵⁵

9.316. This is not, however, the legal test for attributing liability to parents. The assessment of whether a parent exercises decisive influence over a subsidiary turns on the organisational, economic and legal links between the two entities. A shared commercial policy may be inferred from the totality of such links. However, the test does not require a common economic aim in the sense of the parent's influence over commercial conduct or that the parent and subsidiary are active in the same commercial sector.³²⁵⁶ This has been specifically confirmed in more recent caselaw. For example, in T-399/09 *Holding Slovenske v Commission* the EU General Court rejected HSE's argument that it could not be liable for an infringement committed by its subsidiary because it '*never shared any single economic aim*' with its subsidiary.³²⁵⁷ The EU General Court held that:

*'It can be seen from the reasoning of the latter judgment [T-112/05 Akzo v Commission] ... that, contrary to what the applicant appears to believe, the expression in question [a single economic aim on a long-term basis] cannot be understood as meaning that there must be an affinity between the business sectors in which the various legal persons making up an economic unit are active, nor even that the existence of a single economic unit is incompatible with the existence of an activity in several different, entirely unrelated, sectors'.*³²⁵⁸

9.317. Similarly, in *Kendrion v Commission* the Court of Justice followed the Opinion of the Advocate General, who noted that:

'It cannot follow from the fact that a wholly-owned subsidiary is acquired as a financial investment and that its activities are outside the

³²⁵⁵ T-9/99 *HFB v Commission*, EU:T:2002:70, paragraph 54. See also T-11/89 *Shell v Commission*, paragraphs 308-312.

³²⁵⁶ T-682/14 *Mylan v Commission*, paragraph 347 and the cases cited. *Durkan Holdings Limited v OFT* [2011] CAT 6, paragraph 22; Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 87, approved in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 73 to 74.

³²⁵⁷ T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraphs 44 and 46.

³²⁵⁸ T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraph 56 (emphasis added). See also paragraphs 49-50 and 54: '*What is relevant is the question whether ... the applicant, during the infringement period, exercised a decisive influence over its subsidiary, with the result that they could be considered as constituting, during that period, an economic unit. Contrary to the applicant's submission, neither its alleged intention to sell its shareholding in [the subsidiary] to another investor nor the fact that the latter was active in an entirely different commercial sector from its own precludes the exercise of such decisive influence ... the mere fact that the parent company and its subsidiary are active in different economic sectors, or even that the personnel of the parent company have no expertise in the specific commercial sector in which the subsidiary is active does not preclude the exercise of a decisive influence by the parent company over its subsidiary, even if the latter enjoyed a certain level of autonomy in the management of its business*'.

sphere of the parent company's normal operations that the two companies do not comprise the same undertaking. On the contrary: on the assumption that the purpose of an investment is to yield a return, it seems to me that, in order to ensure greater profitability from that investment, any parent company would have a strong incentive to exercise a decisive influence over its subsidiary's commercial policy'.³²⁵⁹

- 9.318. Where a parent company exercises decisive influence over a subsidiary it forms a single undertaking with that subsidiary. That is the legal test to be applied to the Cinven Entities' relationship with the Amdipharm Companies.³²⁶⁰
- 9.319. In any event, in this case not only can a shared commercial policy be inferred indirectly from the totality of the organisational, economic and legal links between the Cinven Entities and the Amdipharm Companies explained in the sections that follow; the evidence explained in the sections above directly shows that the Cinven Entities did share with the AMCo group a specific economic aim throughout the Cinven Period: to exploit the absence of regulation for niche generic drugs in order to extract high profits. That strategy was driven by Cinven.
- 9.320. Cinven's second submission was that [✂].³²⁶¹
- 9.321. The CMA rejects this submission. As explained in paragraph 9.37 above, it is clear that there is no exhaustive set of criteria or 'checklist' to be completed when considering parental liability.³²⁶² Nor is any specific instruction from the parent required.³²⁶³ The CMA considers in detail in the sections that follow an extensive range of economic, organisational and legal links between the Cinven Entities and the Amdipharm Companies, many of which taken in themselves would be sufficient to establish the exercise of decisive influence

³²⁵⁹ Opinion of Advocate General Sharpston in C-50/12 P *Kendrion v Commission*, EU:C:2013:350, paragraph 54, followed in C-50/12 P, EU:C:2013:771.

³²⁶⁰ See C-97/08 *Akzo Nobel v Commission*, EU:C:2009:536, paragraphs 58-59.

³²⁶¹ Document 204970, Cinven RSO in Case 50395, paragraphs 12.6, 12.7 and 12.10-12.14. See also Document 203736, Cinven's RSO, paragraphs 12.2, 12.33-12.48 and 12.50.

³²⁶² See, for example, C-628/10 P *Alliance One v Commission*, EU:C:2012:479, paragraph 45: '*In order to establish whether a subsidiary determines its conduct on the market independently, the Commission is, as a general rule, bound to take into consideration the economic, organisational and legal links which tie that subsidiary to the parent company, which may vary from case to case and cannot therefore be set out in an exhaustive list*'; T-141/07 *General Technic-Otis v Commission*, paragraph 103. See also C-179/12 P *Dow v Commission*, EU:C:2013:605, paragraph 54 and the case law cited: '*The Court of Justice has stipulated that account must be taken of all the relevant factors relating to the economic, organisational and legal links which tie the subsidiary to the parent company, which may vary from case to case and cannot therefore be set out in an exhaustive list*'.

³²⁶³ T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605. See also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraph 22(b); C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 41, citing C-293/13 P *Del Monte v Commission*, EU:C:2015:416, paragraphs 96-97.

(for example, the evidence that Cinven MGP edited and approved the AMCo group budget).³²⁶⁴ The evidence all points in the same direction.

iv. Liability of Cinven MGP

9.322. Cinven MGP exercised decisive influence over the Amdipharm Companies throughout the Cinven Period, as a result of the legal, organisational and economic links between Cinven MGP and the Amdipharm Companies:

- a. Cinven MGP had the ability to exercise decisive influence over the Amdipharm Companies:
 - i. [REDACTED].³²⁶⁵ The CMA therefore concludes, on the basis of the *Akzo* presumption, that AML exercised decisive influence over the Amdipharm Companies. The parties have not disputed this and the *Akzo* presumption has therefore not been rebutted.³²⁶⁶
 - ii. Cinven MGP had the ability to exercise decisive influence over AML (and through AML, over each of AML's wholly-owned subsidiaries, including the Amdipharm Companies) through its: (i) control of Cinven's majority shareholding and voting rights in AML; and (ii) control of Cinven's rights (including veto rights) under an AML shareholders' agreement.³²⁶⁷
- b. Cinven MGP did actually exercise decisive influence over the Amdipharm Companies by:
 - i. exercising Cinven's rights under that shareholders' agreement, including to appoint (and remove) directors to the boards of AML and other AMCo group companies, to approve the AMCo group budget and specified matters such as material transactions, and to obtain strategic and operational information about the AMCo group's performance; and
 - ii. overseeing the AMCo group's commercial conduct as its management sought to implement the strategy of increasing the

³²⁶⁴ The mere holding of a veto right over certain strategic commercial decisions (such as the adoption of a business plan or budget) can in itself confer decisive influence: C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63-67.

³²⁶⁵ Document 200479, structure chart of the Mercury Pharma group as at 31 August 2012; Document 200480, structure chart of the Amdipharm group as at 31 October 2012; and Document 200481, structure chart of the Amdipharm Mercury combined group; Document 200260, structure chart as of 16 December 2013; Document 200261, structure chart as of 13 January 2015; and Document 200519, structure chart of the Fifth Cinven Fund.

³²⁶⁶ Document 204970, Cinven RSO in Case 50395, paragraph 12.4: '*The Cinven [Entities] do not contest the decisive influence that AML held over its subsidiaries within the AMCo Group.*'

³²⁶⁷ As explained below, the shareholders in AML were [REDACTED]. Cinven MGP controlled those [REDACTED], had exclusive authority to act on their behalf, and exercised their rights as shareholders in AML.

prices of niche generic drugs that Cinven and the AMCo group shared.

Cinven MGP had the ability to exercise decisive influence over the Amdipharm Companies

Cinven MGP's control of Cinven's majority shareholding and voting rights in AML

9.323. Cinven MGP controlled a majority of the shares and voting rights in AML [REDACTED].³²⁶⁸

9.324. The shareholders in AML were [REDACTED] legal entities: [REDACTED].³²⁶⁹ [REDACTED].³²⁷⁰ Cinven MGP had exclusive authority to make investment and management decisions for the Cinven Limited Partnerships.³²⁷¹ This made Cinven MGP equivalent to a majority shareholder in AML and the *de facto* holder [REDACTED] over AML and, through it, the Amdipharm Companies, deriving from that shareholding.³²⁷²

9.325. The stakes of the other shareholders were fragmented and none of them held any rights other than those typically granted to minority shareholders.³²⁷³

9.326. [REDACTED].³²⁷⁴

³²⁶⁸ According to the structure charts submitted by Cinven and AMCo (Document 200479, structure chart of the Mercury Pharma group as at 31 August 2012; Document 200480, structure chart of the Amdipharm group as at 31 October 2012; and Document 200481, structure chart of the Amdipharm Mercury combined group; Document 200260, structure chart as of 16 December 2013; Document 200261, structure chart as of 13 January 2015; and Document 200519, structure chart of the Fifth Cinven Fund) [REDACTED] (Cinven MGP's stake at that point can be seen in Document 200519, structure chart of the Fifth Cinven Fund). See Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraph 1.8.

³²⁶⁹ [REDACTED].

³²⁷⁰ [REDACTED].

³²⁷¹ [REDACTED].

³²⁷² The EU Court of Justice has confirmed that decisive influence can be exercised by a legal entity that holds the voting rights in a subsidiary (without necessarily holding the shares): C-595/18 P *Goldman Sachs v Commission*, paragraphs 29-36, upholding T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraphs 50 to 52. Elsewhere, the courts have held that ownership is one, but not the only or a necessary reason for a finding of decisive influence. For example, in C-293/13 P *Fresh Del Monte v Commission*, EU:C:2014:2439, AG Kokott noted that the principles of decisive influence 'can also easily be applied to the case of a partnership' rather than a 'parent company-subsidiary relationship in the traditional sense', and that 'All the parties to the proceedings were in agreement on this point, and the General Court likewise rightly took that premiss as its starting point' (paragraph 75). The EU Court of Justice followed this Opinion: C-293/13 P *Fresh Del Monte v Commission*, EU:C:2015:416, paragraphs 79-80.

³²⁷³ [REDACTED]. Document 200480, structure chart of the Amdipharm group as at 31 October 2012; Document 200481, structure chart of the Amdipharm Mercury combined group; and Document 200519, structure chart of the Fifth Cinven Fund.

³²⁷⁴ Document 200484, Articles of Association of Amdipharm Mercury Limited, clause 4.3.1(a) and 4.3.2(a). [REDACTED].

9.327. [REDACTED].³²⁷⁵ [REDACTED]³²⁷⁶ this meant that in practice Cinven MGP controlled the majority of voting rights in AML and no other shareholder could block any shareholder decisions Cinven MGP wanted to make in relation to AML, and therefore the Amdipharm Companies.

9.328. Cinven MGP's control of Cinven's majority shareholding and voting rights in AML therefore enabled Cinven MGP to exercise decisive influence over AML, and in particular over AML's and the Amdipharm Companies' market conduct.³²⁷⁷

9.329. [REDACTED].³²⁷⁸ [REDACTED].³²⁷⁹

9.330. The CMA nonetheless concludes that Cinven MGP was equivalent to a majority shareholder and that it is an appropriate entity to hold liable for the Infringement committed by the Amdipharm Companies [REDACTED].³²⁸⁰ [REDACTED].³²⁸¹

Cinven MGP's control of Cinven's rights under the AML shareholders' agreement

9.331. During the Cinven Period, the relationship between the shareholders in AML was governed by a shareholders' agreement (the '**AML Shareholders' Agreement**').³²⁸²

9.332. The AML Shareholders' Agreement gave the Cinven Limited Partnerships important rights over AML and over the Amdipharm Companies (both directly, where rights explicitly referred to the AMCo group, and indirectly, through AML as the 100% owner of the Amdipharm Companies). These rights were controlled by Cinven MGP because:

³²⁷⁵ Document LIO3727.1, Cinven's response to question 1 of the CMA's section 26 notice dated 11 July 2017. [REDACTED] (Document LIO3100, CCM Pharma Limited Register of Members and Share Ledger dated 28 September 2012; Document LIO3104, Amdipharm Mercury Limited Register of Members and Share Ledger dated 1 May 2014; and Document LIO3105, Concordia International (Jersey) Limited Register of Members and Share Ledger dated 28 October 2016).

³²⁷⁶ Document LIO3727.1, Cinven's response to question 1 of the CMA's section 26 notice dated 11 July 2017. Document 200471, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraphs 9.3-9.5 and 9.7, and clause 4.1.1 of the Cinven Limited Partnerships' limited partnership agreements (for example, Document 200512, limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership).

³²⁷⁷ As explained in section 9.A.II.b.ii above, the EU General Court has held that '*It is generally the case that if a parent company holds a majority interest in the subsidiary's share capital, that can enable it actually to exercise decisive influence on its subsidiary and, in particular, on the subsidiary's market conduct*'. T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 182; T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 96.

³²⁷⁸ Document 204970, Cinven RSO in Case 50395, paragraphs 12.11 and 12.16 and footnote 685. Cinven repeated these arguments in Document 204971, Cinven RSSO in Case 50395, paragraphs 10.11-10.12.

³²⁷⁹ Document 204970, Cinven RSO in Case 50395, footnote 696.

³²⁸⁰ Document LIO3727.1, Cinven's response to question 1 of the CMA's s.26 notice dated 11 July 2017; Document 200471, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraphs 9.3-9.5 and 9.7.

³²⁸¹ [REDACTED].

³²⁸² Document 200482, AML Shareholders' Agreement. [REDACTED] (Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraph 3.1).

a. [REDACTED].

b. [REDACTED].³²⁸³ [REDACTED].³²⁸⁴

9.333. [REDACTED].³²⁸⁵ [REDACTED].³²⁸⁶

9.334. [REDACTED]:

a. [REDACTED]³²⁸⁷ ([REDACTED]).³²⁸⁸ [REDACTED].

b. [REDACTED].³²⁸⁹

c. [REDACTED].³²⁹⁰

9.335. [REDACTED].³²⁹¹ ([REDACTED].³²⁹²)

9.336. These rights in themselves gave Cinven MGP the ability to exercise decisive influence over AML, whose board set the strategic direction for its wholly-owned subsidiaries, including the Amdipharm Companies³²⁹³ – and over all its subsidiaries, including the Amdipharm Companies.³²⁹⁴ As explained in paragraph 9.287 above, during the Cinven Period Cinven described the AML Shareholders' Agreement as '*a Cinven friendly SHA [shareholders' agreement] ... where we retain full control*'.³²⁹⁵

9.337. [REDACTED].³²⁹⁶

³²⁸³ [REDACTED].

³²⁸⁴ [REDACTED].

³²⁸⁵ [REDACTED].

³²⁸⁶ [REDACTED].

³²⁸⁷ [REDACTED].

³²⁸⁸ Document 200482, AML Shareholders' Agreement, clause 9.1.1.

³²⁸⁹ Document 200482, AML Shareholders' Agreement, clause 9.3.1.

³²⁹⁰ Document 200482, AML Shareholders' Agreement, clause 9.4.1.

³²⁹¹ Document 200482, AML Shareholders' Agreement, clause 9.2.

³²⁹² Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 8] and others 11 April 2014: '[REDACTED]'.

³²⁹³ Document PAD004, AMCo's 'Annual Review 2013', page 16: '*The strategic direction of the AMCo group is set by the board of its ultimate parent company Amdipharm Mercury Limited*'.

³²⁹⁴ As explained above, the EU General Court has held that: '*the ability to decide upon the composition of the board of directors of a company constitutes an objective factor which determines, in itself, whether it is possible to control the decisions that may be adopted by the board and, therefore, by the company concerned. The board of directors constitutes, by definition, the body responsible for administering and representing the company.*' T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 91 (emphasis added). Upheld in C-595/18 P *Goldman Sachs v Commission*.

³²⁹⁵ Document LIO6494.3, 'AMCo Exit Paper' dated 27 February 2015', pages 3 and 13.

³²⁹⁶ Document 200482, AML Shareholders' Agreement, clauses 5.2, 6.1 and Schedule 7 Part A. Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, in which Toshiba's veto rights over the joint venture's material investments, capital participation in or acquisition of a company or other business, and the provision of loans to subsidiary companies were relevant factors in the court's finding that it exercised decisive influence (paragraphs 71 to 72 of the judgment).

a. [REDACTED].³²⁹⁷

b. [REDACTED].

c. [REDACTED].

d. [REDACTED].

e. [REDACTED].³²⁹⁸

9.338. [REDACTED].³²⁹⁹ [REDACTED].

9.339. [REDACTED],³³⁰⁰ [REDACTED].³³⁰¹ [REDACTED]:

a. [REDACTED];

b. [REDACTED].³³⁰²

9.340. [REDACTED].³³⁰³ [REDACTED].³³⁰⁴

9.341. [REDACTED].³³⁰⁵ [REDACTED].³³⁰⁶

9.342. [REDACTED],³³⁰⁷ [REDACTED] Cinven MGP, [REDACTED] effectively had control of strategic commercial decisions with respect to the entire AMCo group (and therefore the Amdipharm Companies) [REDACTED].³³⁰⁸ [REDACTED].

9.343. [REDACTED].³³⁰⁹ [REDACTED]:

a. [REDACTED].³³¹⁰

b. [REDACTED].³³¹¹

c. [REDACTED].³³¹²

³²⁹⁷ Document 200482, AML Shareholders' Agreement, clause 5.2.

³²⁹⁸ Document 200482, AML Shareholders' Agreement, clause 6.1 and Schedule 7 Part A.

³²⁹⁹ Document 200482, AML Shareholders' Agreement, clauses 6.1 and 1.1.

³³⁰⁰ [REDACTED].

³³⁰¹ Document 200482, AML Shareholders' Agreement, clause 6.

³³⁰² Document 200482, AML Shareholders' Agreement, clause 9.10 and Schedule 11.

³³⁰³ Document 200482, AML Shareholders' Agreement, clause 6 and Schedule 7 Parts B and C.

³³⁰⁴ Document 200482, AML Shareholders' Agreement, clause 9.2.1.

³³⁰⁵ [REDACTED].

³³⁰⁶ [REDACTED].

³³⁰⁷ [REDACTED].

³³⁰⁸ Compare T-543/08 *RWE v Commission*, EU:T:2014:627, paragraphs 30 to 32; T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47 (upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006).

³³⁰⁹ Document 200482, AML Shareholders' Agreement, clauses 5.1 and 5.4.

³³¹⁰ Document 200482, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 2.1.

³³¹¹ Document 200482, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 1.

³³¹² Document 200482, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 3.

d. [REDACTED].³³¹³

e. [REDACTED].³³¹⁴

9.344. These information rights ensured that Cinven MGP was able to intervene to protect its investment whenever necessary.

9.345. Cinven MGP's control of [REDACTED] gave it the ability to exercise decisive influence over AML, and over each of its subsidiaries (including the Amdipharm Companies).

Cinven MGP did actually exercise decisive influence over the Amdipharm Companies

9.346. [REDACTED].

Cinven MGP exercised the right to appoint (and remove) directors to the boards of AML and other AMCo group companies

9.347. Cinven MGP exercised the right to appoint directors to AML's board (and to remove the one director it did not appoint).

9.348. Cinven MGP [REDACTED] appointed two Investor Directors to exercise the Majority Investors' rights under the AML Shareholders' Agreement: **[Cinven Senior Employee 1]** and **[Cinven Senior Employee 2]**. [Cinven Senior Employee 1] is a Cinven Partner and [REDACTED].³³¹⁵ [Cinven Senior Employee 2] is a member of Cinven's healthcare sector team, [REDACTED].³³¹⁶

9.349. The Investor Directors sat on the board of AML throughout the Cinven Period.³³¹⁷

9.350. Between 31 October 2012 and 30 July 2014, [REDACTED] also sat on the AML board [REDACTED]. On 30 July 2014, having been asked by [Cinven Senior Employee 1] to leave, he resigned as a director of AML.³³¹⁸

³³¹³ Document 200482, AML Shareholders' Agreement, Schedule 6 Part B, paragraph 5.

³³¹⁴ Document 200482, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 4.3.

³³¹⁵ Document PAD082, Cinven: '[Cinven Senior Employee 1]'.
³³¹⁶ Document PAD076, Cinven: '[Cinven Senior Employee 2]'.

³³¹⁷ Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015; Document LIO3727.1, Cinven's response to the CMA's section 26 notice dated 11 July 2017; clarification in respect of [Cinven Senior Employee 2] in Document 200547, Cinven's response to the CMA's section 26 notice dated 11 November 2016, paragraph 7.2(a).

³³¹⁸ Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 8] and others 11 April 2014: '[Cinven Senior Employee 1] has now asked [REDACTED] to leave the Board'.

- 9.351. For the rest of the Cinven Period (31 July 2014 to 20 October 2015) the board of AML was composed entirely of directors appointed by Cinven MGP. [REDACTED]³³¹⁹ [REDACTED].³³²⁰ [REDACTED].³³²¹
- 9.352. [REDACTED].³³²² Cinven MGP therefore exercised decisive influence over AML, and through AML over the Amdipharm Companies, ‘*through its prevailing presence on [AML]’s Board of Directors*’.³³²³ The AMCo group executive management, including [AMCo Senior Employee 1], [REDACTED] did not sit on the AML board but reported to it. The board of AML met at least once every quarter, with additional meetings held as necessary to discuss specific points such as group restructurings, share transfers to AMCo group managers and the sale of the AMCo group to Concordia Healthcare Corporation (now Advanz).³³²⁴
- 9.353. [REDACTED]. These directors were influential individuals whose appointment to multiple companies throughout the AMCo group served further to entrench Cinven MGP’s decisive influence:
- a. In addition to their positions as Investor Directors on the board of AML, [Cinven Senior Employee 1] and [Cinven Senior Employee 2] were also appointed to the boards of 13 and 20 other AMCo group companies (both holding companies and operating companies) respectively during the Cinven Period.³³²⁵ For [Cinven Senior Employee 2], this included the board of Amdipharm International Holdings Limited, the holding

³³¹⁹ Document 200547, Cinven’s response to the CMA’s section 26 notice dated 11 November 2016, paragraph 7.1.

³³²⁰ Document 200547, Cinven’s response to the CMA’s section 26 notice dated 11 November 2016, response to question 5. Documents 200558, 200559 and 200560, engagement letters dated 6 July 2012, 24 September 2012 and 5 November 2012.

³³²¹ Document 200547, Cinven’s response to the CMA’s section 26 notice dated 11 November 2016, paragraph 7.1.

³³²² Cinven told the CMA that its Investor Directors ‘*each had a number of other functions (unrelated to the AMCo Group)*’ and ‘*estimate that no more than 10-15% of their time was devoted to activities relating to the AMCo Group*’: Document 200471, Cinven’s response to the CMA’s section 26 notice dated 20 October 2016, paragraph 3.12. As explained above, the presence on the subsidiary’s board of directors of individuals who also hold managerial posts within the parent constitutes an organisational link between the two entities. The facts that these individuals may simultaneously be directors of many other companies, and may not be involved in day-to-day operations, are not inconsistent with a finding that this link enables the exercise of decisive influence. Even where one such individual was simultaneously a board member of around 40 other companies, and was not ‘*hands-on*’, instead receiving mainly reports on finance and ‘*major moves*’ from the relevant subsidiary’s managing director around three times a year, that did not prevent the individual from ‘*dealing fairly intensively with*’ the relevant subsidiary, or contributing to the finding that the parent exercised decisive influence. T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraphs 53 to 60; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

³³²³ Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3017, upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89. Currently on appeal to the Court of Justice: C-166/19 P. The General Court noted that ‘*the position of member of the board of directors of a company entails by its very nature legal responsibility for the activities of the company as a whole, including its conduct on the market*’ (paragraph 77 and caselaw cited). Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, in which the fact that AL Industrier AS had the right to appoint six out of 9 members of its subsidiary’s board was a relevant factor in the Commission’s decision to hold it liable (paragraph 1283).

³³²⁴ Document 200471, Cinven’s response to the CMA’s section 26 notice dated 20 October 2016, paragraph 3.4.

³³²⁵ Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015.

company of the Amdipharm group and 100% parent of two of the Amdipharm Companies (Amdipharm UK Limited and Amdipharm Limited). Both [Cinven Senior Employee 1] and [Cinven Senior Employee 2] were also appointed to the board of Mercury Pharma Group Limited, the immediate 100% parent of the other Amdipharm Company, Amdipharm Mercury Company Limited (now Advanz Pharma Services (UK) Limited). The Investor Directors, in addition to sitting on the board of AML, therefore sat on the board of the immediate 100% parent of the company that employed the AMCo group management including [AMCo Senior Employee 1], (see section 9.B.III.c above).

b. [X] senior Cinven Partners individuals were seconded from Cinven Partners and appointed by Cinven MGP to the boards of various AMCo group companies. For example:

- i. [Cinven Senior Employee 4], [X] and a member during the Cinven Period of Cinven Partners' Executive Committee, Investment Committee and Portfolio Review Committee, was a director of Mercury Pharma Group Limited from the start of the Cinven Period until 21 March 2014. He also sat on the boards of the three immediate 100% parents of Mercury Pharma Group Limited until 25 September 2013.³³²⁶
- ii. [Cinven Senior Employee 3], [X] employed during the Cinven Period by Cinven Partners, was appointed as a director of Mercury Pharma Group Limited from December 2014 until the end of the Cinven Period.³³²⁷

9.354. Through the appointment of these individuals to key companies in the AMCo group, Cinven MGP consolidated its decisive influence over the Amdipharm Companies. As board members, they had legal responsibility for the activities of the companies to which they were appointed, including their conduct on the market.³³²⁸ As explained in section 9.B.III.d.vi below, each of these individuals played an important role in devising and implementing Cinven's strategy for the AMCo group, contributing in particular to the recommendations to acquire and combine the Mercury and Amdipharm groups; for the combined AMCo group to make follow-on acquisitions; and for the Fifth Cinven Fund to divest the AMCo group.

³³²⁶ Document 200531, list of directors appointed to Mercury Pharma Group Limited.

³³²⁷ Document 200531, list of directors appointed to Mercury Pharma Group Limited.

³³²⁸ T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraph 77 and caselaw cited.

9.355. Cinven MGP also appointed non-executive directors supplied by the [X] to the boards of several other companies in the AMCo group.³³²⁹

9.356. This ‘*accumulation of posts*’ on the AML board and the boards of AMCo group companies enabled Cinven MGP to ensure that the AMCo group’s conduct was consistent with Cinven’s strategy.³³³⁰

9.357. [X].³³³¹ [X].

9.358. [X].³³³² [X].

9.359. [X].³³³³ [X]: it is not necessary for Cinven MGP’s appointee directors to be closely involved in day-to-day business for their presence to constitute a personal and organisational link enabling the exercise of decisive influence.

Cinven MGP exercised [X] veto rights

9.360. Cinven MGP’s exercise [X] – in particular, over the AMCo group budget – are in themselves sufficient to demonstrate that it exercised decisive influence over AML and the Amdipharm Companies.³³³⁴

9.361. As explained in paragraph 9.42 above, where a parent holds a veto right and attends meetings at which it could veto decisions, that amounts (in law and as a matter of economic reality) to exercising its right, since its approval is a prerequisite.³³³⁵ Even where decisions are taken by the subsidiary’s management, ‘*the fact that the parent company or its representatives must approve those proposals and therefore has the right to reject them is, in fact, evidence of a decisive influence*’.³³³⁶ The contemporaneous evidence shows that Cinven MGP exercised the veto rights it controlled in this way.

The AMCo group budget

9.362. As explained above, Cinven MGP, [X], controlled a veto right over the AMCo group budget: it was to be submitted to the Investor Directors

³³²⁹ Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015.

³³³⁰ Compare T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 184.

³³³¹ Document 204970, Cinven RSO in Case 50395, paragraphs 12.25-12.26.

³³³² Document 204970, Cinven RSO in Case 50395, paragraph 12.26.

³³³³ Document 204970, Cinven RSO in Case 50395, paragraph 12.26.

³³³⁴ Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67.

³³³⁵ Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 73: ‘*the holder of a right of veto over certain decisions of an undertaking must necessarily be consulted before the adoption of any decisions which it is capable of vetoing and must approve those decisions*’.

³³³⁶ T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 114 and caselaw cited, upheld in C-595/18 P *Goldman Sachs v Commission*. See also T-682/14 *Mylan v Commission*, paragraph 350 (currently on appeal to the Court of Justice: C-197/19 P).

appointed by Cinven MGP [REDACTED] and AMCo group management were required to incorporate any amendments they made to it.

9.363. [REDACTED].³³³⁷ The documentary evidence shows that [Cinven Senior Employee 1] and [Cinven Senior Employee 2] (the Investor Directors appointed by Cinven MGP) reviewed drafts of that budget in detail and made edits prior to approving it. For example, in relation to the 2014 budget:

- a. An email exchange relating to the minutes of an AMCo group investor meeting in August 2013 – attended by the Investor Directors – includes a record of detailed discussions of the draft 2014 budget and the timeframe for approval: *'Budget/Planning ... [AMCo Employee] [REDACTED] to present initial planning timetable to Cinven by 9th August. Suggestions [REDACTED]'*. These minutes show that the Investor Directors were involved, on an ongoing basis, in the preparation of the AMCo group's budget and business plan.³³³⁸ The *'Numbers presented to Cinven in September'* 2013 included not only the figures for the 2014 budget but also projections for the 2015 and 2016 budgets.³³³⁹
- b. On 29 November 2013 [REDACTED] [AMCo Senior Employee 6], emailed the Investor Directors: *'Thanks again for your approval of our 2014 budget proposal'*. [AMCo Senior Employee 6] listed a number of *'follow up items'* relating to the details of AMCo's business, on which [Cinven Senior Employee 1] commented. [AMCo Senior Employee 6] asked: *'Can you please let me know in what format, level of detail, etc. you would like to get our final budget?'* [Cinven Senior Employee 1] replied: *'The presentation you gave us is fine, but it would be good to get the full underlying Excel in as much detail as you have it'*.³³⁴⁰ [Cinven Senior Employee 1] later followed up to ask *'when we might be able to get the excel model for the plan'*.³³⁴¹ [AMCo Senior Employee 6] then sent the Investor Directors a revised budget pack for 2014,³³⁴² and separately the underlying Excel file.³³⁴³ These emails demonstrate that the Investor Directors were closely involved in preparation of the AMCo

³³³⁷ Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraph 3.14.

³³³⁸ Document LIO0314, email between [AMCo Senior Employee 8], [AMCo Senior Employee 2], [AMCo Employee] and [AMCo Senior Employee 1] dated 1 August 2013.

³³³⁹ Document 202568, email from [AMCo Senior Employee 4] to AMCo staff dated 3 December 2013.

³³⁴⁰ Document 202585, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 6] dated 2 December 2013.

³³⁴¹ Document 202586, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 6] dated 13 December 2013.

³³⁴² Document 202585, email from [AMCo Senior Employee 6] to [Cinven Senior Employee 1] dated 13 December 2013.

³³⁴³ Document 202586, email from [AMCo Senior Employee 6] to [Cinven Senior Employee 1] dated 17 December 2013.

budget, not only in its final form but in draft, and that they expected to review AMCo's proposals in detail.

- c. Indeed, the Investor Directors requested detailed edits to the draft budget. In an email enclosing draft slides relating to the 2014 budget, [AMCo Senior Employee 6] noted, '*[w]e have now included support slides and included various commentaries. Most of the data requests that [Cinven Senior Employee 1] has asked for (the pricing table is still missing but we will get that done on Monday morning)*'.³³⁴⁴
- d. Ahead of a meeting to discuss the draft budget, [Cinven Senior Employee 1] asked detailed questions: '*Thanks for the preview of the budget document. Below are some things it would be good if we can cover on Thursday ... RWM FY benefit of £[REDACTED]: I am surprised it is as high as this given we have had 8 months benefit in 2013. Is that because UK sales have risen so much? I don't understand the contingency. It is down as [REDACTED] on p4 and p9, but as a higher number on p24. Can you reconcile? I don't understand R&D capitalisation: it is down as [REDACTED] on 4 and p28 but as [REDACTED] on p31 (is the difference the fact [REDACTED])*'.³³⁴⁵ [REDACTED] responded to each of these questions, stating that clarifications would be provided at the meeting and noting in particular that [Cinven Senior Employee 1] had identified some errors in the draft document: '*We took the full year impact, but obviously this is not correct in a bridge format. RWM now reduced to [REDACTED] and the balance captured under [REDACTED]*'. [REDACTED] stated: '*We will send the updated budget deck shortly, now including the ASP table. Looking forward to discuss the budget in more detail with you on Thursday*'.³³⁴⁶
- e. Following this process, the Investor Directors attended an AML board meeting at [REDACTED].³³⁴⁷

9.364. The Investor Directors could at any time have vetoed the budget. Their approval of the budget, and close involvement in its preparation, demonstrates in itself that Cinven MGP, which appointed them and acted through them [REDACTED], exercised decisive influence over AML, and through AML over the Amdipharm Companies.³³⁴⁸ Not only would the AMCo group's

³³⁴⁴ Document LIO0375, email between [AMCo Senior Employee 6] and [AMCo Senior Employee 1] dated 22 November 2013.

³³⁴⁵ Document LIO0755, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 6] and [AMCo Senior Employee 1] dated 25 November 2013.

³³⁴⁶ Document LIO0755, email from [AMCo Senior Employee 6] to [Cinven Senior Employee 1] and [AMCo Senior Employee 1] dated 26 November 2013.

³³⁴⁷ Document 200498, minutes of AML board meeting dated 29 January 2014.

³³⁴⁸ Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67. As explained below, the question of 'decisive influence' for the purposes of merger control, referred to at this point in *Toshiba*, is closely related to the question of decisive influence for the purposes of attributing liability for antitrust infringements.

management not have been able to pass a budget without the Investor Directors' approval, the Investor Directors were also deeply involved in the preparation of that budget and their proposals were all followed.

9.365. [REDACTED].³³⁴⁹ [REDACTED].³³⁵⁰ [REDACTED].

Investor Consent

9.366. The obligation for a subsidiary to engage in prior consultation with its parent or to obtain its prior approval is a strong indication that the parent actually exercises decisive influence over its subsidiary. In particular, in a situation where the parent must approve its subsidiary's proposals, the fact that the subsidiary is required to obtain that approval and therefore the parent company has the right to refuse to give it is evidence of a decisive influence.³³⁵¹

9.367. [REDACTED].³³⁵²

9.368. Cinven MGP exercised this right in practice. For example:

a. [REDACTED].³³⁵³

b. [REDACTED].³³⁵⁴

9.369. [REDACTED].³³⁵⁵ [REDACTED].³³⁵⁶

Cinven MGP exercised the Cinven Limited Partnerships' rights to obtain strategic and operational information about the AMCo group's performance

9.370. A flow of information between a parent and its subsidiary and, *a fortiori*, an obligation to report to the parent, also constitutes an indication of the exercise of control over the subsidiary's decisions. Such information and reports show organisational links between the parent and its subsidiary and

³³⁴⁹ Document 204970, Cinven RSO in Case 50395, paragraph 12.24.

³³⁵⁰ Document 204970, Cinven RSO in Case 50395, paragraph 12.37.

³³⁵¹ T-682/14 *Mylan v Commission*, paragraph 345 (currently on appeal to the Court of Justice: C-197/19 P) and the caselaw cited.

³³⁵² Document 200018, email from [AMCo Senior Employee 1] to AMCo staff dated 2 December 2013.

³³⁵³ Document 200500, minutes of AML board meeting dated 23 September 2014, item 6.5: '*The Chairman noted that all the requisite internal approvals had been given including those under the shareholders' agreement to which the Company [AML] is subject.*'

³³⁵⁴ Document 200503, Investor Director Consent annexed to minutes of AML board meeting dated 15 October 2015.

³³⁵⁵ Document 200496, minutes of AML board meeting dated 27 June 2013, item 6.

³³⁵⁶ Document 200502, minutes of AML board meeting dated 25 February 2015, paragraph 5: '*The chairman reported that Investor Consent (as defined in the Articles) had been provided in order to waive the requirement for an Investor Director to be present in order to form a valid quorum*'; Document 200503, minutes of AML board meeting dated 20 August 2015, item 2.

allow the parent to monitor and control the activities of its subsidiary in order to take specific measures in relation to it.³³⁵⁷

9.371. [REDACTED].

9.372. [REDACTED]:

a. [REDACTED].³³⁵⁸

b. [REDACTED].³³⁵⁹ [REDACTED].

c. [REDACTED].³³⁶⁰

d. [REDACTED].³³⁶¹

e. [REDACTED].³³⁶²

9.373. The provision of this information to Cinven MGP is an indication that Cinven MGP exercised decisive influence over the decisions taken by the AMCo group's executives.³³⁶³ [REDACTED].³³⁶⁴

³³⁵⁷ T-682/14 *Mylan v Commission*, paragraph 351 (currently on appeal to the Court of Justice: C-197/19 P) and the caselaw cited.

³³⁵⁸ Document 200496, Minutes of AML board meeting 29 April 2013: '*It was noted that the March 2013 management accounts pack (the 'Pack') had been circulated to the Board prior to the Meeting and reviewed in detail. [Cinven Senior Employee 2] also requested that [AMCo Employee] add a line to page 10 of the Pack demonstrating the net debt to EBITDA ratio*'. See also the minutes of the meeting on 16 November 2012 (Document 200495, minutes of AML board meetings), at which [Cinven Senior Employee 2] led the discussion on the restructuring and refinancing of the group following the acquisition of the Amdipharm group, and on various proposals for potential acquisitions. [Cinven Senior Employee 2] and [Cinven Senior Employee 1] both attended a meeting (Document 200497, minutes of AML board meeting dated 30 October 2013) at which items discussed included: the company's financial performance and trading from Q3 2013; the September 2013 finance and Amdipharm management accounts pack; the implications of a new PPRS agreement for pricing; new UK product launches and international trading conditions; and acquisitions and potential future targets.

³³⁵⁹ Document 200506, minutes of AMCo investor meeting dated 28 May 2013; Document 200507, minutes of AMCo investor meeting dated 27 June 2013. See also Document 200508, Document 200509, minutes of AMCo investor meetings; Document 200510, minutes of Mercury Pharma Group Limited management meeting dated 19 December 2013.

³³⁶⁰ Document 200547, Cinven's response to the CMA's section 26 notice dated 11 November 2016, paragraph 6.2.

³³⁶¹ Document 200547 Cinven's response to the CMA's section 26 notice dated 11 November 2016 paragraph 6.3.

³³⁶² Document 200547, Cinven's response to the CMA's section 26 notice dated 11 November 2016, paragraph 6.4.

³³⁶³ The Court of Justice has held that the provision by a subsidiary to a parent of information on the implementation of strategic and commercial plans is an indication that the parent exercised control over the decisions drawn up and executed by the subsidiary's executives: C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraphs 104 to 107. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the parent's monitoring of its subsidiary's financial performance was a relevant factor in the attribution of liability (paragraph 3019), upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89.

³³⁶⁴ See, for example, Document 200504 and Document 200505, board minutes of Cinven MGP in which Cinven MGP considered and approved follow-on acquisitions on the basis of briefings given by the Investor Directors and other Cinven staff, and Investment Committee recommendations.

9.374. [REDACTED].³³⁶⁵ [REDACTED].

9.375. [REDACTED].³³⁶⁶ [REDACTED].³³⁶⁷

9.376. [REDACTED].³³⁶⁸ [REDACTED].³³⁶⁹ [REDACTED].³³⁷⁰ The Court of Justice has recently confirmed that the existence of directors' duties to their company does not preclude their acting as a link through which a parent exercises decisive influence over that company.³³⁷¹

Cinven MGP oversaw the AMCo group's commercial conduct and strategy

9.377. As explained at paragraph 9.35 above, decisive influence does not require influence on a subsidiary's commercial conduct: this is not the only factor that is relevant.³³⁷² However, where such influence can be demonstrated (whether indirectly, from the totality of the economic, legal and organisational links between the parent and subsidiary,³³⁷³ or directly from positive evidence of a shared commercial strategy) that is strong evidence of decisive influence.³³⁷⁴ In particular, influence over '*the company's commercial policy in the broadest sense*',³³⁷⁵ and over strategic commercial decisions such as whether its business activities shall be expanded or downsized, whether investments or acquisitions shall be made and whether it shall be sold and for what price, can be particularly important.³³⁷⁶

³³⁶⁵ Document 204970, Cinven RSO in Case 50395, paragraph 12.29.

³³⁶⁶ Document 204970, Cinven RSO in Case 50395, paragraphs 12.20-12.31.

³³⁶⁷ Document 204970, Cinven RSO in Case 50395, paragraph 12.34.

³³⁶⁸ Cinven also noted that the AML Shareholders' Agreement also gave these information rights to [Waymade Senior Employee 1], as minority shareholder in AML (Document 204970, Cinven RSO in Case 50395, paragraph 12.32). However, as a minority shareholder [Waymade Senior Employee 1], did not have comparable rights to Cinven MGP to act on the information received. The provision of the same information to Cinven MGP and to [Waymade Senior Employee 1], therefore conferred decisive influence on Cinven MGP but not on [Waymade Senior Employee 1].

³³⁶⁹ Document 204970, Cinven RSO in Case 50395, paragraph 12.34(c) (emphasis added).

³³⁷⁰ See, e.g., T-395/09 *Gigaset AG v Commission*, EU:T:2014:23.

³³⁷¹ C-595/18 P *Goldman Sachs v Commission*, paragraphs 77, 94-95 and 100.

³³⁷² See further, for example, Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, confirming that decisive influence does not depend only on influence over commercial policy *stricto sensu*, but can include influence over strategy (paragraph 3032), upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89.

³³⁷³ T-682/14 *Mylan v Commission*, paragraph 347 (currently on appeal to the Court of Justice: C-197/19 P) and the cases cited.

³³⁷⁴ *Durkan Holdings Limited v OFT* [2011] CAT 6, paragraph 22; *Akzo Nobel*, EU:C:2009:356, paragraphs 73-74, approving the Opinion of Advocate General Kokott, EU:C:2009:262, paragraph 87. See also T-24/05 *Alliance One & Others v Commission*, EU:T:2010:453, paragraph 170; and *Holding Slovenske*, EU:T:2013:647, paragraph 32.

³³⁷⁵ Opinion of Advocate General Kokott in C-293/13 *Del Monte*, EU:C:2014:2439, paragraph 89 (followed by the Court of Justice).

³³⁷⁶ *Power Cables*, paragraph 779. The courts have therefore rejected the argument that '*residual control over "strategic decisions" and financial supervision are not enough to found a conclusion that [a parent] actually exercised control over its subsidiary*': T-64/06 *FLS Plast A/S v Commission*, EU:T:2012:102, paragraph 47; upheld in C-243/12 P *FLS Plast A/S v Commission*, EU:C:2014:2006.

- 9.378. The contemporaneous evidence demonstrates that Cinven MGP exercised decisive influence over the AMCo group's commercial conduct and strategy (and therefore that of the Amdipharm Companies).
- 9.379. The board of AML, which Cinven MGP controlled, set the strategic direction for its wholly-owned subsidiaries, including the Amdipharm Companies.³³⁷⁷ As explained in section 9.B.III.c above, the AMCo group's executive management – including [AMCo Senior Employee 1], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] – were not directors of or employed by AML but by Advanz Pharma Services (UK) Limited (formerly Amdipharm Mercury Company Limited), its wholly-owned subsidiary. They regularly reported to the AML board.³³⁷⁸
- 9.380. As explained in section 9.B.III.d.i above, Cinven acquired the Mercury and Amdipharm groups in pursuit of a strategy to exploit the fact that '[X]'.³³⁷⁹
- 9.381. The Investor Directors oversaw implementation of that strategy. For example:
- a. A presentation to lenders was delivered jointly by Mercury Pharma group management and the Investor Director [Cinven Senior Employee 2] in September 2012, demonstrating [Cinven Senior Employee 2]'s endorsement of that strategy outwardly towards the group's lenders. This presentation noted that '[X]'.³³⁸⁰
 - b. Following correspondence between [Cinven Senior Employee 3], [AMCo Senior Employee 1], [Cinven Senior Employee 1] and [Cinven Senior Employee 2] on the scope of the non-compete obligation to apply to Waymade following the Amdipharm sale, [Cinven Senior Employee 1] followed up: *'Btw If there is anything you want him [[Waymade Senior Employee 1]] to do with Amdi's portfolio post-signing (eg de-brand XYZ so we have a few months before you start raising prices) you should feel free to ask him direct of course'*.³³⁸¹ [Cinven

³³⁷⁷ Document PAD004, AMCo's 'Annual Review 2013', page 16: *'The strategic direction of the AMCo group is set by the board of its ultimate parent company Amdipharm Mercury Limited'*.

³³⁷⁸ See, eg, Document 200496, minutes of Amdipharm Mercury Limited board meeting dated 29 April 2013; Document 200497, minutes of Amdipharm Mercury Limited board meeting dated 30 October 2013; Document 200498, minutes of Amdipharm Mercury Limited board meeting dated 29 January 2014; Document 200500, minutes of Amdipharm Mercury Limited board meeting dated 31 July 2014; Document 200501, minutes of Amdipharm Mercury Limited board meeting dated 5 November 2014; Document 200501, minutes of Amdipharm Mercury Limited board meeting dated 27 January 2015; Document 200502, minutes of Amdipharm Mercury Limited board meeting dated 24 April 2015; Document 200503, minutes of Amdipharm Mercury Limited board meeting dated 22 July 2015.

³³⁷⁹ Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012', page 3.

³³⁸⁰ Document LIO0231, Project Glacier Lenders Presentation, slides 10, 11 and 27.

³³⁸¹ Document 202327, email from [Cinven Senior Employee 1] to [AMCo Senior Employee 1] and [Cinven Senior Employee 3] dated 12 October 2012.

Senior Employee 1] therefore suggested that the Amdipharm group begin de-branding products after signing, so as to leave some time before AMCo began increasing prices in the Amdipharm portfolio.

- c. The Investor Directors were even involved in formulating the AMCo group's strategy for managing negative press attention as a result of such price increases. An email discussion regarding the minutes of an AMCo group investor meeting in August 2013 notes '*Recent press coverage*', and states, *[AMCo Senior Employee 1] / [Cinven Senior Employee 1] to discuss media handling with PR company*'.³³⁸²

9.382. In fact, the evidence shows that in making day-to-day commercial decisions, the AMCo group's management felt under considerable pressure to achieve the forecasts agreed with the Investor Directors by implementing that strategy.

9.383. In mid-2013, AMCo group management [REDACTED]:

- a. [AMCo Senior Employee 1] explained that '*[t]he key to our comms with Cinven is to have a clearly presented and reasonable (if risky) plan to fill the gap. Talking to [Cinven Senior Employee 1]] today with no substance behind our plans will not be wise*'. Later that day, [AMCo Senior Employee 1] stated: '*I have spoken to [Cinven Senior Employee 1] and he is expecting to receive something from us today and for us to have a detailed discussion on Tuesday morning about what we are going to do*'. AMCo group senior management considered options such as [REDACTED].³³⁸³
- b. [AMCo Senior Employee 1] then emailed a set of slides to [Cinven Senior Employee 1], saying: '*[REDACTED]. If there is anything I can help to explain over the weekend feel free to ask*'.
- c. Later, [AMCo Senior Employee 1] told colleagues, '*I have just had a call with [Cinven Senior Employee 1] and there is a discussion to be*

³³⁸² Document LIO0314, email between [AMCo Senior Employee 8], [AMCo Senior Employee 2], [AMCo Employee] and [AMCo Senior Employee 1] dated 1 August 2013.

³³⁸³ Document LIO0259, email between [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Employee] dated 24 May 2013 and Document LIO0260, email between [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Employee] dated 24 May 2013. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the subsidiary Matrix's board minutes showed that an employee of its parent Mylan had '*informed Matrix's Board of "Mylan's expectations of Matrix in the coming quarters" and advised the Management "to frame strategies to meet such expectations"* – a relevant factor in the Commission's attribution of liability to Mylan (paragraph 3035). Upheld on appeal in T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 344-361 (currently on appeal to the Court of Justice: C-197/19 P).

had to do with the principals [sic] of what we do about [REDACTED]. [AMCo Senior Employee 1] considered [REDACTED],”³³⁸⁴

- d. In response, AMCo group staff put together detailed plans for [REDACTED]. When these were sent to [AMCo Senior Employee 1], he noted that *‘[o]ne of the big issues that our Cinven friends have is [REDACTED]. They are considering whether we may want to accept [REDACTED]’*.³³⁸⁵
- e. AMCo group senior management were of course aware [REDACTED]. [Amdipharm Senior Employee], noted that ‘[REDACTED]’. [AMCo Senior Employee 1] replied: *‘the point that you make in your first sentence is very valid. That will be the topic of conversation at today’s investor meeting ... [REDACTED]’*.³³⁸⁶

9.384. [REDACTED]:

‘[REDACTED]’.

9.385. [REDACTED].³³⁸⁷

9.386. The evidence therefore shows that the AMCo group’s executive management, [REDACTED], felt it necessary to alter the business’s commercial conduct in order to avoid the prospect that the Investor Directors to whom they reported would step in and make changes to ensure that the strategy they shared was successful. This is evidence that Cinven MGP, through those Investor Directors, exercised decisive influence over AML, and through AML over the Amdipharm Companies.

9.387. [REDACTED].³³⁸⁸ The CMA considers that this contemporaneous evidence from senior managers at AMCo, [REDACTED], speaks for itself.

9.388. The CMA therefore concludes, on the basis of the totality of organisational, legal and economic links between Cinven MGP and the Amdipharm Companies considered above (many of which in themselves would suffice), that Cinven MGP exercised decisive influence over the Amdipharm Companies during the Cinven Period.

³³⁸⁴ Document LIO0264, email from [AMCo Senior Employee 1] to [AMCo Employee], [AMCo Senior Employee 8], [AMCo Senior Employee 4], [AMCo Employee] and [Amdipharm Senior Employee], dated 25 May 2013.

³³⁸⁵ Document LIO0275, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 27 May 2013.

³³⁸⁶ Document LIO0277, email from [AMCo Senior Employee 1] to [Amdipharm Senior Employee] dated 28 May 2013.

³³⁸⁷ Document LIO0340, email between [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Employee] dated 22 September 2013; Document LIO0342, email between [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Employee] dated 22 September 2013; and Document LIO0348, email between [AMCo Senior Employee 4], [AMCo Senior Employee 8] and [AMCo Employee] dated 23 September 2013.

³³⁸⁸ Document 204970, Cinven RSO in Case 50395, paragraphs 12.35, 12.40 and 12.41.

v. Liability of Luxco 1

9.389. [REDACTED].³³⁸⁹ Luxco 1 therefore had the ability to exercise decisive influence over Cinven MGP, and the *Akzo* presumption that it did in fact exercise such decisive influence applies.

9.390. Cinven submitted that the [REDACTED].³³⁹⁰

9.391. The CMA does not consider that the evidence adduced by Cinven suffices to rebut the *Akzo* presumption.

9.392. First, it is settled case law that establishing decisive influence does not require proof of intervention in a subsidiary's commercial conduct or policy. A parent may exercise decisive influence over a subsidiary even where it does not make use of any actual rights to determine its conduct, and refrains from giving any specific instructions or guidelines to its subsidiary.³³⁹¹ For this reason the courts have consistently rejected attempts to rebut the *Akzo* presumption on the basis that the parent is not involved in the business of the subsidiary. For example:

- a. In *Stichting Gosselin*, the Court of Justice reversed the General Court's conclusion that the parent company had succeeded in rebutting the *Akzo* presumption. The facts that the parent company's only influence on its subsidiary was through its voting rights and no meeting of shareholders was held were not sufficient to prove that the parent and its subsidiary did not form an economic unit.³³⁹²
- b. Similarly, in *Team Relocations*, an assertion that the subsidiary had managerial autonomy failed to rebut the *Akzo* presumption.³³⁹³
- c. In *Del Monte*, the Court of Justice noted that '*the fact that Del Monte was legally precluded from involvement in the management of Weichert's day-to-day business and that its veto rights did not allow it, inter alia, to impose a particular budget does not mean that Del Monte was precluded altogether from being able to exert decisive influence over Weichert's conduct on the relevant market*'.³³⁹⁴

³³⁸⁹ Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, paragraph 9.11, and Document 200519, structure chart of the Fifth Cinven Fund.

³³⁹⁰ Document 204970, Cinven RSO in Case 50395, paragraphs 12.42-12.43.

³³⁹¹ T-77/08 *Dow v Commission*, EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission*, EU:C:2013:605. See also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraph 22(b). See also C-155/14 P *Evonik Degussa GmbH v Commission*, EU:C:2016:446, paragraph 41, citing *Del Monte*, EU:C:2015:416, paragraphs 96 and 97.

³³⁹² C-440/11 *Commission v Stichting Administratiekantoort Portielje*, EU:C:2013:514, paragraphs 62-68.

³³⁹³ T-204/08 *Team Relocations v Commission*, EU:T:2011:286, paragraph 152.

³³⁹⁴ C-293/13 P *Del Monte v Commission*, EU:C:2015:416, paragraph 88.

9.393. Secondly, [REDACTED].³³⁹⁵ [REDACTED].³³⁹⁶

9.394. The CMA therefore concludes, on the basis of the *Akzo* presumption, that Luxco 1 exercised decisive influence over Cinven MGP and, through Cinven MGP, over the Amdipharm Companies throughout the Cinven Period.

vi. Liability of Cinven Partners

9.395. In identifying the legal entities that exercised decisive influence over the Amdipharm Companies during the Cinven Period, the CMA also finds that Cinven Partners did so, and that liability for the infringement committed by AMCo should be attributed to it. [REDACTED].³³⁹⁷

9.396. Formally, [REDACTED].³³⁹⁸

9.397. As a matter of economic reality, however, Cinven Partners' role in the AMCo group investment was in practice far more significant than the contractual terms of its appointment would suggest.³³⁹⁹

9.398. The CMA concludes that as a matter of economic reality, Cinven Partners – as well as Cinven MGP and Luxco 1 – exercised decisive influence over the Amdipharm Companies and formed an economic unit for the purpose of the 10mg Agreement with the Amdipharm Companies, Cinven MGP and Luxco 1, in particular through the personal links between those legal entities. In particular, the common strategy they pursued, of exploiting the absence of effective regulation for niche generic drugs, was devised and overseen by Cinven Partners staff and is attributable to Cinven Partners.

9.399. In making this finding, the CMA draws on established principles of the law on attribution of liability, which the CMA explains here before setting out below how they apply.³⁴⁰⁰

9.400. As explained in paragraph 9.34 above, when attributing liability the '*principal question*' is whether one entity exercises decisive influence over the other in practice, since '*if it were to be established ... that ... [one entity] did in fact exercise decisive influence over the conduct of [the other], that would*

³³⁹⁵ Document 204970, Cinven RSO in Case 50395, paragraphs 12.42-12.43.

³³⁹⁶ Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 63 to 67 and 73; T-682/14 *Mylan v Commission*, paragraphs 345 and 350 (currently on appeal to the Court of Justice: C-197/19 P) and the caselaw cited; T-419/14 *Goldman Sachs v Commission*, EU:T:2018:445, paragraph 114 (upheld in C-595/18 P *Goldman Sachs v Commission*) and caselaw cited.

³³⁹⁷ [REDACTED].

³³⁹⁸ Document 200523, investment advisory agreement, clause 2.4.

³³⁹⁹ [REDACTED].

³⁴⁰⁰ [REDACTED].

necessarily imply that they were in a position to do so'.³⁴⁰¹ The test focuses on substance over form. For example, in C-440/11 *Stichting Gosselin* Advocate General Kokott stated:

'the decisive factor is ultimately economic reality, since competition law is guided not by technicalities, but by the actual conduct of undertakings'

9.401. It is therefore *'of decisive importance, leaving aside all the formal deliberations on company law, to examine the actual effects of the personal links between [the relevant entities] on everyday business activities'*.³⁴⁰²

9.402. The Court of Justice followed the Advocate General, holding that:

*'the fact that a finding that the author of the infringement and its holding entity form an economic unit does not necessarily presuppose the adoption of formal decisions by statutory organs and that, on the contrary, that unit may also have an informal basis, consisting inter alia in personal links between the legal entities comprising such an economic unit.'*³⁴⁰³

9.403. The CMA is therefore entitled to rely, as an objective factor, on Cinven Partners' level of representation on AMCo group company boards in order to show that Cinven Partners was in a position to, and did in fact, exercise decisive influence over the Amdipharm Companies.³⁴⁰⁴

9.404. As explained in section 9.A.II.b.ii above, the European courts have held that decisive influence may be demonstrated by the presence of parent representatives on the subsidiary's board (*'even though member(s) of the parent company who take on managerial functions within the subsidiary do not have authority as agents of the parent company'*):

'Such an accumulation of posts necessarily places the parent company in a position to have a decisive influence on its subsidiary's market conduct since it enables members of the parent company's board to

³⁴⁰¹ T-24/05 *Alliance One and Others v Commission*, EU:T:2010:453, paragraphs 165 to 167, upheld in C-628/10 P and C-14/11 P *Alliance One and Others v Commission*, EU:C:2012:479. See also T-104/13 *Toshiba Corp. v European Commission*, EU:T:2015:610, paragraph 95; and C-172/12 P *El du Pont de Nemours v Commission*, EU:C:2013:601, paragraph 44; and T-541/08 *Sasol v Commission*, EU:T:2014:628, paragraph 43.

³⁴⁰² Opinion of Advocate General Kokott in C-440/11 *Commission v Stichting Administratiekantoort Portielje*, EU:C:2012:763, paragraphs 71 to 76.

³⁴⁰³ C-440/11 *Commission v Stichting Administratiekantoort Portielje and Gosselin Group NV*, EU:C:2013:514, paragraphs 66 to 68. Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 46. See also Joined cases C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraph 76.

³⁴⁰⁴ T-419/14 *Goldman Sachs v Commission*, paragraph 109, upheld in C-595/18 P *Goldman Sachs v Commission*.

ensure, while carrying out their managerial functions within the subsidiary, that the subsidiary's course of conduct on the market is consistent with the line laid down at management level by the parent company'.³⁴⁰⁵

9.405. An 'accumulation of posts' in the sense of overlapping, simultaneous roles with parent and subsidiary is not required in order to demonstrate the exercise of decisive influence. Such influence may also be demonstrated by informal personal links between parent and subsidiary.³⁴⁰⁶

9.406. Where individuals '*had previously acted at a high management level within [the parent] and subsequently returned to it*', they '*necessarily had thorough knowledge of [the parent's] policy and its commercial objectives and were in a position to cause the [subsidiary's] policy and [the parent's] interests to converge*'. This is the case '*even if they had not retained contractual links with [the parent] and were no longer under its direct authority*'.³⁴⁰⁷ For example, in *Goldman Sachs* the Court of Justice upheld the General Court and Commission's findings that Goldman Sachs exercised decisive influence over its fund's portfolio company Prysmian in part through the personal links Goldman Sachs had with two 'independent' non-executive directors on Prysmian's board, who were not directors, officers, employees or managers of Goldman Sachs. Their personal links to Goldman Sachs consisted of '*previous advisory services*' and '*consultancy agreements*'. Notwithstanding Goldman Sachs' arguments that these links were subject to the directors' duties of independence and to Prysmian's confirmation to regulatory authorities that it considered them independent, the Court of Justice held that:

'The relevance of such personal links lies in the fact that they may suggest that a person, although active for a given company, actually

³⁴⁰⁵ T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 184. See also T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 354-355.

³⁴⁰⁶ C-595/18 P *Goldman Sachs v Commission*, paragraphs 93-95. The Court of Justice has held that even the presence of a single parent company representative on the board of the subsidiary can be a relevant factor among others conferring the ability to exercise decisive influence: '*it is in no way necessary for the accumulation of posts within both the parent company and the subsidiary to concern more than one individual in order to constitute one indication among others of that capacity*'. C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 76. Compare C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 106: '*[the subsidiary's] sole director designated by [the parent] constituted, as a result of his consistent pattern of behaviour, a link between those two companies, by which the information concerning sales, production and financial results were communicated to [the parent]*'.

³⁴⁰⁷ C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 15. As explained in section 9.A.II.b.ii above, the Court of Justice found the exercise of decisive influence by a parent on the basis of (among other factors) the appointment to the subsidiary of individuals who had previously acted at a high management level within the parent, and who subsequently returned to it. The Court of Justice upheld the General Court's finding in T-104/13 *Toshiba v Commission*, EU:T:2015:610. The relevant factors are summarised in paragraphs 14-17 of the Court of Justice's judgment. The quotation relating to contractual links is from paragraph 116 of the General Court judgment.

*pursues, in view of his or her links with another company, the interests of the latter. That may also be the case were a person who sits on the board of directors of a company is connected to another company by means of ‘previous advisory services’ or ‘consultancy agreements’, as the General Court noted in paragraph 106 of the judgment under appeal.*³⁴⁰⁸

- 9.407. The principles established in these cases apply to the individuals appointed by Cinven MGP to AMCo group roles: the Investor Directors [Cinven Senior Employee 1] and [Cinven Senior Employee 2], and the additional directors [Cinven Senior Employee 4] and [Cinven Senior Employee 3] (see paragraphs 9.348 and 9.353 above). Each of these individuals was seconded from Cinven Partners to perform his role in the AMCo group. Together, these Cinven Partners individuals enabled Cinven Partners to ensure that the AMCo group’s conduct was consistent with the strategy set by Cinven Partners.³⁴⁰⁹
- 9.408. In making this finding, the CMA has also had regard to the European Commission’s Consolidated Jurisdictional Notice under Regulation 139/2004 (the ‘**EU Jurisdictional Notice**’), which states:

*‘The investment company usually exercises control by means of the organisational structure, e.g. by controlling the general partner of fund partnerships, or by contractual arrangements, such as advisory agreements, or by a combination of both. This may be the case even if the investment company itself does not own the company acting as a general partner, but their shares are held by natural persons (who may be linked to the investment company) or by a trust.’*³⁴¹⁰

- 9.409. This passage of the EU Jurisdictional Notice concerns the issue of whether an investment company acquires ‘*control*’ for the purposes of the European merger control regime. This is a different issue from attributing liability for antitrust infringements.
- 9.410. However, the point of principle set out in the EU Jurisdictional Notice is relevant to the present case. The concept of ‘*control*’ in merger control refers to the possibility of exercising decisive influence on an undertaking.³⁴¹¹ While it relates to a different regime, that is clearly a related concept to the question of whether a parent exercises decisive influence over a subsidiary for the purposes of attributing liability. For example, in the *Toshiba* case, the

³⁴⁰⁸ C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95.

³⁴⁰⁹ [34].

³⁴¹⁰ EU Jurisdictional Notice, paragraph 15.

³⁴¹¹ Article 3(2) of Regulation 139/2004.

parties accepted that the EU Jurisdictional Notice was relevant to the question of decisive influence for attribution of liability.³⁴¹² The CMA must therefore have regard to the EU Jurisdictional Notice by virtue of section 60A(3) of the Act.³⁴¹³

9.411. The EU Jurisdictional Notice goes on to state:

‘Contractual arrangements with the investment company, in particular advisory agreements, will become even more important if the general partner does not have any own resources and personnel for the management of the portfolio companies, but only constitutes a company structure whose acts are performed by persons linked to the investment company. In these circumstances, the investment company normally acquires indirect control within the meaning of Article 3(1)(b) and 3(3)(b) of the Merger Regulation, and has the power to exercise the rights which are directly held by the investment fund.’³⁴¹⁴

9.412. [REDACTED].³⁴¹⁵

9.413. All of the Cinven individuals appointed to the AMCo group were appointed by Cinven MGP and their actions are attributable to Cinven MGP, as explained above. However, their actions are also attributable to Cinven Partners. In particular, and as further set out in the sections that follow:

- a. They were all members or employees of Cinven Partners [REDACTED].³⁴¹⁶
- b. They set Cinven’s strategy for its investment in the AMCo group in their capacity as Cinven Partners staff – before they were appointed to AML and AMCo group companies by Cinven MGP.
- c. Cinven Partners oversaw the implementation of that strategy through those individuals, who were seconded from Cinven Partners to serve on the boards of AML and AMCo group companies and acted not only

³⁴¹² C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 67. See also the General Court judgment, paragraphs 107 to 111: the EU Jurisdictional Notice’s ‘relevance to the present case is not disputed by the parties’.

³⁴¹³ [REDACTED].

³⁴¹⁴ EU Jurisdictional Notice, paragraph 15.

³⁴¹⁵ The natural persons who ultimately controlled 100% of the shares of Cinven MGP (through their ownership of Luxco 1) were persons linked to Cinven Partners. Specifically, Luxco 1 was owned by three current and one former partner within the Cinven group of advisory companies, which includes Cinven Partners: Document 200471, Cinven’s response to the CMA’s section 26 notice dated 20 October 2016, paragraph 9.14. Paragraph 15 of the EU Jurisdictional Notice specifically refers to the general partner being owned by ‘natural persons (who may be linked to the investment company)’ as being relevant to the question of control.

³⁴¹⁶ Cinven has confirmed that ‘All of the individuals involved with the investment [in the AMCo group] were either members of or employed by Cinven Partners’, which was the only entity that paid their remuneration. Document LIO6537.310, Cinven’s response to the CMA’s section 26 notice dated 16 May 2018, paragraphs 1.2, 8.4 and 9.2.

for Cinven MGP/Luxco 1 and the AMCo group boards on which they served, but also for Cinven Partners, in pursuit of their common strategy and interests.

- d. Through those individuals, Cinven Partners drove the decision to divest the AMCo group. They returned to Cinven Partners when the sale completed.

9.414. The decisive influence that Cinven MGP (and Luxco 1 through Cinven MGP) exercised over the Amdipharm Companies through those individuals is therefore equally attributable to Cinven Partners.

The Investor Directors and other key individuals appointed to AMCo group company boards were Cinven Partners staff

9.415. As explained in section 9.B.III.d.iv above, Cinven MGP [REDACTED] to appoint directors to key AMCo group company boards. In particular, Cinven MGP appointed:

- a. Two Investor Directors, [Cinven Senior Employee 1] and [Cinven Senior Employee 2], to the board of AML, the Amdipharm Companies' ultimate 100% owner. The Investor Directors exercised the rights of the Majority Investors, including to edit and approve the AMCo group budget. The AMCo group executive management, including [REDACTED] [AMCo Senior Employee 1], did not sit on the AML board but reported to it;
- b. [Cinven Senior Employee 1] and [Cinven Senior Employee 2] to the boards of 13 and 20 other AMCo group companies respectively; and
- c. Two other senior individuals, [Cinven Senior Employee 4] and [Cinven Senior Employee 3], to the boards of Mercury Pharma Group Limited, the immediate 100% parent of the company that employed the AMCo group management including [AMCo Senior Employee 1], [REDACTED]. [Cinven Senior Employee 4] was also appointed to the boards of the three immediate 100% parents of Mercury Pharma Group Limited.

9.416. These individuals were all partners or employees of Cinven Partners during the Cinven Period. Cinven has confirmed that *'[a]ll of the individuals involved with the investment [in the AMCo Group] were either members of or employed by Cinven Partners LLP'*.³⁴¹⁷

³⁴¹⁷ Document LIO6537.310, Cinven's response to the CMA's section 26 notice dated 16 May 2018, paragraphs 1.2, 8.4 and 9.2.

- a. [Cinven Senior Employee 1] has been a Cinven Partner [X] and [X].³⁴¹⁸ [X] took over the role of Cinven Limited in February 2012.³⁴¹⁹ He was an LLP Member of Cinven Partners [X].³⁴²⁰
- b. [Cinven Senior Employee 2] is now a Cinven Partner [X]. He is a member of Cinven's healthcare sector team, [X].³⁴²¹ During the Cinven Period, he was employed as a [X].³⁴²² He was an LLP Member of Cinven Partners [X].³⁴²³
- c. [Cinven Senior Employee 4] is [X]. He joined Cinven [X] and is '[X]'.³⁴²⁴ [X].³⁴²⁵ [X]. He was [X] he transferred to become [X].³⁴²⁶
- d. [Cinven Senior Employee 3] is described as a 'Partner' on Cinven's website. He was employed by Cinven Partners during the Cinven Period. He joined Cinven [X] and is a member of its healthcare sector team.³⁴²⁷

9.417. These individuals were seconded from Cinven Partners to their roles in the AMCo group [X].³⁴²⁸ [X].³⁴²⁹

9.418. As Cinven Partners staff, the actions of these individuals are attributable to Cinven Partners:

- a. The CAT has confirmed that an employee '*will typically be part of the undertaking that employs him or her*' and that the acts of employees can be attributed to their employer.³⁴³⁰ All that is required is that the employee is authorised generally to act on the employer's behalf – i.e. that he or she act within the powers given to him or her by their

³⁴¹⁸ Document PAD082, Cinven: '[Cinven Senior Employee 1]'.
³⁴¹⁹ Document LIO6490.5, '[Cinven Senior Employee1]'s partner letter dated 17 February 2012'.
³⁴²⁰ According to Companies House.
³⁴²¹ Document PAD076, Cinven: '[Cinven Senior Employee 2]'.
³⁴²² Document 200471, Cinven's response to the CMA's section 26 notice dated 20 October 2016, footnote 20.
³⁴²³ According to Companies House.
³⁴²⁴ Document PAD058, Cinven: '[Cinven Senior Employee 4]'.
³⁴²⁵ Document PAD059, 'Cinven appoints [X]'.
³⁴²⁶ According to Companies House.
³⁴²⁷ Document PAD077, Cinven: '[Cinven Senior Employee 3]'.
³⁴²⁸ [X].
³⁴²⁹ Document LIO6537.310, Cinven's response to the CMA's section 26 notice dated 16 May 2018, paragraphs 8.4 and 9.2.
³⁴³⁰ *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 358. See also *Tesco v OFT* [2012] CAT 31, paragraph 62 and the cases cited: '*Since an undertaking comprising a body corporate can only act through the individuals employed by it, the acts or conduct of an undertaking are inevitably performed by those individuals. It follows that any act by any employee could, potentially, lead to an infringement attributable to their corporate employer, with whom they comprise the same undertaking*'.

employment.³⁴³¹ [REDACTED];³⁴³² [REDACTED].³⁴³³ The actions of [Cinven Senior Employee 2] and [Cinven Senior Employee 3], as Cinven Partners employees with contractual obligations to act on behalf of Cinven Partners during the Cinven Period, are therefore attributable to Cinven Partners.

b. The actions of [Cinven Senior Employee 1] and [Cinven Senior Employee 4], as LLP members of Cinven Partners during the Cinven Period, are also attributable to Cinven Partners:

i. [REDACTED].³⁴³⁴

ii. The Court of Justice has held that: *'for Article 101 TFEU to apply, it is not necessary for there to have been action by, or even knowledge on the part of, the partners or principal managers of the undertaking concerned; action by a person who is authorised to act on behalf of the undertaking suffices'*.³⁴³⁵ Not only were both [Cinven Senior Employee 1] and [Cinven Senior Employee 4] LLP members of Cinven Partners; they were also 'Authorised Signatories' of Cinven Partners,³⁴³⁶ with [REDACTED].³⁴³⁷ They (particularly [Cinven Senior Employee 4], as [REDACTED] towards the end of the Cinven Period) were equivalent to directors, a position which *'entails by its very nature legal responsibility for the activities of the company [or in this case, partnership] as a whole'*.³⁴³⁸

iii. Further, the members of an LLP such as Cinven Partners are deemed in law to be agents of the LLP.³⁴³⁹ The European courts have held that *'where an agent works for his principal, he can in principle be regarded as an auxiliary organ forming an integral part of the latter's undertaking and bound to carry out the*

³⁴³¹ See e.g. C-100/80 *Musique Diffusion v Commission*, paragraphs 97-98; C-40/73 *Suiker Unie v Commission*, paragraphs 539 and 542; C-68/12 *Slovenska sporitel'na v Commission*, paragraph 25; T-588/08 *Dole v Commission*, paragraphs 581-582; T-56/99 *Marlines v Commission*, paragraph 60. See also the CMA's *Paroxetine* decision, paragraph 9.19.

³⁴³² [REDACTED].

³⁴³³ [REDACTED].

³⁴³⁴ Document LIO6497.1, 'Cinven Partners LLP Partnership Agreement dated 17 February 2012', clause 13.1.2.

³⁴³⁵ C-68/12 *Slovenská sporiteľňa*, EU:C:2013:71, paragraph 25; and Joined cases C-100/80 to 103/80 *Musique Diffusion française and Others v Commission*, EU:C:1983:158, paragraph 97 (see also T-588/08 *Dole v Commission*, EU:T:2013:130, paragraph 581). Although action by principal managers is therefore not required, where it is present this is a strong factor establishing liability of the undertaking they manage.

³⁴³⁶ Document LIO7764, Cinven's response to question 3 of the CMA's section 26 notice dated 6 November 2018.

³⁴³⁷ [REDACTED].

³⁴³⁸ T-705/14 *Unichem v Commission*, paragraph 77. See also T-77/92 *Parker Pen v Commission*, paragraphs 78-82.

³⁴³⁹ Section 6(1) of the Limited Liability Partnerships Act 2000 states that: 'Every member of a limited liability partnership is the agent of the limited liability partnership'.

principal's instructions and thus, like a commercial employee, forms an economic unit with his undertaking'.³⁴⁴⁰ The CMA finds, on the basis of the evidence set out in this section, that [Cinven Senior Employee 1] and [Cinven Senior Employee 4] were acting for Cinven Partners (as well as the AMCo group boards on which they sat) in administering the AMCo group investment.³⁴⁴¹

Cinven Partners set the strategy for the AMCo group investment through those individuals

- 9.419. As explained in paragraph 9.52 above, the EU General Court has held that it is not necessary for the purposes of demonstrating the exercise of decisive influence that the parent have control over day-to-day operations; rather, what counts is '*influence over the general strategy which defines the orientation of the undertaking*'.³⁴⁴²
- 9.420. As explained in section 9.B.III.d.i above, Cinven's strategy for its investments in the Mercury Pharma and Amdipharm groups, and their combination to create the AMCo group, was to exploit '*niche formulations*' where '*the competitive forces may not work to suppress prices*' and which '*are typically below the radar*' of the DHSC and NHS.³⁴⁴³ Bringing the Mercury Pharma and Amdipharm groups together in pursuit of this strategy was designed to secure Cinven's longer-term objective of increasing the value of both groups for sale.
- 9.421. Cinven's strategy – and especially its implementation through a merged group under the management of [AMCo Senior Employee 1], Mercury Pharma's existing CEO with extensive experience of this business model – is attributable to Cinven Partners. It was devised by individuals acting in their capacity as Cinven Partners staff:
- a. The investment recommendation for Cinven's acquisition of the Mercury Pharma group, discussed at paragraphs 9.270 to 9.271 above, which explained that the '*investment attraction*' of the Mercury Pharma group was its ability to exploit the absence of effective regulation for niche generic drugs and increase prices while remaining '*below the radar*' of authorities, and also the plan to bring Mercury Pharma and Amdipharm together under the management of [AMCo Senior

³⁴⁴⁰ T-56/99 *Marlines v Commission*, EU:T:2003:333, paragraph 60 and caselaw cited; and C-40/73 *Suiker Unie v Commission*, EU:C:1975:78, paragraph 480.

³⁴⁴¹ Compare C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95.

³⁴⁴² T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 121, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission*, EU:C:2009:262, paragraph 73.

³⁴⁴³ Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012', pages 3, 6 and 8.

Employee 1] (*'it would be a synergistic combination with Mercury, and the levers [AMCo Senior Employee 1] has pulled on pricing etc. would be applicable to Amdipharm'*) was authored by [Cinven Senior Employee 1], [Cinven Senior Employee 4], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and two other individuals. It was dated 2 July 2012.³⁴⁴⁴

- b. The investment recommendation for Cinven's acquisition of the Amdipharm group, discussed at paragraph 9.272 above, which referred to *'our investment thesis for the combination of Mercury and Amdipharm'* and stated that *'The primary growth levers for Amdipharm [X]'*, was prepared by [Cinven Senior Employee 4], [Cinven Senior Employee 1], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and three other individuals. It was dated 9 July 2012 and was prepared on Cinven Partners headed paper.³⁴⁴⁵
- c. The final recommendation for Cinven's acquisition of the Mercury Pharma and Amdipharm groups, discussed at paragraph 9.274 above, which explained that the *'investment thesis'* was to *'Drive growth in UK through optimisation of the Amdipharm UK portfolio in an identical manner to what Mercury have done in the last 2 years – a low risk value lever'*: in other words to increase prices for niche generic drugs (*'the same strategy that [AMCo Senior Employee 1] and the team have successfully executed at Mercury'*), was also authored by [Cinven Senior Employee 4], [Cinven Senior Employee 1], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and three other individuals. It was dated 30 July 2012.³⁴⁴⁶

9.422. These recommendations were all prepared before Cinven had acquired either the Mercury Pharma or Amdipharm groups. They were also prepared (with the exception of the final recommendation³⁴⁴⁷) before any of these individuals was appointed to roles on the boards of AML and other AMCo group companies. The work of those individuals in preparing the investment

³⁴⁴⁴ Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012'.

³⁴⁴⁵ Document LIO6490.4, 'Annex 2.2 - memorandum to the IC titled 'Amdipharm - initial investment recommendation' dated 9 July 2012'. Compare C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, in which the fact that most of the documents found during the Commission's inspections were on the letterhead of Knauf Gips KG, with its address and details, was one relevant factor in the Court's finding that Knauf Gips KG should be liable for the infringement (paragraphs 104 to 106).

³⁴⁴⁶ Document LIO6491.1, 'Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012'.

³⁴⁴⁷ [Cinven Senior Employee 1] and [Cinven Senior Employee 2] were appointed to the board of AML on 23 July 2012, a week before the final investment recommendation was submitted to Cinven Partners' Investment Committee, in preparation for the acquisitions. Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015; clarification in respect of [Cinven Senior Employee 2] in Document 200547, Cinven's response to the CMA's section 26 notice dated 11 November 2016, paragraph 7.2(a).

recommendations, and the strategy they set out, are therefore attributable to Cinven Partners.

- 9.423. This was made particularly clear in the Cinven press release announcing the sale of the AMCo group to Concordia Healthcare Corporation (now Advanz) in September 2015. [Cinven Senior Employee 1] – described as ‘*Partner at Cinven*’³⁴⁴⁸ – stated:

*‘Cinven successfully created AMCo – through the combination of two businesses – as a result of bilateral transactions and our strong healthcare focus and track record. We saw an opportunity to create significant value through the consolidation of the relatively fragmented, off-patent, niche pharmaceuticals market and AMCo has certainly achieved that.’*³⁴⁴⁹

- 9.424. The press release noted that Cinven created the AMCo group in 2012, and that:

*‘Cinven’s Healthcare team identified the opportunity to consolidate the niche pharmaceutical market more than two years prior to this’*³⁴⁵⁰

- 9.425. As explained above, [Cinven Senior Employee 1] [REDACTED]. That team ‘*identified the opportunity to consolidate the niche pharmaceutical market more than two years prior*’ to the acquisitions of the Mercury Pharma and Amdipharm groups in 2012 – before the Fifth Cinven Fund was set up and began fundraising.

- 9.426. The recommendations for the two acquisitions were prepared and submitted to the Investment Committee of Cinven Partners. [REDACTED].³⁴⁵¹ It was made up [REDACTED], including [Cinven Senior Employee 4].³⁴⁵² As explained above, that investment case was not a proposal for a passive investment, but a plan to combine two previously independent pharmaceutical groups, bring them under a single management team, and pursue a strategy of focussing on ‘*niche*’ generic drugs. A plan, in other words, to actively set the business plan and strategy of the combined AMCo group.

- 9.427. On the basis of those recommendations, that committee agreed to recommend that the Fifth Cinven Fund make binding offers for the two

³⁴⁴⁸ Compare the description of [Cinven Senior Employee 1] as ‘*a partner in Cinven*’ in the *Times*’ account of the sale: Document PAD157, The *Times*: ‘*Firm’s £1.5bn drug profit is bitter pill for taxpayer*’, June 2016.

³⁴⁴⁹ Document PAD066, Cinven: ‘*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*’.

³⁴⁵⁰ Document PAD066, Cinven: ‘*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*’ (emphasis added).

³⁴⁵¹ [REDACTED].

³⁴⁵² Document LIO6537.310, Cinven’s response to question 3 of the CMA’s section 26 notice dated 16 May 2018.

groups.³⁴⁵³ Although the decision to make those offers was for Cinven MGP to take (as the general partner managing the limited partnerships into which passive investors had moved their funds and therefore the manager of those funds that were used, alongside loans, to acquire them), Cinven MGP only had the option to do so because Cinven Partners had devised the investment thesis and put it forwards. Cinven Partners determined the terms of those offers, including the maximum price to be paid. [REDACTED].

Cinven Partners oversaw the implementation of that strategy through those individuals

9.428. Once the Mercury Pharma and Amdipharm groups had been acquired and combined, Cinven Partners continued to oversee the implementation of the strategy its staff had devised. It did so through its secondees on the AML and AMCo group company boards, who acted not only for Cinven MGP/Luxco 1 and the AMCo group boards on which they served, but also for Cinven Partners, in pursuit of their common strategy and interests.

9.429. [REDACTED].³⁴⁵⁴ [REDACTED].³⁴⁵⁵

9.430. As explained in paragraphs 9.404 to 9.406 above, where individuals who have acted at a high management level within a parent are present on the subsidiary's board, this places them in a position to cause the subsidiary's policy and the parent's interests to converge. This is the case even where those individuals do not retain contractual links with the parent, are no longer under its direct authority, and do not have authority as its agents.³⁴⁵⁶ In this case, however, these individuals did in fact retain contractual links with Cinven Partners; did have authority as agents of Cinven Partners; and remained under Cinven Partners' authority during the Cinven Period.

9.431. As explained in paragraphs 9.421 to 9.427 above, as [REDACTED] ([Cinven Senior Employee 4] and [Cinven Senior Employee 1]); [REDACTED] ([Cinven Senior

³⁴⁵³ Document LIO6491.1, 'Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012', item 2. Document LIO6490.3, 'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012', item 2.

³⁴⁵⁴ Document 200523, [REDACTED].

³⁴⁵⁵ Cinven submitted that: 'It is a significant stretch for the CMA to assert that a professional service company making available secondees resources and providing investment advice to its client exercised decisive influence over their client's portfolio company because the professional service firm retained service contracts and remunerated their staff while on secondment' (Document 204971, Cinven RSSO in Case 50395, paragraph 10.15). However, the CMA is not seeking to hold a third-party professional services company liable simply for providing professional services. The CMA has found that Cinven Partners was not in any meaningful sense a third party: it was in fact the driving force of the investment which was overseen by a few core individuals with overlapping roles in Cinven Partners and the AMCo group.

³⁴⁵⁶ T-132/07 *Fuji Electric Co. Ltd v Commission*, EU:T:2011:344, paragraph 184; T-104/13 *Toshiba v Commission*, EU:T:2015:610, paragraph 116, upheld in C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraphs 15 and 76; C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraph 106; C-595/18 P *Goldman Sachs v Commission*, paragraphs 89 and 93-95; T-682/14 *Mylan v Commission*, EU:T:2018:907, paragraphs 354-355.

Employee 2]) and employee ([Cinven Senior Employee 3]) of Cinven Partners, these individuals had played key roles in devising Cinven Partners' strategy for the AMCo group investment. They had thorough knowledge of Cinven Partners' policy and commercial objectives. As directors on AMCo group company boards, they were in a position to cause the AMCo group's policy and Cinven Partners' interests to converge. In particular:

- a. As explained in section 9.B.III.d.iv above, the Investor Directors sat on the board of the ultimate 100% owner of all the Amdipharm Companies, including the company that employed the AMCo group's executive management. They held (and exercised) veto rights over the AMCo group's business plan and commercial conduct.
- b. [REDACTED] [Cinven Senior Employee 1] would naturally be expected to discharge his duties as an Investor Director on the AML board with an eye to the broader interests of Cinven Partners and its goal of attracting further investment in its healthcare portfolio. If the investment in the AMCo group was successful, this was not only to the benefit of the investors in the Fifth Cinven Fund, whose interests Cinven MGP represented, but also of Cinven Partners, whose reputation would be enhanced (as is evident from the positive press after Cinven divested AMCo) which would assist in obtaining future investments.
- c. As [REDACTED],³⁴⁵⁷ [Cinven Senior Employee 4] too would naturally be expected to discharge his duties on the board of Mercury Pharma Group Limited and its three immediate holding companies with an eye to the same broader interests.

9.432. [REDACTED].

9.433. [REDACTED]. This meant that in practice, they were required to advance the interests of each of:

- a. The AMCo group companies whose boards they served and to which they owed fiduciary duties;
- b. The Majority Investors of the Fifth Cinven Fund, whose managing partner Cinven MGP appointed them; and
- c. Cinven Partners, their employer or partnership.

³⁴⁵⁷ See Document PAD091, [REDACTED].

9.434. Cinven submitted [REDACTED].³⁴⁵⁸

9.435. The law on parental liability (like competition law in general) depends not on contractual or company law technicalities but on economic reality.³⁴⁵⁹ The CMA finds that as a matter of economic reality – notwithstanding the terms of their appointment on paper – the Investor Directors also acted for Cinven Partners.

9.436. [REDACTED].³⁴⁶⁰ However, there is nothing unusual about this situation. Company directors often serve on multiple boards and owe duties to each of them. Directors of a subsidiary company often also serve on the parent's board. In such a situation they owe duties to both parent and subsidiary and are required to advance the interests of both.³⁴⁶¹ [REDACTED].³⁴⁶²

9.437. The CMA finds that such a distinction is artificial in this case, particularly given that those interests were aligned. As explained in sections 9.B.III.d.i and ii above, the interests of all the Cinven Entities, AML and the Amdipharm Companies were aligned in pursuit of their common strategy of exploiting the profit opportunities presented by niche generic drugs, and each of the Cinven Entities stood to gain if the investment in the AMCo group was a success.³⁴⁶³ Cinven did not suggest any way in which the interests of the Cinven Entities and the AMCo group were not aligned. These individuals were therefore perfectly able to discharge their overlapping duties.

9.438. The evidence shows that they did so in practice.

9.439. The investment recommendations for AMCo group follow-on acquisitions during the Cinven Period were prepared by the individuals Cinven Partners seconded to the AMCo group in their capacity as Cinven Partners staff, for consideration and approval by the Cinven Partners Investment and Portfolio

³⁴⁵⁸ Document 204970, Cinven RSO in Case 50395, paragraphs 12.47-12.50. See also Document 203736, Cinven's RSO, paragraph 12.62.

³⁴⁵⁹ C-440/11 *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV*, EU:C:2013:514, paragraphs 66-68. See also Opinion of Advocate General Kokott, EU:C:2012:763, paragraphs 71-76: Compare C-623/15 P *Toshiba v Commission*, EC:C:2017:21, paragraph 46. See also Joined cases C-293/13 P and C-294/13 P *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, EU:C:2015:416, paragraph 76.

³⁴⁶⁰ Document 204970, Cinven RSO in Case 50395, paragraph 12.56.

³⁴⁶¹ The General Court has confirmed that appointee directors on a subsidiary board can act in more than one capacity, where the interests of parent and subsidiary are aligned. Their fiduciary duties to the subsidiary do not necessarily conflict with their continued role as representatives of the parent. The court also noted that the parent's appointment of directors to the subsidiary's supervisory board '*would not have made sense if the [parent] had intended that the supervisory board be composed of persons entirely independent from the [parent]*'; and that '*the [parent] affirms that the members which it appointed to [the subsidiary]'s supervisory board could not be considered 'solely as [its] representatives', thereby admitting that they also acted in that capacity*': T-399/09 *Holding Slovenske v Commission*, EU:T:2013:647, paragraphs 75-77.

³⁴⁶² Document 204971, Cinven RSSO in Case 50395, paragraph 10.14(e) (emphasis in original).

³⁴⁶³ [REDACTED].

Review Committees.³⁴⁶⁴ [REDACTED]. This gave Cinven Partners, through the individuals it seconded to the AMCo group, control over the pipeline of investments for the Fifth Fund and the AMCo group.³⁴⁶⁵

9.440. Cinven Partners exercised that control to ensure that strategic and material acquisitions by the AMCo group were consistent with its investment strategy. For example:

- a. In February 2013, [Cinven Senior Employee 3] wrote to the Investment Committee to '*seek IC approval to proceed*' with the AMCo group's acquisition of Fucithalamic on behalf of the '*Amco Team*'.³⁴⁶⁶
- b. In April 2014, [REDACTED] sought approval from the Investment Committee and Portfolio Review Committee for the AMCo group to make an offer for Archimedes Pharma, stating: '*Please let me know if you are happy for us to proceed*'.³⁴⁶⁷
- c. [REDACTED].³⁴⁶⁸
- d. An update for the Portfolio Review Committee on the acquisition of Focus Pharmaceuticals, on Cinven Partners headed paper, was prepared by [Cinven Senior Employee 1], [Cinven Senior Employee 2] and [Cinven Senior Employee 3] in August 2014. It explained the strategic fit of the Focus and AMCo business models (both being '*virtual*' businesses with no R&D), and asked the Committee to give approval '*to increase our offer*'.³⁴⁶⁹ The final investment recommendation was also prepared by [Cinven Senior Employee 1], [Cinven Senior Employee 4], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and two other individuals on Cinven Partners headed paper. It noted that Focus had an [REDACTED].³⁴⁷⁰

9.441. During the course of the Cinven Period, regular papers on the AMCo group investment were submitted to the Cinven Partners Portfolio Review

³⁴⁶⁴ [REDACTED].

³⁴⁶⁵ See, for example, Document LIO6496.10, '*Minutes of the Cinven MGP quarterly Board Meeting dated 27 August 2015*', page 5: in relation to one potential investment, '[REDACTED]'. The minutes of Cinven MGP board meetings on 22 November 2012 and 14 November 2013 stated that: '[REDACTED]': Document LIO6496.9, '*Minutes of the Cinven MGP quarterly Board Meeting dated 22 November 2012*'; Document LIO3114, Minutes of the Cinven MGP Quarterly Board meeting dated 14 February 2013.

³⁴⁶⁶ Document LIO6537.58, email from [Cinven Senior Employee 3] to IC Members and PAs dated 1 February 2013.

³⁴⁶⁷ Document LIO6537.135, email from [Cinven Senior Employee 2] to [Cinven Senior Employee 1] dated 30 April 2014.

³⁴⁶⁸ Document 200500, AML board meeting minutes dated 27 June 2014, paragraph 4.2.

³⁴⁶⁹ Document LIO6492.10, '*Focus Pharmaceuticals - AMCo bolt-on*' dated 6 August 2014'.

³⁴⁷⁰ Document LIO6494.1, '*Focus Pharmaceuticals - Final Investment Recommendation*' dated 17 September 2014', page 3.

Committee (see paragraph 9.372 above).³⁴⁷¹ These papers included updates on matters such as the integration of the Amdipharm and Mercury groups; AMCo management; acquisitions; financing; the AMCo group ‘*Strategy agenda*’; the budget (noting that [REDACTED]³⁴⁷² [REDACTED];³⁴⁷³ and trading conditions.³⁴⁷⁴ The Portfolio Review Committee papers also included a ‘*Strategy scorecard*’ with a summary of risks and opportunities.

9.442. Once approved, investment recommendations were presented by Cinven Partners staff to the board of Cinven MGP. [REDACTED].

9.443. [REDACTED].³⁴⁷⁵

9.444. [REDACTED].³⁴⁷⁶

9.445. [REDACTED].

9.446. [REDACTED].³⁴⁷⁷

9.447. [REDACTED].³⁴⁷⁸

9.448. The Cinven Partners individuals seconded to AMCo group company boards therefore continued to oversee implementation of the strategy they had devised for the investments in the Mercury Pharma and Amdipharm groups, in their capacity as Cinven Partners staff.

9.449. Other key Cinven Partners staff also played a role. [REDACTED]: *‘reminded the Board that Amco comprised a merger between Mercury Pharma and Amdipharm. He added that the Company was trading strongly post the merger, with*

³⁴⁷¹ As explained above, the EU Court of Justice has held that the provision by a subsidiary to a parent of information on the implementation of strategic and commercial plans is an indication that the parent exercised control over the decisions drawn up and executed by the subsidiary’s executives: C-90/09 P *General Química v Commission*, EU:C:2011:21, paragraphs 104 to 107. Compare Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, in which the parent’s monitoring of its subsidiary’s financial performance was a relevant factor in the attribution of liability (paragraph 3019), upheld on appeal in T-705/14 *Unichem v Commission*, EU:T:2018:915, paragraphs 69-89.

³⁴⁷² Document LIO6492.7, ‘Q4 PRC Paper on AMCo dated December 2013’, page 5.

³⁴⁷³ Document LIO6492.8, ‘Q1 PRC Paper on AMCo dated March 2014’, page 3. See also Document LIO6492.11, ‘Q3 PRC Paper on AMCo dated September 2014’, page 3: ‘Organic performance was driven by significant growth in the UK (largely thanks to price increases on AMCo’s largest products)’.

³⁴⁷⁴ Document LIO6492.3, ‘Q4 PRC Paper on Mercury & Amdipharm dated December 2012’; Document LIO6492.4, ‘Q1 PRC Paper on AMCo dated March 2013’; Document LIO6492.5, ‘Q2 PRC Paper on AMCo dated June 2013’; Document LIO6492.6, ‘Q3 PRC Paper on AMCo dated September 2013’; Document LIO6492.7, ‘Q4 PRC Paper on AMCo dated December 2013’; Document LIO6492.8, ‘Q1 PRC Paper on AMCo dated March 2014’; Document LIO6492.11, ‘Q3 PRC Paper on AMCo dated September 2014’; and Document LIO6494.2, ‘Q4 PRC Paper on Amco dated December 2014’.

³⁴⁷⁵ Document LIO3118, investment recommendation for Archimedes acquisition dated 18 June 2014, pages 4 and 7. The ‘investment attractions’ of the target included its ‘Differentiated, niche drug portfolio’ and ‘Potential to leverage strong UK presence of AMCo to drive top-line growth from legacy products’. The ‘key levers to protect our investment’ included ‘revenue uplifts for non branded products in the UK’.

³⁴⁷⁶ Document LIO3118, Minutes of Cinven MGP Board meeting dated 26 June 2014.

³⁴⁷⁷ Document 200504, ‘AMCo bolt-on M&A opportunities’ dated 1 April 2015, pages 12, 13.

³⁴⁷⁸ Document 200504, Minutes of Cinven MGP board meeting dated 2 April 2015.

trading results above the Adviser's plan. The Adviser was in the very early stages of considering additional add-on investments for Amco.' This demonstrates Cinven Partners' oversight of the AMCo group investment's performance at the most senior level.³⁴⁷⁹

Cinven Partners drove the decision to divest the AMCo group through those individuals

- 9.450. The evidence also shows that although the ultimate sale of the AMCo group was formally approved by Cinven MGP as managing general partner of the Fifth Cinven Fund, the decision to sell was driven by Cinven Partners, in particular through the individuals it second to AMCo group company boards.
- 9.451. A recommendation for an AMCo group follow-on acquisition was prepared for the Cinven Partners Investment Committee in October 2013. [REDACTED]. The recommendation [REDACTED] stated: *'We are working on the assumption that we will need to be ready to sell AMCo in Q1 2016 to support the raising of fund 6'*.³⁴⁸⁰ This statement makes clear that even as early as 2013, the decision to sell the AMCo group would be based on Cinven Partners' broader perspective on the various Cinven funds, and the need to raise capital for the next fund.
- 9.452. The *'AMCo exit paper'* prepared in February 2015 and discussed in paragraphs 9.287 to 9.290 above was authored by [Cinven Senior Employee 1], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and one other individual, on Cinven Partners headed paper. It was presented to the Cinven Partners Portfolio Review Committee.³⁴⁸¹ The document makes clear that Cinven Partners was the entity that devised the plan for divestment, just as it had devised the plan for investment. As explained above, the paper referred to initiatives to improve the attractiveness of the AMCo group on exit [REDACTED]. It recommended that Cinven look to sell the AMCo group to a trade buyer in 2015 and noted that *'We have a Cinven friendly SHA in place, where we retain full control in exit (including information rights and controlling access to bidders)'*. [REDACTED].
- 9.453. In July 2015 [Cinven Senior Employee 1], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and two other individuals prepared a briefing for the Cinven Partners Investment and Portfolio Review Committees, on Cinven Partners headed paper, on an offer for the AMCo group from Concordia Healthcare (now Advanz). The briefing stated, '[REDACTED]'. Under "Why

³⁴⁷⁹ Document LIO6496.11, *'Minutes of the Cinven MGP quarterly Board Meeting dated 21 November 2013'*.

³⁴⁸⁰ Document LIO6492.1, *AMCo add-on acquisition recommendation dated 31 October 2013*, pages 2 and 3 (emphasis added).

³⁴⁸¹ Document LIO6494.3, *'AMCo Exit Paper' dated 27 February 2015'*,

now' / timing considerations', the briefing noted: *'AMCo still expects to meet its 2015 budget at EBITDA level, however it is clear that the low-hanging fruit have been taken'*.³⁴⁸² These statements demonstrate that it was Cinven Partners that evaluated the strength and terms of the offer to purchase the AMCo group and engaged with the potential buyer, in part on the basis of its view that its strategy of increasing the prices of niche generic drugs had now reaped the '[X]'.³⁴⁸³

9.454. The recommendation for the sale of the AMCo group prepared in August 2015 was authored by [Cinven Senior Employee 1], [Cinven Senior Employee 2], [Cinven Senior Employee 3] and two other individuals, on Cinven Partners headed paper. It was presented to the Cinven Partners Portfolio Review Committee by [Cinven Senior Employee 1] and [Cinven Senior Employee 3] for unanimous approval before it was presented to Cinven MGP.³⁴⁸³ [X].³⁴⁸⁴ [X].

9.455. Cinven submitted [X].³⁴⁸⁵ However, this is not the right way to approach the evidence. As explained in paragraph 9.37 above, the Court of Justice has confirmed that *'The existence of an economic unit may ... be inferred from a body of consistent evidence, even if some of that evidence, taken in isolation, is insufficient to establish the existence of such a unit'*.³⁴⁸⁶ The CMA finds that the documentary evidence, taken together and as a whole, demonstrates the exercise of decisive influence by Cinven Partners.

e. Liability of Advanz

9.456. The CMA attributes liability for the 10mg Agreement, and for the resulting financial penalty, to Advanz from 21 October 2015 to 24 June 2016, jointly and severally with the Amdipharm Companies.

9.457. This is because the Amdipharm Companies were wholly owned by Advanz throughout that period.

³⁴⁸² Document LIO6496.1, 'AMCo CRX Offer dated 15 July 2015', pages 2 and 4. See also Document LIO6496.2, 'AMCo CRX Offer updated dated 21 August 2015'.

³⁴⁸³ Document LIO6537.293, email from [Cinven Senior Employee 1] to PRC Members and others dated 26 August 2015; document LIO6537.295, email from [Cinven Senior Employee 3] to PRC Members dated 26 August 2015.

³⁴⁸⁴ Document LIO3119, minutes of Cinven MGP board meeting dated 27 August 2015.

³⁴⁸⁵ Document 204970, Cinven RSO in Case 50395, paragraph 12.59.

³⁴⁸⁶ C-407/08 P *Knauf Gips v Commission*, EU:C:2010:389, paragraph 65.

- 9.458. On 21 October 2015, the AMCo group was acquired by Advanz (then known as Concordia Healthcare Corp.)³⁴⁸⁷ and from that date until 24 June 2016, the Amdipharm Companies were all indirectly wholly owned by Advanz.³⁴⁸⁸
- 9.459. Advanz therefore had the ability to exercise decisive influence over the Amdipharm Companies during this period, and the CMA applies the *Akzo* presumption that it did actually exercise such influence.³⁴⁸⁹ Advanz has not disputed this and the *Akzo* presumption has therefore not been rebutted.

³⁴⁸⁷ Document PAD068, Concordia: '*Completes AMCo acquisition*'. Concordia Healthcare Corp. announced its name change to Concordia International Corp. on 28 June 2016: Document PAD069, Prnewswire: '*Concordia Healthcare Corp. Announces Name Change to Concordia International Corp. and Comments on Brexit's Impact on the Company's Business*'. Concordia International Corp. announced its name change to Advanz Pharma Corp. on 29 November 2018: www.prnewswire.com/news-releases/concordia-international-corp-announces-name-change-to-advanz-pharma-corp-300757781.html. Advanz Pharma Corp. was renamed Advanz Pharma Corp. Limited on 1 January 2020, when it changed its domicile to Jersey: [Advanz-Pharma-Corp.-Limited-Management-Discussion-and-Analysis-17-March-2021.pdf](http://advanzpharma.com/Management-Discussion-and-Analysis-17-March-2021.pdf) (advanzpharma.com), page 7.

³⁴⁸⁸ Document 200264, Annex 5.1 to AMCo's response to the CMA's section 26 notice dated 23 August 2016; Document 202007, '*Annex 2: Updated structure chart*', attachment to Document 202009, Concordia's response to the CMA's section 26 notice dated 21 August 2017.

³⁴⁸⁹ Compare Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, in which the Commission attributed liability to '*parent companies which at the time of events exerted decisive influence over subsidiaries that signed any of the agreements covered by this Decision ... together with the subsidiary that actually signed the agreement*' (paragraph 1237).

10. THE CMA'S ACTION

A. The CMA's decision

- 10.1. On the basis of the evidence and analysis set out in this Decision, the CMA has made a decision that Auden/Actavis has infringed the Chapter II prohibition as it held a dominant position in the relevant market(s) and abused its dominant position by charging excessive and unfair prices:
- a. from 1 October 2008 to 31 July 2018, for 10mg hydrocortisone tablets (the 10mg Unfair Pricing Abuse); and
 - b. from 1 October 2008 to 8 January 2017, for 20mg hydrocortisone tablets (the 20mg Unfair Pricing Abuse).
- 10.2. On the basis of the evidence and analysis set out in this Decision, the CMA has also made a decision that Auden/Actavis and its potential competitors Waymade and AMCo have infringed the Chapter I prohibition by participating in the Agreements, which constituted agreements under which Auden/Actavis made substantial monthly payments to its potential competitors in return for which they agreed not to enter the market with their own hydrocortisone tablets. The Agreements, therefore, had as their object the prevention, restriction or distortion of competition within the UK. Specifically:
- a. from 11 July 2011 to 30 April 2015, Auden and Waymade infringed the Chapter I prohibition by participating in the 20mg Agreement;
 - b. from 23 October 2012 to 30 October 2012, Auden and Waymade infringed the Chapter I prohibition by participating in the 10mg Agreement; and
 - c. from 31 October 2012 to 24 June 2016, Auden/Actavis and AMCo infringed the Chapter I prohibition by participating in the 10mg Agreement.
- 10.3. The 10mg Unfair Pricing Abuse, the 20mg Unfair Pricing Abuse, the 10mg Agreement and the 20mg Agreement constitute separate and distinct infringements of the Act.
- 10.4. On the basis of the evidence and analysis set out in this Decision, the CMA has made a decision to hold the entities to whom liability is attributed in section 9 (*Undertakings and Attribution of Liability*) of this Decision liable for the infringements committed by Auden/Actavis, AMCo and Waymade.

B. Financial penalties

- 10.5. Section 36(1) of the Act provides that on making a decision that an agreement has infringed the Chapter I prohibition, the CMA may require undertakings party to the agreement to pay the CMA a penalty in respect of the infringement.
- 10.6. Section 36(2) of the Act provides that on making a decision that conduct has infringed the Chapter II prohibition, the CMA may require the undertaking concerned to pay the CMA a penalty in respect of the infringement.
- 10.7. However, pursuant to section 36(3) of the Act the CMA may impose a penalty under sections 36(1) and/or (2) only if it is satisfied that the infringement has been committed intentionally or negligently by the undertaking.
- 10.8. For the reasons set out below, the CMA finds that the Infringements were committed intentionally or at the very least negligently. The CMA has therefore imposed financial penalties in respect of the Infringements for which liability is attributed in line with section 9 above.
- 10.9. The penalties have been calculated in accordance with the CMA's published guidance³⁴⁹⁰ and relevant legislation.³⁴⁹¹

I. The CMA's margin of appreciation in determining the appropriate penalty

- 10.10. The CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.³⁴⁹² The CMA is not bound by its decisions in relation to whether to impose financial penalties or the calculation of any such penalties in previous cases under the Act. It makes assessments on a case-by-case basis,³⁴⁹³ having regard to all relevant circumstances and the objectives of its policy on financial penalties. This is in line with its statutory requirements and the twin objectives of the CMA's policy on financial

³⁴⁹⁰ Guidance as to the appropriate amount of a Penalty (CMA73), published April 2018 (the '**CMA penalties guidance**').

³⁴⁹¹ The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000/309) and the Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004 (SI 2004/1259).

³⁴⁹² Provided that any penalty that the CMA imposes under the Act is within the range of penalties permitted by section 36(8) of the Act, calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (the 2000 Turnover Order), and calculated having regard to the CMA penalties guidance in accordance with section 38(8) of the Act. The CMA's margin of appreciation is referred to in, for example, *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 168, and *Umbro Holdings, Manchester United, JJB Sports and Allsports v OFT* [2005] CAT 22, paragraph 102.

³⁴⁹³ See, for example, *Kier Group and Others v OFT* [2011] CAT 3, paragraph 116: '*other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent*'. See also *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 97: '*[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case*'. See also CMA penalties guidance, paragraph 2.6.

penalties, as reflected in the CMA penalties guidance.³⁴⁹⁴ These objectives require the CMA to reflect the seriousness of the infringement and ensure the deterrence of the undertaking on which the penalty is imposed and to deter others from engaging in agreements or conduct that infringes any prohibition(s) under the Act.³⁴⁹⁵

- 10.11. The CMA has concluded that it is appropriate in the circumstances of this case to exercise its discretion under section 36(1) of the Act to impose financial penalties on the Auden/Actavis, AMCo and Waymade undertakings given the serious nature of the Infringements and to deter similar conduct in the future.

II. Intention and negligence

a. Legal framework

- 10.12. If an undertaking's conduct infringes the Chapter I prohibition or the Chapter II prohibition, the CMA may require the undertaking concerned to pay a penalty in respect of the infringement(s) if it is satisfied that the infringement(s) have been committed intentionally or negligently.³⁴⁹⁶ The CMA is not, however, obliged to specify whether it considers the infringement to be intentional or negligent.³⁴⁹⁷

- 10.13. The CAT has defined the terms 'intentionally' and 'negligently' as follows:

'an infringement is committed intentionally for the purposes of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition.

[...]

An infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition'.³⁴⁹⁸

- 10.14. Intention or negligence relates to the facts, not the law. The CMA is not required to show that the undertaking knew that its conduct infringed the Act – what matters is not whether the undertaking was aware of 'any specific

³⁴⁹⁴ CMA penalties guidance, paragraph 1.3.

³⁴⁹⁵ The Act, section 36(7A); CMA penalties guidance, paragraph 1.3.

³⁴⁹⁶ The Act, section 36(1), 36(2) and 36(3).

³⁴⁹⁷ *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraphs 453 to 457; see also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 221.

³⁴⁹⁸ *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 221.

legal characterisation of its conduct, *'but whether it was aware of its anti-competitive nature'*.³⁴⁹⁹

- 10.15. This is consistent with the approach taken by the EU Court of Justice which has confirmed:

'the question whether the infringements were committed intentionally or negligently [...] is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty'.³⁵⁰⁰

- 10.16. These principles were applied by the Court of Appeal in *Ping v CMA*.³⁵⁰¹ The CAT recently confirmed in *Paroxetine* that the principles set out at paragraphs 10.12 to 10.15 above are the principles applicable for the purpose of section 36(3) of the Act, noting that the question is whether the relevant undertakings *'knew or should have known'* that the agreements in question *'were anti-competitive in nature'*.³⁵⁰²
- 10.17. AMCo submitted that the correct legal test for establishing intention or negligence under section 36(3) of the Act is whether the undertaking was aware that its conduct was *'probably'* or *'clearly'* unlawful, based on the criteria set out by the CAT in *Cardiff Bus* and *Sainsbury's/Mastercard*.^{3503,3504} The CMA does not accept these representations. The CAT confirmed in *Paroxetine* the legal framework for assessing intention/negligence under section 36(3) of the Act. The CMA notes in particular that the principles in *Cardiff Bus* are not applicable as these were developed, and apply, in the context of an award of exemplary damages. The *Cardiff Bus* principles were applied in *Sainsbury's/Mastercard* also in the context of a damages claim. Neither the CAT nor the Court of Appeal has applied the principles in *Cardiff Bus* to section 36(3) of the Act.

³⁴⁹⁹ *Royal Mail Plc v Office of Communications* [2019] CAT 27, paragraph 782. See also *Napp*, paragraph 456.

³⁵⁰⁰ C-280/08 P *Deutsche Telekom v Commission*, EU:C:2010:603, paragraph 124.

³⁵⁰¹ *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117.

³⁵⁰² *Generics (UK) Limited Glaxosmithkline Plc, Xellia Pharmaceuticals APS, Alpharma LLC Actavis UK Limited Merck KGAA v CMA* [2021] CAT 9 (*'Paroxetine'*), paragraphs 117 and 121.

³⁵⁰³ *2 Travel Group Plc v Cardiff City Transport Services Limited* [2012] CAT 19 (*'Cardiff Bus'*), paragraph 489f; *Sainsbury's Supermarkets Limited v Mastercard* [2016] CAT 11 (*'Sainsbury's/Mastercard'*), paragraph 322f.

³⁵⁰⁴ See Document 205848, AMCo's RDPS, paragraphs 4.5 to 4.9, and Document 205947, AMCo's submission to the CMA dated 22 December 2020, paragraphs 13 and 14. See also Document 205813, Accord-UK's RDPS, paragraph 4.3 and Document 205802, Intas/Accord-UK's RDPS, paragraph 30.

- 10.18. Ignorance or a mistake of law is no bar to a finding of intentional (or, a *fortiori*, negligent) infringement, even where such ignorance or mistake is based on independent legal advice.^{3505, 3506}
- 10.19. In some cases, the undertaking's intention will be confirmed by internal documents. However, in other cases, and in the absence of any evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred.³⁵⁰⁷ If, for example, a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive effect, it may be legitimate to infer that it is acting '*intentionally*' for the purposes of section 36(3).³⁵⁰⁸
- 10.20. The case law is clear that an undertaking will be aware of the anti-competitive nature of its conduct where it is aware of the '*essential facts*' underpinning the legal finding of abuse.³⁵⁰⁹ In cases of unfair pricing, therefore, the CMA will consider whether the undertaking knew or should have known the essential facts justifying the CMA's findings that (i) the

³⁵⁰⁵ C-681/11 *Bundeswettbewerbsbehörde v Schenker & Co. AG*, EU:C:2013:404, paragraph 38: '*the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not be unaware of the anti-competitive nature of that conduct*'; and paragraph 41: '*It follows that legal advice given by a lawyer cannot, in any event, form the basis of a legitimate expectation on the part of an undertaking that its conduct does not infringe Article 101 TFEU or will not give rise to the imposition of a fine.*'

³⁵⁰⁶ AMCo submitted representations on the relevance of legal advice to a finding of intention or negligence, specifically stating that there was '*a consistent body*' of case law establishing that legal advice excludes a finding of intention or negligence on the part of the relevant undertaking (Document 205947, AMCo's submission to the CMA dated 22 December 2020, paragraphs 32 and 33; Document 205848, AMCo's RDPS, paragraphs 2.13.2, 4.7, 4.26 to 4.27, and 4.33). The CMA does not accept these representations: none of the cases which AMCo cited establishes that legal advice precludes a finding of intention/negligence. This issue is considered further in section 10.B.II.e.iv below where the legal framework is applied to the facts of AMCo's legal advice with respect to the 10mg Agreement. *Schenker* is the relevant authority and the CMA's approach to the legal test for intention and negligence was recently confirmed by the Court of Justice in C-591/16 P *Lundbeck v Commission*, paragraphs 156 to 158 as well as by the CAT in *Paroxetine* (see above).

³⁵⁰⁷ *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

³⁵⁰⁸ *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

³⁵⁰⁹ Case 322/81 *NV Nederlandsche Banden-Industrie Michelin v Commission* ECLI:EU:C:1983:313, [1983] ECR 3461, paragraph 107: '*In that respect it must be emphasized that Michelin NV was aware of the factual elements justifying both the finding of the existence of the dominant position on the market and the assessment of the contested discounts system as an abuse of that system*'; Joined Cases T-259/02 to T-264/02 and T-271/02 *Raiffeisen Zentralbank Österreich v Commission* ECLI:EU:T:2006:396, [2006] ECR II-5169, paragraph 206: '*...whether or not the applicants were aware of the interpretation of the cross-border criterion adopted by the Commission or the case-law is not decisive; what is important is whether they knew of the circumstances specifically giving rise to the capability of the cartel to affect trade between Member States or, at least, whether they could not have been unaware of them*'; Case T-286/09 *Intel v Commission* ECLI:EU:T:2014:547, paragraph 1601: '*An undertaking is aware of the anti-competitive nature of its conduct where it is aware of the essential facts justifying both the finding of a dominant position on the relevant market and the finding by the Commission of an abuse of that position*'; and Opinion of AG Mazák in Case C-280/08P *Deutsche Telekom v Commission* ECLI:EU:C:2020:212, paragraph 39: '*First of all, according to the case-law, an undertaking is aware of the anti-competitive nature of its conduct when it is "aware of the factual elements justifying both the finding of the existence of a dominant position on the market and the assessment of [the finding by the Commission of] an abuse of that position" ...Therefore, suffice it to point out that since the awareness of infringing competition rules is not decisive, there may be intentional fault even where the undertaking does not know the interpretation of those rules by the Commission*'.

undertaking was in a dominant position, and (ii) the undertaking's price was unfair.³⁵¹⁰

b. Application to Auden/Actavis: the Unfair Pricing Abuses

10.21. Based on the evidence set out in this Decision, the CMA concludes that the undertaking Auden/Actavis knew or should have known the essential facts justifying the CMA's findings in relation to the Unfair Pricing Abuses:

- a. That it was a dominant undertaking in the relevant market(s); and
- b. That its prices were unfair.

10.22. In relation to the finding of intention/negligence at the level of the undertaking:

- a. Accord-UK submitted that the CMA is required to prove intention or negligence separately for each of the periods from 1 October 2008 to 28 May 2015 (for which it is solely liable) and for the period from 29 May 2015 to 1 August 2016 (Allergan's ownership period).³⁵¹¹ The CMA disagrees with this representation. Section 36(3) of the Act refers to intention or negligence on the part of the '*undertaking*', so it is not necessary to establish intention or negligence at the level of each entity that is held liable for the infringement committed by the undertaking. Once intention or negligence is established for the '*undertaking*', the CMA does not need to meet this test again where there is a change of ownership but there is economic continuity. The CMA can rely on evidence relating to one entity to establish the intention or negligence of the undertaking of which that entity forms or formed part during the relevant period. The CMA has established intention/negligence in respect of the Auden/Actavis undertaking as set out in this section. Accord-UK cited *Parker Hannifin v Commission*³⁵¹² in support of its argument that the intention or negligence of a legal entity cannot be attributed to its economic successor. However, the case directly contradicts Accord-UK's argument: in that case the Court upheld a 30% increase in the fine imposed on the economic successor as a result of its predecessor's role of ringleader in the cartel, despite the fact that the successor did not even exist during that period. The actions of the predecessor's employees in leading the cartel led to the successor's fine being increased.

³⁵¹⁰ *Competition and Markets Authority v Flynn Pharma Ltd* [2020] EWCA Civ 339, paragraph 97.

³⁵¹¹ Document 205813, Accord-UK's RDPS, paragraph 4.6.

³⁵¹² T-146/09 *Parker Hannifin v Commission*, paragraph 54.

- b. Allergan submitted that Allergan's actions were '*(at most) negligent*' because of its lack of direct control or visibility over decision making.³⁵¹³ The CMA disagrees with the factual basis for these statements in light of Allergan's actual knowledge of Auden/Actavis's position in the market and hydrocortisone tablet pricing. In any event, intention/negligence is assessed at the level of the undertaking and Allergan was the parent company at the relevant time so was part of the infringing undertaking. Therefore, the CMA does not need to establish that Allergan itself acted intentionally or negligently with respect to the Unfair Pricing Abuses, as the CMA has established that Allergan formed part of the undertaking and that this undertaking committed the infringement intentionally or negligently. The same is true for the 10mg Agreement. The CMA therefore does not accept Allergan's representation.

10.23. The CMA therefore finds that Auden/Actavis knew or should have known that its conduct was exploitative. Therefore, the CMA finds that Auden/Actavis committed the Unfair Pricing Abuses intentionally or, at the very least, negligently.

i. Dominance

10.24. Auden/Actavis knew or should have known that as the sole and subsequently major supplier of hydrocortisone tablets, it was a dominant undertaking in the relevant market(s).³⁵¹⁴

10.25. Evidence supporting this includes, for example:

- a. In August 2012, [Auden Senior Employee 1] informed the DHSC that '*we are currently the only suppliers of Hydrocortisone 10mg and 20mg tablets in the UK*'.³⁵¹⁵
- b. A PowerPoint presentation in relation to 'Project Guardian' dated February 2014 stated, among other things, that Auden sought '*to retain*'

³⁵¹³ Document 205791, Allergan's RDPS, paragraphs 47 to 51 in the context of steps 3 and 4 of the CMA's calculations. Allergan also submitted more broadly that there was no intention or negligence on the part of Allergan, which the CMA rejects for the reasons noted in this paragraph (Document 205791, Allergan's RDPS, paragraph 92).

³⁵¹⁴ Accord-UK and Intas/Accord-UK submitted that it could not have acted intentionally or negligently as there was legal uncertainty as to whether it was dominant given the market context of falling prices and widespread entry, and submitted that a finding of dominance in this context is novel: Document 205813, Accord-UK's RDPS, paragraph 4.22; Document 205802, Intas/Accord-UK's RDPS, paragraphs 7 to 9. The CMA does not accept these representations. The examples set out in this sub-section demonstrate that Auden/Actavis must have been aware, could not have been unaware, or at least ought to have known that, as the sole and subsequently major supplier of hydrocortisone tablets, it was a dominant undertaking in the relevant market(s) throughout the period at issue in this case. See also the CMA's findings on dominance as set out in section 4.C of the Decision.

³⁵¹⁵ Document 000321, email from [Auden Senior Employee 1] to DHSC dated 9 August 2012.

it's [sic] market leading position in hydrocortisone tablet supply to the NHS' (emphasis added), adding that it should be 'proactive ahead of Amdipharm's product entry into the UK market in attempt to hold Auden Mckenzie share above 50% and as close to the existing position as possible'. In its conclusion, the presentation stated that Auden 'has the most established generic in the market and holds marketing authorisation for the most indicated disease states'.³⁵¹⁶

- c. In June 2014, [Auden Senior Employee 4] emailed the DHSC about the inclusion of 10mg hydrocortisone tablets in Category M of the Drug Tariff. [Auden Senior Employee 4] stated that '*Auden Mckenzie is currently the only supplier of a fully licensed Hydrocortisone 10mg Tablet in the UK market*'.³⁵¹⁷
- d. In September 2014, Allergan considered acquiring AM Pharma. In an internal presentation, it highlighted that the orphan designation for Plenadren '*[e]ffectively grant[ed] exclusivity to Auden Mckenzie until 2022*'.³⁵¹⁸ PwC provided a financial due diligence report to Actavis UK Limited in December 2014 highlighting '*the current lack of competition*'.³⁵¹⁹
- e. Shortly before Allergan's acquisition of the AM Pharma in May 2015, [AMCo Senior Employee 1] noted that '*According to [Auden Senior Employee 1] Actavis will continue his strategy*' of using the orphan designation to undermine independent entry.³⁵²⁰ In September 2015, after taking over sales of hydrocortisone tablets from AM Pharma, [X]: '*Clearly currently in UK we have all the market and some export, we expect competition which will impact volume and price*'.³⁵²¹ Actavis UK Limited later continued AM Pharma's strategy to maintain its dominant position, implementing a '*communications plan*' drawing on the 'Project Guardian' materials.
- f. In January 2016, [X] estimated Actavis's market share in an email (copying [Actavis Senior Employee 3], [X]) at '*100% plus*'.³⁵²² Although

³⁵¹⁶ Document 00135, 'Project Guardian' slide pack dated February 2014.

³⁵¹⁷ Document 00157, email exchange between [Auden Senior Employee 4] and the DHSC dated 5 June 2014.

³⁵¹⁸ Document 00705, Project Apple presentation dated September 2014.

³⁵¹⁹ Document 00681, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016, Annex 11, page 17: Project Apple due diligence report dated 11 December 2014.

³⁵²⁰ Document 202954, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2], [AMCo Senior Employee 6] and [AMCo Senior Employee 3] dated 20 May 2015.

³⁵²¹ Document 02312, email from [Actavis Senior Employee 4] to [X] dated 28 September 2015 (emphasis added).

³⁵²² Document 02302, email from [X] to [X] (copying [Actavis Senior Employee 3]) dated 18 January 2016.

Alissa had entered by then, this demonstrates Actavis's own views on the strength of its market position.

- g. As explained in section 9.B.I.c, Intas and Accord were made aware of the CMA's investigation prior to the acquisition of Actavis UK Limited, including that this involved a potential abuse of a dominant position. When Intas and Accord acquired Actavis UK Limited, [Actavis Senior Employee 1] [REDACTED] and [Actavis Senior Employee 3] [REDACTED]. [REDACTED], [Actavis Senior Employee 3] [REDACTED]. As explained above, prior to the Intas acquisition [Actavis Senior Employee 1] and [Actavis Senior Employee 3] had been made aware of Auden's efforts to protect its dominant position through 'Project Guardian', and had monitored entry into the market.³⁵²³ [Actavis Senior Employee 3] had briefed Actavis UK Limited's field teams on the differences between Alissa's product and Actavis UK Limited's as part of its '*communications plan*', following Alissa's launch and input from AM Pharma.³⁵²⁴ After its acquisition by Intas and Accord, Actavis UK Limited therefore continued to operate under the management that had previously taken steps to preserve its dominant position.³⁵²⁵

10.26. Auden/Actavis therefore knew or should have known that it had a dominant position.

ii. Prices were unfair

10.27. Auden/Actavis knew or should have known the essential facts establishing that its prices during the infringement periods were unfair.

10.28. Evidence supporting this includes, for example:

- a. As explained in section 5 above, Auden/Actavis increased prices for hydrocortisone tablets by over 10,000% from less than £1 per pack (the price charged under the drug's previous owner, which had sold the drug since 1955) to £72 per pack. These increases were not

³⁵²³ See for example Document 00438, email from [Actavis Senior Employee 3] to [Actavis Senior Employee 1] and others dated 15 October 2015 highlighting that Alissa had launched its product; and Document 02306, email from [Actavis Senior Employee 3] to [Actavis Senior Employee 1] and [Actavis Senior Employee 2] dated 4 September 2015, discussing entry by Waymade. See also Document 02337, email from [Actavis Senior Employee 3] to [Auden Senior Employee 4] dated 16 October 2015, in relation to the entry of Alissa.

³⁵²⁴ Document 02337, email from [Actavis Senior Employee 3] to [Auden Senior Employee 4] dated 16 October 2015.

³⁵²⁵ Accord-UK submitted that the CMA cannot rely on the fact that Accord-UK was aware of the CMA's investigation to establish intention. See Document 205813, Accord-UK's RDPS, paragraph 4.23. The CMA considers this factor to be relevant in establishing whether an undertaking knew or should have known that it was dominant in the relevant market(s) and that its conduct had been provisionally found to be abusive. This factor is one of a number that, in the CMA's view, establish that Auden/Actavis acted intentionally or negligently. Further examples show Auden/Actavis's conduct after it became aware of the investigation, and was continuing to operate in the same way.

accompanied by any material increases in production costs; nor had there been any investment in R&D in the product. On the contrary, the price increases were implemented in respect of a very old drug, which was long off patent, had been genericised, and in respect of which Auden/Actavis made no material investments or innovations since genericisation. Indeed, Auden/Actavis added no benefits for patients beyond those already available through the original hydrocortisone tablets first sold in 1955.

- b. Auden/Actavis's prices for hydrocortisone tablets exceeded any reasonable measure of its costs plus a reasonable return. The purchase price of its product remained stable, and although Actavis's prices decreased from 2016 onwards, they remained significantly in excess of cost plus a reasonable return.³⁵²⁶
- c. Auden/Actavis knew what its costs were and what its prices were. It knew that the disparity between those figures did not reflect any additional costs, investment or benefit to patients that would increase the economic value of its product significantly beyond costs plus a reasonable return (and in any event ought to have known this):
 - i. In interview with the CMA, [Auden Senior Employee 1] and [Auden Senior Employee 2] were both unable to point to any actual increase in costs relating specifically to hydrocortisone tablets.³⁵²⁷
 - ii. Allergan conducted extensive due diligence before acquiring AM Pharma and PwC informed it of the cost per pack of 10mg hydrocortisone tablets in December 2014.³⁵²⁸
 - iii. As explained above, Intas and Accord were made aware of the CMA's investigation prior to their acquisition of Actavis UK Limited, including that this involved a potential abuse of charging excessive and unfair prices for hydrocortisone tablets.
- d. Indeed, Auden/Actavis was aware that it was able to exploit its dominant position by increasing prices (and in any event should have known this):

³⁵²⁶ See section 5.C.III above.

³⁵²⁷ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, p.63. Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, pp.18-25.

³⁵²⁸ Document 00681, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016, Annex 11, page 21: Project Apple due diligence report dated 11 December 2014.

- i. The financial due diligence report prepared by PwC in December 2014 highlighted the *'current lack of competition'* and the fact that *'there appears to be scope for further price increases, albeit this will be subject to negotiation with the Company's customers'*.³⁵²⁹ After the acquisition, Auden/Actavis continued to implement such *'further price increases'*.
- ii. Aware of the costs involved in supplying the product and of the lack of competition, Allergan internal presentations in December 2014 and January 2015 highlighted hydrocortisone tablets as a *'[n]ear term cash cow'*.³⁵³⁰

10.29. None of the contemporaneous evidence seen by the CMA shows any regard for the interests of the NHS in any strategic decision making in relation to prices by Auden/Actavis. In fact, [Auden's External Consultant] advised Auden in relation to 'Project Guardian' that *'[t]here is a risk of negative reaction / price sensitivity if we raise profile'*, when discussing the possibility of approaching NHS stakeholders to address the potential launch of skinny label hydrocortisone tablets.³⁵³¹

c. Application to Auden/Actavis: the Agreements

- 10.30. Based on the evidence set out in this Decision, the CMA concludes that the undertaking Auden/Actavis cannot have been unaware that its conduct in participating in the Agreements was anti-competitive in nature. In particular, it knew or should have known that:
- a. each of Waymade and AMCo was its potential competitor at the time of the relevant Agreements;
 - b. it was making significant payments to each of Waymade and AMCo; and
 - c. those payments were in exchange for non-entry of Waymade and AMCo (as the case may be) for the duration of the Agreements;
- and, therefore, that the Agreements were anti-competitive in nature.

³⁵²⁹ Document 00681, AM Pharma's response to the CMA's section 26 notice dated 23 June 2016, Annex 11, page 17: Project Apple due diligence report dated 11 December 2014.

³⁵³⁰ Document 00679, Project Apple: Auden Mckenzie (UK) presentation dated December 2014; and Document 00706, Project Apple: Auden Mckenzie (UK) presentation dated January 2015.

³⁵³¹ Document 00135, 'Project Guardian' Slide Pack dated February 2014.

10.31. The CMA therefore finds that Auden/Actavis entered into the Agreements intentionally or, at the very least, negligently.

i. Potential competitors

Waymade

10.32. Auden knew or should have known of Waymade's position as a potential competitor when it entered into the **20mg Agreement** in July 2011.

10.33. Evidence of this includes, for example:

- a. In an email on 28 June 2011, shortly before the parties entered into the 20mg Agreement, [Auden Senior Employee 2] recognised: *'if Waymade had their own licence and achieved 50% mkt share at current pricing then they would net £50K per mth.'*³⁵³² This demonstrates Auden's perception of Waymade as a competitive threat, derived from Waymade's 20mg MA. Auden expressed concern that it could lose half of its volumes to Waymade.
- b. [Auden Senior Employee 1] stated in interview with the CMA: *'I recall having an internal discussion which acknowledged Waymade was our competitor and that we could supply it with hydrocortisone tablets...'*. [Amdipharm Senior Employee] also told the CMA in interview that Auden would have been aware that Waymade had an MA and that this *'would put Waymade in a stronger competitive position in the market'*.³⁵³³
- c. In a subsequent interview, [Auden Senior Employee 1] explained that the 20mg Agreement was a way for Auden to *'maintain [its] volume'*; and Auden could not maintain its volume if Waymade entered the market: *'[Waymade] had a 20 milligram [MA] and it was either for us to do nothing, which we could have, or to supply them, which would maintain our volume and still make us money, so that's what we did.'*³⁵³⁴ Auden was therefore aware that Waymade had an MA and could have entered independently, which would have meant Auden would not have maintained its volume (ie its market share).

³⁵³² Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

³⁵³³ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.16 and 1.17; Document 302140, transcript of [Amdipharm Senior Employee] interview dated 7 June 2018, page 29, lines 24 and 25; page 31, lines 11 to 12.

³⁵³⁴ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 31, line 27 and page 32, lines 1 to 3 (emphasis added).

- d. The fact that Auden entered into the 20mg Agreement in itself demonstrates its awareness of the competitive threat posed by Waymade's 20mg MA and work to develop its own product.
- 10.34. Auden knew or should have known of Waymade's position as a potential competitor at the time that it entered into the **10mg Agreement** in October 2012. Evidence of this includes, for example:
- a. [Auden Senior Employee 1] said that Auden's approach to the 10mg Agreement was the same as the 20mg: Auden 'wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]'.³⁵³⁵ In a later interview, [Auden Senior Employee 1] stated: 'they [Waymade] had said, 'look we've got a product and we would like to take supply from you'. So again, in the same scenario [as the 20mg Agreement] as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable.'³⁵³⁶
 - b. As explained in section 6.B.II.b above, Waymade obtained its 10mg MA on 27 September 2012. From July 2011 until that date, Auden sold Waymade 10mg hydrocortisone tablets at market rate. However, very shortly after Waymade obtained the 10mg MA, from October 2012 Auden reduced Waymade's supply price by 97%, to £1 per pack. This dramatic change in Auden's supply price to Waymade is explained by the competitive threat that Waymade represented by virtue of its 10mg MA. The 10mg Agreement therefore in itself demonstrates Auden's awareness of the competitive threat posed by Waymade's 10mg MA and work to develop its own product.

AMCo

- 10.35. Auden/Actavis knew or should have known of AMCo's position as a potential competitor to Auden/Actavis from 31 October 2012, when it replaced Waymade as Auden's counterparty to the **10mg Agreement**, onwards.
- 10.36. Auden was asked shortly after the public announcement of the sale of the Amdipharm group to continue to supply Amdipharm, which would now be part of AMCo and not Waymade, with 10mg hydrocortisone tablets under the

³⁵³⁵ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.20 (emphasis added).

³⁵³⁶ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68 (emphasis added).

10mg Agreement.³⁵³⁷ Auden continued to supply AMCo under the 10mg Agreement and increased AMCo's allocation of monthly packs from 2,000 to 6,000 packs at £1 per pack. The low prices were no longer available to Waymade. Auden must therefore have been aware that it was now AMCo that held the threat of independent entry with its own 10mg product over Auden. As [Auden Senior Employee 1] indicated in his witness statement, that price was not available to other customers who were '*pure wholesalers*'.³⁵³⁸ His rationale for the 10mg Agreement was to protect Auden's volumes against Amdipharm's entry.

10.37. When Auden was considering ending the 10mg Agreement in January 2014, it launched 'Project Guardian' specifically in response to the threat of AMCo's entry. This is important evidence confirming that Auden knew or should have known that AMCo was its potential competitor when the two parties renewed the terms of the 10mg Agreement in June of the same year:

- a. The stated purpose of 'Project Guardian' was '*to ensure that its [Auden McKenzie's] current market share for the supply of hydrocortisone tablets ... is maintained or strengthened at a time when a competitors [sic] product (namely Amdipharm Mercury Company Limited [AMCo] hydrocortisone tablets 10mg ...) threatens to weaken Auden McKenzie's market share*'.³⁵³⁹ Auden was therefore responding to its awareness of the threat of competition from AMCo, notwithstanding the orphan designation.
- b. On 12 February 2014, [Auden Senior Employee 4] emailed an external consultant about the possibility of reintroducing the 'Hydrocortone' brand as a protective measure, noting that the only other MA for hydrocortisone tablets '*is held by Amdipharm, who will launch their product in Q2/3 2014*'.³⁵⁴⁰ Auden therefore understood that AMCo would imminently be entering the market with its own product, and was concerned to take steps to protect its position.

³⁵³⁷ Document 200348, transcript of [Amdipharm Senior Employee] interview dated 4 August 2016, page 16 lines 2 to 8. [Auden Senior Employee 1] explained that '*after the move from Waymade to Amdipharm ... In 2012, we supplied Amdipharm at a price of £1 per pack*'. Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20. See also Document 300331, email from [Waymade Senior Employee 1] to [Amdipharm Senior Employee] dated 13 November 2012.

³⁵³⁸ [Auden Senior Employee 1] stated that '*We did not offer this price to other customers as those other customers would have been pure wholesalers, whereas Amdipharm was not only a wholesaler, but carried out a range of work including product development and product marketing and sales*'. Document 00725, witness statement of [Auden Senior Employee 1] dated 12 September 2016, paragraph 1.20.

³⁵³⁹ Document 00062F, Professional Advice (Hydrocortisone) Proposal Prepared for Auden McKenzie (Pharma Division) Ltd by [Auden's External Consultant] dated 6 February 2014, Client Requirements (emphasis added).

³⁵⁴⁰ Document 00164, email from [Auden Senior Employee 4] to [X] (MAP BioPharma) dated 12 February 2014.

- c. Slides prepared for the project in February 2014 compared the Auden and AMCo products side by side and stated: *'It is ... essential to be proactive ahead of Amdipharm's product entry into the UK market in attempt to hold Auden Mckenzie share about 50% and as close to the existing position as possible*'. The slides went on to conclude that despite Auden's position as *'the most established generic in the market ... new competitor entry remains a real threat and action is necessary to avoid unnecessary decline in share*'.³⁵⁴¹ Auden therefore perceived a real and specific threat to its market position from entry by AMCo.
- d. On 4 April 2014 [Auden Senior Employee 4] stated: *'The competitor product will launch mid-May/beginning June ... so we should get these letters out asap*'.³⁵⁴² In context, [Auden Senior Employee 4] was referring to AMCo's 10mg product:
 - i. A *'communications proposal'* prepared by an external consultancy firm for Auden in April 2014 explained that *'Auden Mckenzie is reacting to a potential threat to its market share of hydrocortisone 10mg tablets. The threat comes from new arrival, Amdipharm [AMCo], whose product may be adopted as a cheaper alternative to the current market leader*'.³⁵⁴³
 - ii. The letters Auden sent to key external stakeholders, attempting to discourage use of AMCo's product off-label, specifically referred to AMCo's 10mg product.³⁵⁴⁴

10.38. In the negotiations leading to the Second Written Agreement, in June 2014 [AMCo Senior Employee 1] told [AMCo Senior Employee 8] about a conversation he had with [Auden Senior Employee 1]: *'As for the start date yes it is for delivery this month ... I told him [[Auden Senior Employee 1]] that if not we will launch our own*'.³⁵⁴⁵ This statement was a direct threat to enter and take market share from Auden. Auden responded by agreeing to the Second Written Agreement, which involved supplying double the volume supplied to AMCo before, thus demonstrating that Auden took this direct threat seriously.

³⁵⁴¹ Document 00135, 'Project Guardian' slide pack dated February 2014, slides 7, 9 and 33.

³⁵⁴² Document 00110A, email from [Auden Senior Employee 4] to [Auden's External Consultant] dated 4 April 2014.

³⁵⁴³ Document 00137, 'A communications proposal to support "Project Guardian"', submitted by Salix Consulting dated 16 April 2014, slide 3.

³⁵⁴⁴ See, for example, Document 00119, template letter to chief pharmacists dated 14 April 2014.

³⁵⁴⁵ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8], [AMCo Senior Employee 4], [AMCo Senior Employee 6] and [AMCo Senior Employee 2] dated 15 June 2014.

- 10.39. Allergan, which acquired AM Pharma in May 2015, was also aware that the orphan designation did not preclude suppliers of skinny label products such as AMCo (whose MA was in the public domain) from being a potential competitor. An internal Auden email from [Auden Senior Employee 1] to [Auden Senior Employee 5] stated that in November 2014, *'Actavis [now Allergan] were seriously concerned about the new Orion license [sic] been [sic] used "Off label" and the impact this would have on their investment if they acquired Auden.'*³⁵⁴⁶ As described above, this led to a reduction in the purchase price for AM Pharma with the aim of providing a *'complete de-risking'* for Allergan.
- 10.40. After taking over supplies of hydrocortisone tablets, and performance of the 10mg Agreement, from AM Pharma in September 2015, Accord-UK continued to be aware of the competitive threat exerted by AMCo. As [Actavis Senior Employee 1] (Accord-UK) confirmed in his interview, Actavis was supplying AMCo at a low price *'effectively competing against AMCo's in-house or contract relationship with another supplier'* (ie Aesica).³⁵⁴⁷ Accord-UK was therefore aware that AMCo had an alternative option, whether in-house or through another supplier, and therefore that AMCo exerted a competitive threat on Auden/Actavis. Further, as explained in section 3.F.III.p above, following the sale of AM Pharma to Allergan, in October 2015 the materials Auden had prepared for 'Project Guardian' were collected and circulated internally within Accord-UK.³⁵⁴⁸ Accord-UK then implemented a *'communications plan'*, drawing directly on those materials in the first quarter of 2016.³⁵⁴⁹ Therefore, it also understood more generally that skinny label suppliers (like AMCo) posed a threat of independent entry.

ii. Payments

- 10.41. Auden/Actavis knew or should have known that it was making significant payments to each of Waymade and AMCo.
- 10.42. In relation to the **20mg Agreement**:
- a. As explained in section 6.D.II.b.i, the majority of the payments were in cash, under the Buyback. Auden received monthly invoices from Waymade for these payments. It therefore must have known (and in

³⁵⁴⁶ Document 302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

³⁵⁴⁷ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 18 lines 12 to 13.

³⁵⁴⁸ Document 02316, email from [Auden Senior Employee 4] to [Actavis Senior Employee 3] dated 15 October 2016.

³⁵⁴⁹ Document 00656, AM Pharma's response to the CMA's section 26 notice dated 23 May 2016, paragraph 14.10.

any event should have known) that it was making these payments to Waymade. As explained above, these payments initially amounted to £24,000 per month and increased substantially.

- b. Auden must also have known (and in any event should have known) that by supplying the remaining 200 packs to Waymade at a heavily discounted rate which amounted to a margin transfer to Waymade, it was giving Waymade a considerable benefit over other customers:
 - i. Auden knew that it had agreed to supply Waymade at a heavily discounted rate compared to its other customers (initially 87%): as explained above, [Auden Senior Employee 2] initially proposed to supply Waymade at market rate (£34.50) before reducing the price to £4.50 a week later;
 - ii. [Auden Senior Employee 2]'s proposal of 28 June 2011 stated *'Selling [Waymade] 1K packs per month to enable them just under a third mkt share at £4.50 per pack would net them £30K per mth'*.³⁵⁵⁰ As explained above, £24,000 of that £30,000 derived from the Buyback. [Auden Senior Employee 2]'s calculation therefore necessarily implied that Waymade could expect to make a monthly profit of £6,000 from reselling the 200 packs: implying a resale price of £34.50, the same as Auden's price at the time.³⁵⁵¹ Auden therefore understood that by supplying Waymade with a specified volume of packs at a 'special' discounted price, Waymade could expect to make a significant profit margin from selling those packs in the market at a higher resale price.
 - iii. [Auden Senior Employee 2] further demonstrated his understanding of the mechanics of the margin transfer when he stated in his email of 28 June 2011 that he *'[w]ould be happier allowing a lower price on the 20mg because it would be in their interest to maintain high resale price'*.³⁵⁵²

10.43. In relation to the **10mg Agreement**:

- a. Just as in relation to the 20mg Agreement, Auden/Actavis must have known (and in any event should have known) that the 10mg Agreement – which entailed supplying each of Waymade and AMCo at a 97%

³⁵⁵⁰ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

³⁵⁵¹ 200 x £34.50, less cost of goods (200 x £4.50).

³⁵⁵² Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

discount on its ASP to other customers – would allow Waymade and AMCo to make a significant profit margin on resale of the packs, and that the supply therefore amounted to significant monthly payments to Waymade and AMCo.

- b. Internal documents produced by Accord-UK staff after it took over sales of hydrocortisone tablets from AM Pharma demonstrate its continued awareness of the opportunity cost to Actavis that these supply terms represented, and therefore the profit it allowed AMCo to make. Actavis's commercial staff assured [REDACTED]: *'I make sure that they [AMCo] have just the 1 order a month for 12,000 packs'*.³⁵⁵³ [Actavis Senior Employee 2] noted: *'vols should be 12k per month (one to keep an eye on)'*.³⁵⁵⁴
- c. In her interview with the CMA, [Actavis Senior Employee 2] confirmed Actavis's awareness of the opportunity cost of continuing to supply AMCo with 10mg hydrocortisone tablets at the discounted price: *'we knew what the opportunity cost was. I suppose, if you like, it was all tied up in the purchase of the entire Auden McKenzie business... we knew the breadth and depth of the contract'*.³⁵⁵⁵ Actavis's awareness of the *'opportunity cost'* of providing AMCo with the discount demonstrates that it must have been aware of the discount amounting to margin transfer to AMCo: in continuing to supply AMCo on these terms Actavis was foregoing profit on those volumes.

iii. In exchange for non-entry

- 10.44. Auden/Actavis knew or should have known that the counter-performance for the payments it made under the Agreements was that Waymade and AMCo would not enter the market independently with their own hydrocortisone tablets for the duration of the relevant Agreement.
- 10.45. As explained in section 6.D.II.c.i, Auden designed the **20mg Agreement** with the goal of ensuring that Waymade did not enter the market. In any event, Auden ought to have known that this was the reason for the payments. Auden offered Waymade a substantially reduced price in order to maintain its volumes, which in a finite market necessarily meant Waymade would not be entering the market if the negotiations were successful:

³⁵⁵³ Document 02335, email from [REDACTED] to [Actavis Senior Employee 1] dated 24 February 2016.

³⁵⁵⁴ Document 02329, email from [Actavis Senior Employee 2] to [REDACTED] dated 7 September 2015.

³⁵⁵⁵ Document 203351, transcript of [Actavis Senior Employee 2] interview dated 22 July 2019, page 16, lines 15 to 20.

- a. [Auden Senior Employee 2] of Auden confirmed that it was the threat to Auden's volumes that prompted him to offer the substantial discount: *'it was key that we maintain our volumes on this line so we'd be happy to supply at a lower price'*.³⁵⁵⁶ [Auden Senior Employee 2]'s statement confirms that Auden would only have supplied Waymade *'at a lower price'* if Waymade did not enter the market with its own 20mg hydrocortisone tablets. The aim of the *'lower price'* was to *'maintain our [Auden's] volumes'*. This would only have been achieved if Waymade did not enter the market.
- b. Auden understood that *'If Waymade had their own licence and achieved 50% mkt share at current pricing then they would net £50K per mth'*. [Auden Senior Employee 2] therefore designed his proposal to neutralise this threat, on the understanding that Waymade would be *'not bringing the product to market.'*³⁵⁵⁷
- c. Further, the terms on which the parties agreed in the 20mg Agreement included the *'RAMA clause'*. This provision that the parties would re-visit the 20mg Agreement's terms if a third party was granted a 20mg MA further demonstrates that the payments were given in the expectation that Auden would remain the only supplier on the market.

10.46. As explained in section 6.D.II.c.ii, Auden agreed the **10mg Agreement** on the same basis as the 20mg Agreement – to protect its volumes from the threat of entry that Waymade and later AMCo derived from its 10mg MA:

- a. In interview with the CMA, [Auden Senior Employee 1] confirmed that Auden's approach to the 10mg Agreement was the same as the 20mg Agreement. [Auden Senior Employee 1] further stated: *'they [Waymade] had said, 'look we've got a product and we would like to take supply from you'. So again, in the same scenario as long as we, we gave them supply, which would again maintain our volumes ... that was acceptable.'*³⁵⁵⁸ As with the 20mg Agreement, the explanation for the payments is therefore that they were in exchange for Waymade not entering the market with its own 10mg hydrocortisone tablets, and Auden knew or should have known this.

³⁵⁵⁶ Document 00716, transcript of [Auden Senior Employee 2] interview, page 16, lines 3 to 4. He confirmed this in a subsequent interview, in which he said that Auden was *'keen to make sure that we maintain our volumes of this product for the purposes of the contract manufacturer'* (Document 301358, transcript of [Auden Senior Employee 2] interview dated 23 May 2018, part 1, page 17, lines 18 to 20).

³⁵⁵⁷ Document 00031C, email from [Auden Senior Employee 2] to [Auden Senior Employee 1] dated 28 June 2011.

³⁵⁵⁸ Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68.

- b. [Auden Senior Employee 1] confirmed that the rationale for making payments to AMCo under the 10mg Agreement remained to protect Auden's volumes. He stated specifically with respect to supplying AMCo that AMCo was not a '*pure wholesaler*' and that '*[w]e wanted to protect our volumes ordered through Tiofarma for 10mg tablets as well.*'³⁵⁵⁹
- c. In December 2013 Auden was '*still supplying hydrocortisone [to AMCo] but ... being increasingly aggressive and threatening that the orphan drug status of their product means that our product ... is not comparable to theirs*'.³⁵⁶⁰ As explained in section 6.D.II.c.ii above, Auden's stance demonstrates that continued supply (ie continued payments) to AMCo was contingent on non-entry by AMCo, since the issue of whether AMCo's skinny label product was '*comparable*' to Auden's would not otherwise be relevant.
- d. Further, as mentioned above, during the negotiation of the Second Written Agreement [AMCo Senior Employee 1] stated in an email to [AMCo Senior Employee 8], '*As for the start date yes it is for delivery this month ... I told him [[Auden Senior Employee 1]] that if not we will launch our own*'.³⁵⁶¹ [AMCo Senior Employee 1]'s statement to [Auden Senior Employee 1] made clear to Auden that it could neutralise the threat of AMCo's entry by renewing and increasing the payments under the 10mg Agreement, which it did ten days later.
- e. In interview with the CMA, [X] [Actavis Senior Employee 1] stated that the reason for Actavis continuing to make the £1.78 supply price available to AMCo after it took over performance of the 10mg Agreement in September 2015 was that Actavis '*was effectively competing against AMCo's in-house or contract relationship with another supplier*' (ie Aesica).³⁵⁶² '*Competing against*' Aesica to supply AMCo necessarily entails Actavis understanding that if the 10mg Agreement continued (ie if Actavis '*won*'), AMCo would not enter with its Aesica-manufactured product. Indeed, [Actavis Senior Employee 1] confirmed this when he stated that '*AMCo's alternative [to supply from*

³⁵⁵⁹ Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.

³⁵⁶⁰ Document 200160, Mercury Pharma Group Limited management meeting minutes dated 19 December 2013.

³⁵⁶¹ Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8], [AMCo Senior Employee 4], [AMCo Senior Employee 6] and [AMCo Senior Employee 2] dated 15 June 2014 (emphasis added).

³⁵⁶² Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 18 lines 12 to 13.

Actavis] was using their MA and getting it contract manufactured elsewhere'.³⁵⁶³

- 10.47. In light of the factors set out at paragraphs 10.32 to 10.46 above, the CMA concludes that the undertaking Auden/Actavis knew or should have known that the Agreements were anti-competitive in nature.
- 10.48. Accord-UK and Cinven submitted that intention or negligence cannot be established because the anti-competitive terms of the Agreements had to be inferred.³⁵⁶⁴ The CMA does not accept these submissions.
- 10.49. As is clear from the evidence and analysis set out in section 6.D of this Decision, the CMA has not simply '*inferred*' AMCo's or Waymade's agreement not to enter from its conduct or from the absence of any other explanation. The CMA finds on the basis of a significant body of evidence, taken together and assessed as a whole, that the parties entered into the Agreements and each of the constituent elements of those Agreements has been extensively evidenced. The body of evidence on which the CMA has relied includes contemporaneous documentary evidence and corroborating *ex post* interview evidence. The CMA finds in particular that the anti-competitive terms of the Agreements were clear to all the key players in the negotiations, who each understood the reason for the payments from Auden/Actavis.
- 10.50. In any case, it is wrong in law to state that if part of an infringement finding is based on inference this would preclude the imposition of penalties. That would only be the case if it cannot be established that the undertaking knew or should have known that its conduct had the object or would have the effect of restricting competition.

d. Application to Waymade

- 10.51. Based on the evidence set out in this Decision, the CMA concludes that the undertaking Waymade cannot have been unaware that its conduct in participating in the Agreements was anti-competitive in nature. In particular, it knew or should have known that:

³⁵⁶³ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 17 line 26 and page 18 line 1 (emphasis added). See also page 18 lines 16 to 21: '[CMA interviewer]: So, was your understanding then for as long as you're supplying AMCo at this price, they won't be getting supply from their own alternative CMO and entering with their own product? [[Actavis Senior Employee 1]]: Well, that's my understanding now. And that was I think one of the terms that AMCo needed to give notice if they use their own, different source.'

³⁵⁶⁴ Document 205813, Accord-UK's RDPS, paragraph 4.32. Document 205805, Cinven's RDPS, paragraph 2.11.

- a. it was a potential competitor to Auden/Actavis at the time of the relevant Agreements;
- b. it was receiving significant payments from Auden/Actavis; and
- c. those payments were in exchange for Waymade's non-entry with its own products for the duration of the Agreements;

and, therefore, that the Agreements had as their object the restriction of competition.

10.52. The CMA therefore finds that Waymade entered into the Agreements intentionally or, at the very least, negligently.

i. Potential competitor

10.53. Waymade knew or should have known during its time as counterparty to the Agreements that it was a potential competitor to Auden. As explained in section 6.D.II.c above, Waymade was aware that it exerted competitive pressure on Auden and used the threat of entry as leverage to convince Auden to enter both Agreements.

10.54. As explained in section 6.C.II.b.ii above, at the time that Waymade entered into the **20mg Agreement** in July 2011, Waymade had an MA for 20mg hydrocortisone tablets and could have entered the market with the Third Validation Batch which had passed all necessary testing and had been packed for sale. Extensive evidence confirms that Waymade must have been aware that it had real concrete possibilities of entering the market (see section 6.C.II.b.ii above) and therefore that it was a potential competitor. In any event, it should have known that it was a potential competitor.

10.55. At the time that Waymade entered into the **10mg Agreement** in October 2012, Waymade had an MA for 10mg hydrocortisone tablets and had made significant investments in order to enter the market. Again, extensive evidence confirms that Waymade must have been aware that it had real concrete possibilities of entering the market (see section 6.C.II.b.iii above) and therefore that it was a potential competitor. In any event, it should have known that it was a potential competitor.

ii. Payments

10.56. Waymade knew or should have known that it was receiving significant payments from Auden/Actavis in relation to both the 10mg Agreement and the 20mg Agreement.

10.57. As explained in section 6.D.II.b above, in relation to the **20mg Agreement**:

- a. The majority of the payments were in cash, under the Buyback. Waymade sent monthly invoices to Auden/Actavis for these payments. It therefore must have known that it was receiving these payments from Auden/Actavis. It even had to use an accounting code for '*promotional activities*' that did not reflect any such activities to account for the payments it was receiving from Auden. In any event, Waymade should have known that it was receiving these payments.
- b. Waymade must also have known that by receiving the 200 packs from Auden/Actavis at a heavily discounted rate, it would be able to make a significant profit margin on resale. It had received an email with Auden's prevailing prices, and subsequently it was offered the heavily discounted £4.50 price. It could not have been unaware that this represented a significant discount. In any event, Waymade should have known this.

10.58. As explained in section 6.D.II.b above, in relation to the **10mg Agreement**, the £1 price Waymade paid for 2,000 packs of 10mg hydrocortisone tablets was a 97% discount on the price it had been paying only a few days earlier (£34.50 in September 2012), and on Auden's ASP to its other customers (£31.80). Waymade had previously been paying a price of £34.50 per pack, so it should have known that its new £1 price represented a significant discount.

iii. In exchange for non-entry

10.59. Waymade knew or should have known that the counter-performance for the payments it received under the Agreements was its agreement not to enter the market with its own hydrocortisone tablets.

10.60. As explained in section 6.D.II.c.i above, Waymade clearly understood that receiving monthly payments and entering the market were mutually exclusive options, and therefore that the payments were in exchange for its agreement not to enter the market. In any event, Waymade should have known this. Extensive evidence confirms that Waymade used its 20mg product as leverage to obtain the payments in the 20mg Agreement. Such leverage is only effective on the understanding that sufficient payments would neutralise the threat of entry.

10.61. Further, as explained above, Waymade delayed its reformulation work in 2011 as a result of its negotiations with Auden, and froze its product when it succeeded in obtaining the 20mg Agreement, demonstrating its awareness

that in exchange for the payments it received, it would not enter (see section 6.D.II.c.i above).

10.62. Waymade approached the **10mg Agreement** in the same way as the 20mg Agreement, and the individuals involved demonstrated their awareness that the payments under this agreement were in exchange for non-entry in interviews with the CMA:

- a. [Waymade Senior Employee 1] stated: *'His [[Auden Senior Employee 1]]'s volumes would start dropping, once we fight him [[Auden Senior Employee 1]] in the market, which we would'*.³⁵⁶⁵
- b. [Waymade Senior Employee 1] also stated: *'They gave the product to us at a price because we had told them [Auden] that we can manufacture it at a certain price, and for them [Auden] not to lose their volumes, it would be attractive for them [Auden] to supply the product'*.³⁵⁶⁶ In order to allow Auden to *'not lose their volumes'*, Waymade would need to refrain from entering the market with its own competing product.
- c. [Waymade Senior Employee 1] also stated: *'... as far as he [[Auden Senior Employee 1]] is concerned, I have got the licence and I have got another source.'* He added: *'As soon as we come in the market, his volumes will start diminishing so his costs will start going up, and that's how the market works.'*³⁵⁶⁷
- d. [Amdipharm Senior Employee] also stated: *'Perhaps Auden Mckenzie responded to an inference from me that it could either supply Waymade, or I'd get someone else to supply me and if Auden Mckenzie wanted to retain its manufacturing volumes, then it might agree to supply me.'*³⁵⁶⁸

e. Application to AMCo

10.63. Based on the evidence set out in this Decision, the CMA concludes that the undertaking AMCo cannot have been unaware that its conduct in participating in the 10mg Agreement was anti-competitive in nature. In particular, it knew or should have known that:

³⁵⁶⁵ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 140, lines 3 to 4.

³⁵⁶⁶ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 12, lines 1 to 3 (emphasis added).

³⁵⁶⁷ Document 302145, transcript of [Waymade Senior Employee 1] interview dated 27 June 2018, page 138, lines 12 to 20 and page 140, lines 14 to 16.

³⁵⁶⁸ Document 200354, Witness Statement of [Amdipharm Senior Employee] dated 24 October 2016, paragraph 1.22 (emphasis added).

- a. it was a potential competitor to Auden/Actavis at the time of the 10mg Agreement;
- b. it was receiving significant payments from Auden/Actavis; and
- c. those payments were in exchange for AMCo's non-entry with its own product for the duration of the 10mg Agreement;

and, therefore, that the 10mg Agreement had as its object the restriction of competition.

10.64. The CMA therefore finds that AMCo entered into the 10mg Agreement intentionally or, at the very least, negligently.³⁵⁶⁹

i. Potential competitor

10.65. AMCo knew or should have known during its time as counterparty to the **10mg Agreement** that it was a potential competitor to Auden/Actavis.

10.66. As explained in section 6.C.II.b.iv above, when the Amdipharm group was sold to Cinven on 31 October 2012, all the factors which made Waymade a potential competitor to Auden were transferred to AMCo. The AMCo undertaking effectively stepped into the Waymade undertaking's shoes as a potential competitor to Auden effective from 31 October 2012. AMCo had real concrete possibilities of entering the market: '*sufficient preparatory steps*' had been taken to demonstrate its '*firm intention and an inherent ability*' to enter the market. In particular:

- a. Entry was possible in the short term. AMCo had acquired Waymade's 10mg MA³⁵⁷⁰ and an approved process to produce 10mg hydrocortisone tablets. From 31 October 2012 AMCo was never further away than around six to eight months from having market-ready 10mg hydrocortisone tablets with which it could have independently entered the market. This is demonstrated by each instance where AMCo made a serious push for obtaining market-ready product. See further section

³⁵⁶⁹ AMCo submitted that it had not had an opportunity to make representations on the CMA's case on intention and negligence for fining purposes (see Document 205848, AMCo's RDPS, paragraphs 2.6 to 2.13). AMCo makes this assertion on the basis of the legal test it submitted should apply, which has no basis in law as addressed above at paragraph 10.17. In any event, the CMA's case was clearly set out in the SSO issued to AMCo and so there is no basis for such a complaint. Cinven submitted that the CMA had not substantiated its findings of intention/negligence against AMCo and that intention/negligence cannot in any case be established (Document 205805, Cinven RDPS, paragraphs 2.1 to 2.5). The CMA does not accept these submissions. The CMA establishes intention/negligence to the requisite standard on the part of AMCo in paragraphs 10.63 to 10.72. As set out above, intention and negligence applies at the level of the undertaking so any distinction along the lines of the respective ownership periods for AMCo and Cinven is artificial for the purposes of the CMA's jurisdiction to impose a penalty under s.36(3) of the Act.

³⁵⁷⁰ On 31 October 2012 AMCo acquired the beneficial interest in the MA with the Amdipharm acquisition and the legal transfer was completed after approval was obtained from the MHRA on 9 May 2013.

6.C.II.b.iv (in particular, section '*Entry remained possible in the short term*'). In particular, AMCo used the threat of its imminent potential entry as leverage in its negotiations with Auden and declared its potential to enter the market during these negotiations.³⁵⁷¹ For example, [AMCo Senior Employee 1] reported internally that he had used AMCo's competitive threat to Auden to negotiate for an increased volume (supply of 12,000 packs) of 10mg hydrocortisone tablets, stating that he had told [X]: '*I told him that if not we will launch our own*'.³⁵⁷² In interview, [AMCo Senior Employee 1] stated that '*I wanted him [[Auden Senior Employee 1]] to understand that we were able to launch*' because he thought '*that it [AMCo's ability to enter] was more likely to help him [[Auden Senior Employee 1]] give me some better terms*'.³⁵⁷³

- b. Entry was economically viable. This is supported, for example, by AMCo internal documents that demonstrated that AMCo could enter the market and make substantial profit, and AMCo's actions in dedicating considerable resources to developing a product which would be ready for launch. See further section 6.C.II.b.iv (in particular, section '*Entry continued to be economically viable*').
- c. There were no insurmountable barriers to entry. In particular, AMCo and Auden did not consider that the orphan designation afforded to Plenadren would prevent AMCo's entry into the market. See further section 6.C.II.b.iv (in particular '*There were no insurmountable barriers to entry*') and section 3.E.IV.³⁵⁷⁴

10.67. Therefore, the CMA concludes that AMCo knew or should have known it was a potential competitor.³⁵⁷⁵

ii. Payments

10.68. AMCo knew and/or should have known that it was receiving significant monthly payments from Auden/Actavis as the counterparty to the 10mg Agreement. As explained in section 6.D.II.b.ii above, the £1 price AMCo paid

³⁵⁷¹ As set out above, the CAT has considered that an undertaking which holds an MA and '*with a declared intention of entering the market in the near future*' should be regarded as a potential competitor (see *Lexon (UK) Limited v Competition and Markets Authority* [2021] CAT 5, paragraph 234).

³⁵⁷² Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 6], [AMCo Senior Employee 8] and [AMCo Senior Employee 2] dated 15 June 2014

³⁵⁷³ Document 201997, [AMCo Senior Employee 1] interview transcript dated 7 June 2018, page 25 lines 1 and 10 to 11. See also pages 2 to 3.

³⁵⁷⁴ In addition, Auden viewed AMCo as a potential competitor: see section 6.C.II.b.iv, in particular section '*Auden perceived AMCo to be a competitive threat*'.

³⁵⁷⁵ In reaching this conclusion the CMA has relied on AMCo's own evidence and evidence relating to Waymade staff that moved across to AMCo, that supports the finding that AMCo was a potential competitor.

for 2,000 and then 6,000 packs per month, and the £1.78 price it subsequently paid for 12,000 packs per month, of 10mg hydrocortisone tablets, represented a discount of around 97% on Auden's ASP to its other customers (£32 in November 2012, £47 in June 2014 and £63 in June 2016).

- 10.69. AMCo knew what the prevailing ASPs in the market were, as it was itself reselling Auden's 10mg hydrocortisone tablets making a considerable margin. It could therefore not have been unaware that its £1 and £1.78 prices represented a significant discount that allowed it to make a significant profit. In any event, it ought to have known this.³⁵⁷⁶

iii. In exchange for non-entry

- 10.70. AMCo knew or should have known that the counter-performance for the payments it received under the 10mg Agreement was its agreement not to enter the market with its own 10mg hydrocortisone tablets.
- 10.71. As explained in 6.D.II.c above, AMCo clearly understood that receiving monthly payments and entering the market independently of Auden/Actavis were mutually exclusive options, and therefore that the payments were in exchange for its agreement not to enter the market.
- 10.72. In any event, AMCo ought to have known this. Evidence of this includes, in particular:
- a. AMCo acted consistently in using the threat of competitive entry as leverage to secure continued and increasing payments. In particular, AMCo actively communicated its continued commitment not to enter independently by negotiating with Auden to raise the price it paid to continue buying off AMCo's entry in June 2014. [AMCo Senior Employee 1] made a direct threat to '*launch our own [10mg tablets]*' in order to secure the volume (and therefore payment) increase in the Second Written Agreement.
 - b. AMCo took steps to cancel its 10mg product development and ensure its launch-ready 10mg product would not be sold in the UK when it succeeded in obtaining increased payments in the Second Written Agreement, demonstrating its awareness that in exchange for the

³⁵⁷⁶ Cinven submitted that AMCo could not have been aware of the restrictive effects of the 10mg Agreement because of (i) barriers to AMCo's independent entry, and (ii) AMCo's understanding that the 10mg Agreement enhanced competition (Document 205805, Cinven RDPS, paragraphs 2.13 to 2.15). For the reasons set out in this paragraph, the CMA does not accept Cinven's submissions, as AMCo has been found to be a potential competitor at the material time and AMCo should have known that fact (including that there were no insurmountable barriers to entry) and of the anti-competitive nature of the 10mg Agreement.

payments it received, it would not enter. See further the detailed evidence set out at section 6.D.c.ii (in particular '*AMCo suspends its own 10mg product development on the same day as entering into the Second Written Agreement*').

- c. AMCo used its 10mg tablets to provide a '*back-up*' option in case the 10mg Agreement should end. AMCo's treatment of its Aesica product as a '*back-up*' (like its use as leverage in negotiations with Auden) demonstrates its adherence to its commitment not to enter with its own 10mg tablets. See further the detailed evidence set out at section 6.D.c.ii (in particular '*AMCo's treatment of its 10mg tablets as a 'back-up' in case the 10mg Agreement ended*').

iv. **AMCo's External Legal Advice**

10.73. AMCo engaged the external law firm Pinsent Masons LLP between June 2013 and June 2014 to advise on:

- a. whether AMCo could obtain a full label 10mg MA;
- b. whether competition law risks could arise from the undocumented 10mg supply arrangement with Auden that AMCo had acquired with the Amdipharm group; and
- c. the negotiation of the Second Written Agreement.

10.74. Pinsent Masons advised AMCo as follows:

- a. On 20 December 2013, a regulatory partner within the firm advised that the MHRA was precluded from granting AMCo a 10mg MA with the indication '*adrenal insufficiency*'.³⁵⁷⁷
- b. The competition law team of the firm issued an audit report on 28 August 2013, advising that the undocumented supply arrangement posed a '*medium*' competition law compliance risk for AMCo and should be formalised; and in an updated report issued on 27 January 2014, that the risk could be reduced to '*low*' provided the arrangement was brought to an end;³⁵⁷⁸

³⁵⁷⁷ Document 201088, advice from Pinsent Masons to [Amdipharm Senior Employee] dated 20 December 2013, page 3.

³⁵⁷⁸ Document 201100, Pinsent Masons competition law compliance audit report dated 27 January 2014, paragraphs 8.5.1 and 8.6.2.

- c. A competition law associate advised on the drafting of the First³⁵⁷⁹ and Second Written Agreements;³⁵⁸⁰ and
- d. The same associate advised on 6 June 2014 that:

*‘As a result of the orphan designation for 10mg hydrocortisone, AmCo [sic] cannot supply its 10mg hydrocortisone into the market in respect of the main therapeutic use, i.e. the treatment of adrenal insufficiency. The orphan designation is akin to an IP right and as such, from a competition law perspective in respect of this product and the orphan indication AmCo and Auden would not be considered competitors whilst the orphan designation was in place’.*³⁵⁸¹

- e. On the basis of this assumption the associate advised AMCo that entering into the Second Written Agreement was compatible with competition law.³⁵⁸²

10.75. AMCo waived privilege over this advice in order to disclose it to the CMA and submitted that it meant:

- a. The CMA had no power to fine AMCo for any infringement, as AMCo could not have committed it intentionally or negligently.³⁵⁸³ AMCo could not have known that it was a potential competitor of Auden,³⁵⁸⁴ given that its lawyers had advised that the orphan designation ‘was *irreversible and that the regulatory barrier created by it was insurmountable*’;³⁵⁸⁵ or that the 10mg supply deal was anti-competitive, given that both the First and Second Written Agreements were cleared for competition law compliance by external lawyers;³⁵⁸⁶ and

³⁵⁷⁹ Document 201970, email from [AMCo Senior Employee 8] to Pinsent Masons dated 30 May 2014: AMCo ‘will be looking to do a further 2 year agreement, based on the previous supply agreement for hydrocortisone that you and I drafted’.

³⁵⁸⁰ See, eg, document 201099, email from Pinsent Masons to [AMCo Senior Employee 8] dated 28 June 2014.

³⁵⁸¹ Document 201971, email from Pinsent Masons to [AMCo Senior Employee 8] dated 6 June 2014.

³⁵⁸² Document 201102, email from Pinsent Masons to [AMCo Senior Employee 8] dated 9 February 2017, paragraph 4.

³⁵⁸³ Document 205848, AMCo’s RDPS, paragraphs 2.13.2, 2.13.3, 4.24-4.33 and 6.29-6.51. See also Document 205947, AMCo’s submission to the CMA dated 22 December 2020, paragraph 13. Cinven made the same arguments: Document 205805, Cinven’s RDPS, paragraphs 1.9(d), 1.10 and 2.16–2.24. See also Document 205813, Accord-UK’s RDPS, paragraph 4.32.1.

³⁵⁸⁴ Document 204922, AMCo’s RSSO, paragraphs 3.37.2, 3.208-3.209, 3.617-3.620 and 4.93-4.97. See also Document 205848, AMCo’s RDPS, paragraph 6.17. See also Document 204967, Cinven’s RSSO, paragraphs 9.18 and 10.12.

³⁵⁸⁵ Document 204922, AMCo’s RSSO, paragraphs 3.37.2, 3.618-3.620.

³⁵⁸⁶ Document 205848, AMCo’s RDPS, paragraphs 4.25 and 6.46-6.47. See also paragraph 6.53 and Document 204922, AMCo’s RSSO, paragraphs 3.376, 3.600-3.602, 3.625-3.631, 3.693-3.703, 4.96, 5.107-5.111 and 6.96. See also Document 203737, AMCo’s RSO, paragraphs 12.7-12.15; 3.304-3.308; and 3.312-3.320; and Document 205805, Cinven’s RDPS, paragraph 2.21.

- b. If the CMA had the power to fine AMCo, any fine should be zero or only nominal.³⁵⁸⁷

10.76. The CMA rejects these submissions for the following reasons.

The law

10.77. As a matter of principle, the fact that an undertaking may commit an infringement following legal advice does not negate the existence of that infringement or preclude a finding of intention or negligence.^{3588, 3589} Intent and negligence relate to the undertaking's awareness of whether its conduct is anticompetitive, not whether it is unlawful.³⁵⁹⁰

³⁵⁸⁷ Document 205848, AMCo's RDPS, paragraphs 2.14, 2.17.3(c), 2.21.3, 4.31, 4.70.2, 6.66, 7.15.3(d), 7.32.1 and 7.46-7.52. See also document 205947, AMCo's submission to the CMA dated 22 December 2020, paragraphs 34-36; and also Document 205805, Cinven's RDPS, paragraphs 1.13, 1.16-1.17, 1.19, 3.15, 3.34-3.35, 3.43 and 3.50.

³⁵⁸⁸ C-681/11 *Bundeswettbewerbsbehörde v Schenker & Co*, EU:C:2013:404, paragraphs 37-38, 40-41 and 43, recently confirmed in C-591/16 *P Lundbeck v Commission*, paragraphs 156-158 and *Generics (UK) Limited Glaxosmithkline Plc, Xellia Pharmaceuticals APS, Alpharma LLC Actavis UK Limited Merck KGAA v CMA* [2021] CAT 9 [2021] CAT 9, paragraphs 114 to 117. AMCo submitted that the principle set out in *Schenker* does not apply in this case, in particular referring to the 'general position' described by Advocate General Kokott in her Opinion in that case that reliance on legal advice 'must have a bearing in cartel proceedings for the imposition of fines' (Opinion of AG Kokott in Case C-681/11 *Bundeswettbewerbsbehörde v Schenker & Co*, EU:C:2013:404, paragraph 58) (Document 205848, AMCo's RDPS, paragraph 4.31; Document 205947, AMCo's submission to the CMA dated 22 December 2020, paragraph 36; See also Document 205805, Cinven's RDPS, paragraph 2.24). AMCo also submitted that *Schenker* related only to the question of legitimate expectation, and not to the question of whether an infringement has been committed intentionally or negligently (Document 205947, AMCo's submission to the CMA dated 22 December 2020, paragraph 31). The CMA rejects these submissions. The Advocate General's statement in *Schenker* – which was not replicated in the judgment – was confined to a scenario where the relevant legal advice had been 'provided on the basis of a full and accurate description of the facts by the undertaking concerned', the advice dealt 'comprehensively' with the relevant decision-making practice of the European Commission and case law of the European Courts and the substance of the advice was not 'manifestly incorrect' (see paragraphs 66 to 68). These were part of an extensive range of 'minimum requirements' suggested by the Advocate General for recognising legal advice 'as the basis for an error of law precluding liability' (paragraphs 62 to 71), none of which was followed by the Court of Justice and none of which applies in this case. While *Schenker* did consider the principle of legitimate expectation in relation to the action of the Austrian national competition authority in sanctioning the cartel under national law, this was only one part of the judgment. The main part of the judgment concerned whether a fine could be imposed on an undertaking for acting intentionally or negligently in relation to an infringement (see in particular paragraph 31).

³⁵⁸⁹ AMCo submitted that notwithstanding *Schenker*, there was 'a consistent body' of case law establishing that legal advice excludes a finding of negligence or intent on the part of the relevant undertaking (Document 205947, AMCo's submission to the CMA dated 22 December 2020, paragraphs 32 and 33; Document 205848, AMCo's RDPS, paragraphs 2.13.2, 4.7, 4.26-4.27 and 4.33). However, none of the cases AMCo cited is inconsistent with *Schenker*. The cases cited concern other issues, such as when undertakings may need to take legal advice to assess the consequences of their actions and the care that undertakings are expected to exercise. The cases do not concern the relevance of legal advice to an undertaking's liability for a competition law infringement or the weight legal advice should be afforded by a competition authority. *Schenker* is the relevant precedent (as recently confirmed in C-591/16 *P Lundbeck v Commission*, paragraphs 156-158 and *Generics (UK) Limited Glaxosmithkline Plc, Xellia Pharmaceuticals APS, Alpharma LLC Actavis UK Limited Merck KGAA v CMA* [2021] CAT 9, paragraphs 116-117) and it is unequivocal.

³⁵⁹⁰ See, for example, C-681/11 *Bundeswettbewerbsbehörde v Schenker & Co*, EU:C:2013:404, paragraph 37 and the cases cited; T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraph 762, upheld in C-591/16 *P Lundbeck v Commission*, paragraphs 156-158; *Generics (UK) Limited Glaxosmithkline Plc, Xellia Pharmaceuticals APS, Alpharma LLC Actavis UK Limited Merck KGAA v CMA* [2021] CAT 9, paragraph 121. As explained in section 10.B.II.a (*Intention and negligence: Legal framework*), AMCo's alternative test for intention/negligence, relating to awareness of unlawfulness, is wrong in law.

10.78. Even if AMCo's external lawyers had advised that AMCo was not a potential competitor of Auden and that the 10mg Agreement was compliant with competition law on the basis of a complete and correct understanding of the facts, this would therefore not preclude the CMA from finding that the 10mg Agreement was an infringement or from finding that AMCo acted intentionally or negligently in committing that infringement.³⁵⁹¹

The facts

10.79. In any event, when AMCo's external legal advice is placed in context it provides no justification for reducing the amount of the penalty imposed on AMCo and no justification for a finding that the infringement was committed negligently rather than intentionally.³⁵⁹²

10.80. Focussing specifically on each relevant piece of advice and AMCo's contemporaneous understanding of market conditions:

- a. The 20 December 2013 advice does not relate to whether or not AMCo could compete with Auden with its skinny label tablets;
- b. The 6 June 2014 advice rests on an incorrect understanding of the orphan designation and its implications for the legal and economic context; and
- c. AMCo knew that it was a potential competitor of Auden notwithstanding the orphan designation and therefore knew that the 6 June 2014 advice was incorrect.

³⁵⁹¹ Compare Decision in Case AT.39685 *Fentanyl*, recitals 356 to 357 and 465; Decision in Case AT.39226 *Lundbeck*, recitals 695 to 698, 1296 and footnote 1227; and T-472/13 *Lundbeck v Commission*, EU:T:2016:449, paragraphs 832-835 and 839 (upheld in C-591/16 P *Lundbeck v Commission*, paragraphs 156 to 158).

³⁵⁹² AMCo cited COMP/M.7184 *Marine Harvest/Morpol* and T-704/14 *Marine Harvest v Commission* as authority for its submission that reliance on legal advice '*can negate a finding of both intent and negligence*' (Document 205848, AMCo's RDPS, paragraphs 4.26-4.28 (emphasis in original)). This case does not establish a principle that legal advice can negate a finding of negligence or intent – which would be contrary to *Schenker*, the higher precedent. The Commission and General Court applied the principle from *Schenker* that legal advice does not exempt an undertaking from a penalty or affect whether an infringement has occurred. However, the Commission (upheld by the General Court) held that on the facts, *Marine Harvest* had acted negligently rather than intentionally in failing to notify its acquisition of a minority stake as a concentration with an EU dimension before it was implemented. The limited and late legal advice it had received contributed to that finding. Legal advice may therefore be relevant to a finding of a negligent infringement rather than an intentional one. However, that would not be justified in this case. The facts of *Marine Harvest* are very different from this one: while the question whether the acquisition of a minority stake leads to de facto control and therefore a notification obligation is a complex one with limited precedent, all undertakings should be aware that market exclusion agreements are illegal. The same applies to *Sainsbury's v MasterCard* [2016] CAT 11, which AMCo also cited (Document 205848, AMCo's RDPS, paragraphs 4.29 to 4.30): in that case the CAT held that it would not have been clear to MasterCard that its multilateral interchange fees would have been unlawful, particularly given the CAT's finding that this did not amount to an object infringement (paragraphs 322-323). A market exclusion agreement is the prime example of an object infringement. AMCo cannot have been unaware that a market exclusion agreement is anticompetitive. Compare *Generics (UK) Limited GlaxoSmithKline Plc, Xellia Pharmaceuticals APS, Alpharma LLC Actavis UK Limited Merck KGAA v CMA* [2021] CAT 9, paragraph 141.

The 20 December 2013 advice

- 10.81. As explained above, on 20 December 2013 AMCo's external lawyers advised that the MHRA was precluded from granting AMCo an MA for 'adrenal insufficiency'.³⁵⁹³
- 10.82. As explained in section 3.D.III, the effect of the orphan designation was that the MHRA would not grant an MA to new entrants that included the protected indication 'adrenal insufficiency in adults'. However, nothing in Pinsent Masons' advice suggests that 'the regulatory barrier created by [the orphan designation] was insurmountable' as AMCo submitted.³⁵⁹⁴ The advice said nothing about the potential for AMCo to compete with Auden's full label tablets, whether for the protected indication through off-label supply or outside the protected indication for children and/or other conditions.

The 6 June 2014 advice

- 10.83. On 6 June 2014 an associate in the competition law team at Pinsent Masons recorded her attendance on a conference call between AMCo and Auden to negotiate the Second Written Agreement in an email to [REDACTED] [AMCo Senior Employee 8]:

*'Prior to the call I discussed with you the extent to which AmCo [sic] would be considered a competitor of Auden in relation to the 10mg product (which AmCo has a pipeline source). As a result of the orphan designation for 10mg hydrocortisone, AmCo cannot supply its 10mg hydrocortisone into the market in respect of the main therapeutic use, i.e. the treatment of adrenal insufficiency. The orphan designation is akin to an IP right and as such, from a competition law perspective in respect of this product and the orphan indication AmCo and Auden would not be considered competitors whilst the orphan designation was in place (however for other products 20mg hydrocortisone AmCo and Auden would be considered competitors, hence my presence on the call as a safeguard).'*³⁵⁹⁵

- 10.84. These statements are based on an incorrect interpretation of the orphan designation and its impact on the economic and legal context of the present case. The analysis of whether an undertaking is a potential competitor depends on the legal and economic context, which was not properly taken

³⁵⁹³ Document 201088, advice from Pinsent Masons to [Amdipharm Senior Employee] dated 20 December 2013, page 3.

³⁵⁹⁴ Document 204922, AMCo's RSSO, paragraphs 3.37.2, 3.618 to 3.620.

³⁵⁹⁵ Document 201971, email from Pinsent Masons firm to [AMCo Senior Employee 8] dated 6 June 2014. See also Document 201102, email from external law firm to [AMCo Senior Employee 8], 9 February 2017, paragraph 3.

into account in the advice, which as a result failed to reflect the relevant decision-making practice of the European Commission and case law of the European courts.

- 10.85. First, the orphan designation did not prevent AMCo from supplying its 10mg hydrocortisone tablets into the market for the treatment of adrenal insufficiency. The orphan designation prevented the MHRA from granting AMCo an MA with the indication '*for the treatment of adrenal insufficiency in adults*', and therefore AMCo from marketing its 10mg hydrocortisone tablets for that indication.
- 10.86. On any view, the orphan designation did not offer absolute protection and was not an insurmountable barrier. AMCo had an MA, although it lacked the adult adrenal insufficiency indication. AMCo was therefore authorised by the MHRA to place its product on the market. On no interpretation of the Orphan Medicinal Products Regulation could AMCo be restricted from competing with Auden outside the protected indication.³⁵⁹⁶
- 10.87. Secondly, it would not have been unlawful for pharmacists to dispense AMCo's skinny label product 'off-label' to patients falling under the protected indication, because prescriptions for hydrocortisone tablets tend to be open and an open prescription for hydrocortisone tablets can be filled with a skinny label product that is bioequivalent to full label tablets (see section 3.E.III above). The orphan designation was therefore also not an insurmountable barrier to AMCo competing with Auden within the protected indication.
- 10.88. On any reading of the orphan designation regime, AMCo would therefore have been a potential competitor to Auden outside the protected indication, and there was also a possibility that pharmacists would be willing to switch to its product for patients falling under the protected indication. The advice, in no uncertain terms and without caveats, that 'in respect of this product and the orphan indication *AmCo and Auden would not be considered competitors whilst the orphan designation was in place*', was therefore wrong.

AMCo knew that it was a potential competitor of Auden notwithstanding the orphan designation

- 10.89. Moreover, AMCo knew that the 6 June 2014 advice was wrong. AMCo's conduct and internal, contemporaneous AMCo documents show that AMCo

³⁵⁹⁶ In fact, AMCo submitted that because of the legal advice it '*considered in good faith that it could only compete in respect of the negligible market comprising that 2%-10% of patients using HT*' (Document 203737, AMCo's RSO, paragraph 3.508), indicating that it did not understand the advice to mean it was precluded from competing at all with Auden. See also Document 204922, AMCo's RSSO, paragraph 3.209.

consistently understood that the orphan designation did not preclude competition between itself and Auden. This evidence is discussed in detail in section 3.E.IV (*Demand for hydrocortisone tablets*) above and Annex D.

- 10.90. Before it received the December 2013 advice it is clear that AMCo consistently believed that it would be able to gain market share from Auden if it entered with its skinny label hydrocortisone tablets.
- 10.91. In November 2013 when it sought to formalise the 10mg supply arrangement AMCo initially sought to obtain 18,000 packs from Auden (equating to 24% of total volumes). This corresponded to AMCo's initial estimate of the volume it stood to win if it launched its skinny label tablets.³⁵⁹⁷
- 10.92. Further, before receiving the 20 December 2013 advice AMCo had already reached the view that it should not pursue the potential acquisition of Auden's hydrocortisone business because its value was likely to fall following the entry of skinny label competitors, notwithstanding the orphan designation. On 2 December 2013 [AMCo Senior Employee 2], [REDACTED], stated: *'There's too much risk around the value of the assets, and his [[Auden Senior Employee 1]'s] expectations would be pretty high. I suspect he's keen to sell because he knows generics may be around the corner.'* [REDACTED] [AMCo Senior Employee 1] agreed: *'[AMCo Senior Employee 2] is right'*.³⁵⁹⁸
- 10.93. The 20 December 2013 advice did not change AMCo's view that the orphan designation was no insurmountable barrier to entry, as demonstrated by a consistent and large body of evidence.
- 10.94. Shortly after Pinsent Masons provided its December 2013 advice, [AMCo Senior Employee 1] asked [AMCo Senior Employee 2], *'Maybe our DD work [on Auden's hydrocortisone business] might find a way for us to get rid of the orphan status?'* [AMCo Senior Employee 2] responded: *'feedback from Pinsent Masons is that the Orphan Status is legitimate and going to be hard to knock back. We will almost certainly have to have the limited indication.'* [AMCo Senior Employee 1] responded:

³⁵⁹⁷ Document 202552, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 15 November 2013 and attachment, Document 202553, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden Mckenzie (Pharma Division) Limited and Amdipharm Limited, page 20, Schedule A. See also Document 202557, email from [Amdipharm Senior Employee] to [REDACTED] dated 15 November 2013. AMCo's forecasts for 2014 are set out in document 202660, spreadsheet titled 'model (2)', sheet 'assume generics launched' attached to document 202659, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 4] dated 23 May 2014, which reflects a forecast of 18,000 packs per month or 24% market share. See also Document 202597, email from [AMCo Senior Employee 4] to [AMCo Employee] and [AMCo Senior Employee 1] dated 20 December 2013.

³⁵⁹⁸ Document 200018, emails between [AMCo Senior Employee 2] and [AMCo Senior Employee 1] dated 2 and 4 December 2013.

*'I wonder if we believe Pinsents know what they are talking about?'*³⁵⁹⁹

- 10.95. [AMCo Senior Employee 2] replied attaching the 20 December 2013 advice, adding:

*'However, I have just received the prescribing data for Hydrocortisone 10mg ... It shows that only 22% of Rx's are specified as Adrenal, and there are multiple other indications widely in use, not the 90+% for adrenal insufficiency that [Amdipharm Senior Employee] was once referring to. That means labelling shouldn't be that important, hopefully
● Pharmacists will dispense our product, regardless of label, and [Auden Senior Employee 1] claim that we have an inferior product is irrelevant anyway, when it can be shown to be bioequivalent. It just doesn't have the labelling for one protected indication. Therefore I think we can push back a bit harder! I've sent an email to [Amdipharm Senior Employee] suggesting the same.'*³⁶⁰⁰

- 10.96. [AMCo Senior Employee 1] replied: 'Very interesting!! Thanks'.³⁶⁰¹

- 10.97. A few minutes before sending his email to [AMCo Senior Employee 1], [AMCo Senior Employee 2] separately sent an email to [Amdipharm Senior Employee] stating:

'According to the data on IMS, only 22% of prescriptions are specifically identified as Adrenal, with a long list of others. That gives us a bit more strength to say to [Auden Senior Employee 1] that we don't mind having limited labelling. Pharmacists will dispense it anyway, regardless of labelling. Therefore, we should still be arguing using 100% of the market as our negotiating position for supply volumes!'

●³⁶⁰²

- 10.98. A fortnight after Pinsent Masons had advised that AMCo could not obtain a full label 10mg MA, AMCo therefore continued to hold the view that it could nonetheless expect to win market share from Auden's full label product (both within and outside the protected indication). AMCo's 22 January PPRM report estimated that its Aesica 10mg product could sell 12,000 packs a month and attain a gross profit of 94% on the assumption that '*Indication*

³⁵⁹⁹ Document 200165, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] and [AMCo Senior Employee 8] dated 2 January 2014.

³⁶⁰⁰ Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 2 January 2014.

³⁶⁰¹ Document 200165, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 2 January 2014.

³⁶⁰² Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.

limitations do not restrict sales'.³⁶⁰³ This equated to approximately 16% of total volumes.

10.99. This view was the reason AMCo ultimately withdrew from negotiations to acquire Auden's hydrocortisone business. Although [AMCo Senior Employee 8] proposed an adjusted valuation for that business '*on the basis that we think there will be generic competition and we don't think the orphan drug status is safe*', [AMCo Senior Employee 2] noted that '*I can't see that it's for us at this price tag. We have no idea how many generics may be lined up for coming to market... Good news from [X] multi-functional meeting is that it seems we can be on the market in around 3 months.*'³⁶⁰⁴ On 29 January 2014 the minutes of AMCo's top company board reported that it would not be proceeding with the acquisition of Auden's hydrocortisone business '*due to the vendor's price expectations and the threat of generic competition to many of its products.*'³⁶⁰⁵

10.100. AMCo continued to believe that its skinny label 10mg tablets were capable of winning market share from Auden's full label product throughout the first half of 2014, when it negotiated with Auden to formalise the 10mg supply arrangement. In particular, as explained in section 6.D.II.c above, AMCo successfully used the threat that it would enter with that skinny label product and take market share from Auden to secure increased payments in the Second Written Agreement.

10.101. After Auden offered to continue supplying AMCo with its hydrocortisone tablets in the first half of April 2014, [AMCo Senior Employee 1] '*asked [AMCo Senior Employee 5] [X] what our Aesica cost and volume expectations are*' for the purposes of the negotiation with Auden.³⁶⁰⁶ On 22 April 2014 [AMCo Senior Employee 5] responded that AMCo expected that it could sell 10,000 packs a month of its Aesica product: approximately 13% of total volumes.³⁶⁰⁷

10.102. On the following day, [AMCo Senior Employee 2] commented internally that '*[i]t seems [Auden Senior Employee 1] isn't being as bold about his*

³⁶⁰³ Document 200090, 22 January 2014 PPRM slides, slide 10.

³⁶⁰⁴ Document 200071, email from [AMCo Senior Employee 8] to [AMCo Senior Employee 2] dated 7 January 2014 (emphasis added), and email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 8 January 2014.

³⁶⁰⁵ Document 200498, Minutes of a Meeting of the Board of Directors of Amdipharm Mercury Limited on 29 January 2014, page 15. See also Document 200102, Strategic Development, Monthly Report, Product Acquisitions, January 2014, page 3

³⁶⁰⁶ Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014 (emphasis added).

³⁶⁰⁷ Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 22 April 2014.

indication claims now, which may reflect our belief that it's not as important as he was once suggesting'.³⁶⁰⁸

10.103. AMCo expressed the same view during May 2014. For example, during AMCo's negotiations to acquire Waymade's 20mg MA, [AMCo Senior Employee 2] wrote to Waymade on 15 May 2014 to explain that *'It is our belief (because we have submitted a generic MA ourselves) that generics can launch with the limited labelling. Therefore generics aren't blocked from the market*'.³⁶⁰⁹ This reflected AMCo's internal view that Waymade's full label 20mg MA was *'just another dossier, with a minor advantage of the indication (which we don't believe is worth that much, but worth something potentially)*' and not worth Waymade's asking price *'because of the risk of the development work required, and the uncertainty about the label, and the risk of additional generics*'.³⁶¹⁰

10.104. It is therefore established, first, that the December 2013 advice had no impact on how AMCo viewed its own product's potential to compete with Auden's full label product. AMCo had a skinny label MA, was aware that it would not be able to obtain a full label MA, and it forecast that it would nonetheless be able to sell between 10,000 and 18,000 packs per month. On no reading of the evidence did AMCo believe it was precluded from competing with Auden.

10.105. The 6 June 2014 advice contained no further legal analysis beyond the December 2013 advice in relation to the impact of the orphan designation. In any event, notwithstanding the 6 June 2014 advice AMCo continued to believe that its skinny label product was capable of competing with Auden's full label product.

10.106. The associate who provided the 6 June 2014 advice relied on [X] AMCo Senior Employee 8]'s expertise. The statements quoted in paragraph 10.83 above read as though the associate was repeating what [AMCo Senior Employee 8] had told her during their conversation: *'Prior to the call I discussed with you the extent to which AmCo [sic] would be considered a competitor of Auden in relation to the 10mg product (which AmCo has a pipeline source). As a result of the orphan designation for 10mg hydrocortisone, AmCo cannot supply its 10mg hydrocortisone into the market...'*

³⁶⁰⁸ Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 6], [AMCo Senior Employee 1] and [AMCo Senior Employee 8] dated 23 April 2014 (emphasis added).

³⁶⁰⁹ Document 200116, email from [AMCo Senior Employee 2] to [X] dated 15 May 2014 (emphasis added).

³⁶¹⁰ Document 200109, email from [AMCo Senior Employee 2] to AMCo management dated 11 April 2014, (emphasis added).

10.107. The associate went on to ask:

'Is there a risk of AmCo inadvertently supplying for orphan designation? What are the consequences if you do this?'

10.108. [AMCo Senior Employee 8] replied:

*'Pharmacy bears the responsibility to ensure that the correct product is dispensed (which is why Auden has been writing to pharmacy, not us, to point out the fact that we don't have this indication). So long as we make sure that our product does not misrepresent itself as covering additional indications that are not on its licence (which will not happen), our Medical team consider that we would be ok. The issue would be how Auden react... I suspect we would end up in the OD dispute that we are now facing, but I don't think there is much we can do about that, unless we decide to abandon this product market which we really don't want to do.'*³⁶¹¹

10.109. This exchange shows that [AMCo Senior Employee 8] understood that AMCo was not precluded from competing with Auden, either outside the protected indication or within it. [AMCo Senior Employee 8] understood (correctly) that pharmacists were responsible for dispensing and could choose to dispense AMCo's product against an open prescription, and that provided AMCo did not misrepresent its product as full label this would not create liability for AMCo as a supplier (*'our Medical team consider that we would be ok'*). Instead, the issue would be *'how Auden react'*: [AMCo Senior Employee 8] anticipated that in response to AMCo's launch Auden would likely intensify its efforts to persuade pharmacists against off-label dispensing, which it had already begun with Project Guardian (*'we would end up in the OD dispute that we are now facing'*). [AMCo Senior Employee 8] stated that AMCo nonetheless did not wish to *'abandon this product market'*: [AMCo Senior Employee 8] understood that unless it did so, this dispute, and therefore some level of competition between Auden and AMCo, would result.

10.110. On 15 June 2014 – nine days after Pinsent Masons' advice that 'from a competition law perspective in respect of this product and the orphan indication AmCo and Auden would not be considered competitors' – [AMCo Senior Employee 1] told other senior staff at AMCo that supply under the Second Written Agreement:

³⁶¹¹ Document 201971, email from [AMCo Senior Employee 8] to Pinsent Masons dated 6 June 2014.

'is for delivery this month so that [AMCo Senior Employee 4] can get the sales this month. I told him [[Auden Senior Employee 1]] that if not we will launch our own'.

10.111. [AMCo Senior Employee 1] told AMCo staff: 'I went in with 12k per month when I knew that [AMCo Senior Employee 4] had forecast 10k per month'.³⁶¹²

10.112. Ten days before the Second Written Agreement was signed, AMCo was therefore still forecasting demand for 10,000 packs of its skinny label product each month and had successfully used the competitive threat of launching its product as negotiating leverage to secure Auden's commitment to continue supplying. AMCo therefore cannot have been unaware that it was a potential competitor of Auden notwithstanding the orphan designation: that was the premise on which it had successfully obtained the Second Written Agreement.

Conclusion

10.113. Pinsent Masons' advice was not provided on the basis of a full and accurate understanding of the facts as AMCo understood them.

10.114. First, AMCo's own understanding of the legal and economic context was that it would be able to compete with Auden for at least some of the market, as is evident from the forecasts and the other contemporaneous evidence set out above. AMCo recognised that the protected indication did not cover the entire market, that its product was bioequivalent with the full label product and that pharmacists '*will dispense our product, regardless of label*',³⁶¹³ thus acknowledging both that it could compete for the part of the market not covered by the protected indication and that pharmacists may be willing to dispense AMCo's product to patients covered by the protected indication.

10.115. Secondly, AMCo did not disclose to Pinsent Masons the full extent of its negotiations with Auden and the common understanding on the basis of which it was operating and which it was about to renew when it received the 6 June 2014 advice. AMCo had consistently used its own product as leverage in negotiations with Auden, from which it was clear to AMCo that Auden perceived it as a competitive threat. Shortly after AMCo received the 6 June 2014 advice, [X] successfully used the threat of launching its skinny

³⁶¹² Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 4], [AMCo Senior Employee 8], [AMCo Senior Employee 2] and [AMCo Senior Employee 6] dated 15 June 2014 (emphasis added).

³⁶¹³ Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 8] dated 2 January 2014.

label product in order to secure the Second Written Agreement from Auden. AMCo did not disclose this to Pinsent Masons.

- 10.116. AMCo's external legal advice therefore provides no basis for negating the CMA's finding that the 10mg Agreement infringed competition law, or for reducing the penalty imposed on AMCo for that infringement. AMCo understood the competitive relationship between its skinny label product and Auden's product and therefore knew that the June 2014 advice was incomplete and incorrect.

III. Legal certainty

- 10.117. The case parties have submitted representations that there was/is genuine uncertainty as to the applicable legal tests and that the CMA's approach to the infringements is '*novel*'. They argued that this should be taken into account for both intention/negligence and as mitigation at all steps of the calculations (suggesting that no or only a nominal penalty should be imposed, or that reductions are appropriate, in particular, at step 3):

- a. With respect to the Unfair Pricing Abuses, the parties submitted that there was a lack of certainty as to the legal test for unfair pricing (citing the CAT's judgment in *Phenytoin*), a lack of recent unfair pricing cases, and (in the case of the Intas period of ownership of Accord-UK) the '*novelty*' of the CMA's approach to dominance during a period of competitive entry and falling prices mean the parties could not have known or foreseen that they were infringing the law. The parties also assert that the CMA's approach to determining the reasonable price and the level of price that the CMA would consider lawful was not known at the time of the conduct, and that the CMA's approach is novel and was therefore not predictable or foreseeable at the time.³⁶¹⁴
- b. Accord-UK and Intas referred to comments made by the Court of Appeal in *Phenytoin*, arguing that the Court of Appeal recognised that it was open to the parties to refer to the CMA's change of position and "*uncertainty in the law as evidenced by changes in that position*" when arguing whether the conduct took place intentionally or negligently and/or in potential mitigation.³⁶¹⁵
- c. Cinven and AMCo submitted that there was a lack of clarity regarding the application of Chapter I/Article 101 at the time of the infringement

³⁶¹⁴ Document 205813, Accord-UK's RDPS, paragraphs 1.15.3, 4.12 to 4.16, 4.27, 10.7.1, 10.12 and 10.59.4; Document 205791, Allergan's RDPS, paragraph 36; Intas/Accord-UK's RDPS paragraphs 10 to 28 and 67 to 68.

³⁶¹⁵ Document 205802, Intas/Accord-UK's RDPS, paragraph 33; Document 205813, Accord-UK's RDPS paragraphs 1.5.3, 4.3, 4.15, and 10.7.

as a result of lack of specific/relevant legal precedent.³⁶¹⁶ In their submission the CMA can therefore not impose a fine or any more than a nominal fine.³⁶¹⁷

a. Unfair Pricing Abuses

10.118. The CMA does not accept these representations. Excessive pricing is not a new legal concept or type of abuse. In fact, it has been recognised and included as a form of abuse of a dominant position since the creation in 1957 of the European Economic Community, the predecessor to the European Union. The seminal case on the test for unfair pricing is the judgment of the Court of Justice in *United Brands* which was delivered in 1978. It has been a part of domestic competition law since the enactment of the Act.

10.119. The Court of Appeal's judgment in *Phenytoin* confirmed that the legal test is as set out in *United Brands*, which was widely acknowledged throughout the infringement period. The change confirmed by the Court of Appeal in *Phenytoin* relates only to the approach to be taken by the CMA to the alternatives of the unfair limb of the test when a dominant firm submits exculpatory evidence; this change did not make the legal test unclear or uncertain. There is a difference between the gradual clarification of legal concepts by the courts, on the one hand, and the full implications of the law being reasonably foreseeable, on the other.³⁶¹⁸ Even if there were uncertainty as to the legal test at the relevant time (which the CMA does not accept), the level of excessiveness in this case was very large such that there could have been no doubt as to the fact prices were unfair - an infringement would be found irrespective of the legal test applied. Over the eight years following its April 2008 decision to de-brand hydrocortisone tablets (for the majority of which it was the sole supplier), Auden/Actavis increased prices by over 10,000% relative to the prices charged before it acquired the licences. In preparing for acquiring AM Pharma, Allergan recognised that the product was a '*near-term cash cow*'.³⁶¹⁹ The undertaking was at all times aware that it was exploiting a position of limited to no competition. See also section 10.B.II.b above and section 10.D.III.a below.

³⁶¹⁶ Document 205848, AMCo's RDPS, paragraphs 6.52 to 6.64; Cinven's RDPS, paragraph 3.55 (citing the CMA's decision in *Paroxetine*, Case CE-9531/11, paragraphs 1.25 and 11.58).

³⁶¹⁷ Document 205848, AMCo's RDPS, paragraphs 2.13.3, 4.12 to 4.23 (in the context of awareness of the infringing behaviour under AMCo's submissions on the appropriate legal test), and 6.52 to 6.64; Document 205805, Cinven's RDPS, paragraph 3.55. AMCo also referred to previous Commission and EU Court decisional practice where no fine or a nominal fine was imposed where there was either genuine uncertainty on the behalf of the undertaking as to whether the conduct was lawful, or where the undertaking reasonably/genuinely believed that the contested agreement was lawful. See Document 205947, AMCo's submission dated 22 December 2020 paragraph 14, and Document 205848, AMCo's RDPS, paragraph 2.13.3.

³⁶¹⁸ T-99/04 *AC-Treuhand v Commission* ECLI:EU:T:2008:256, paragraphs 143 to 150.

³⁶¹⁹ Document 00706, Project Apple Presentation January 2015, Executive Summary and Hydrocortisone Background.

Project Guardian is also strong evidence that Auden sought to protect its market position at a time when it was increasing prices where there was a lack of competition and wished to maintain that lack of competition. This was not an innocent breach.

- 10.120. Competition law, and in particular abusive pricing conduct, always involves a degree of discretion as to how the law is applied to the specific circumstances of the case in question. This does not prevent the imposition of a sanction when an infringement has been found and the predictability or otherwise of the CMA's approach is not a relevant consideration in the setting of a penalty. For example, the General Court in *Sasol v Commission*³⁶²⁰ held that *'were the fine to be imposed for participation in an unlawful cartel to be more or less predictable, this would have highly damaging consequences for European Union competition policy, since the undertakings committing the infringements could directly compare the costs and benefits of their unlawful activities, and also take into account the chances of being discovered, and thus attempt to ensure that those activities are profitable'*.
- 10.121. Arguments around legal uncertainty or the novel nature of infringements have also been addressed in other recent cases (eg in the Commission's *Pay for delay* cases and in the CMA's *Ping* case).³⁶²¹ In *Lundbeck*, the court expressly held that a clarification of the legal test in competition law cases does not violate Article 7 of the ECHR, and Article 49 of the Charter of Fundamental Rights of the European Union.
- 10.122. For example, in *Lundbeck*, the General Court held that *'the principle of legal certainty and the principle that penalties must have a proper legal basis, laid down by Article 7 of the ECHR, and Article 49 of the Charter of Fundamental Rights of the European Union, cannot be interpreted as prohibiting the gradual clarification of the rules of liability [...]*'.³⁶²² This was confirmed by the Court of Justice on appeal, dismissing the argument around the novelty of the penalties in those pay-for-delay cases.³⁶²³
- 10.123. The mere fact that the CMA has not brought many excessive pricing cases in the past does not render excessive pricing conduct legal, nor does it create a legitimate expectation to this effect. Both the European Commission and the CMA have a wide discretion, based on their prioritisation principles, when deciding which types of cases, and in which sectors, to pursue at any

³⁶²⁰ T-541/08 *Sasol v Commission* ECLI:EU:T:2014:628, paragraph 207.

³⁶²¹ See, e.g. *Ping v CMA* [2020] EWCA Civ 13, paragraphs 117 to 122.

³⁶²² Judgment of the General Court of 8 September 2016, *Lundbeck v Commission* (T-472/13, EU:T:2016:449), paragraph 763 (emphasis added).

³⁶²³ Case C-591/16 P *Lundbeck v Commission*, paragraph 166.

given time. These priorities change over time. The intelligence and evidence available to the CMA also changes.

- 10.124. It follows that the CMA does not accept the parties' assertion that the principle of legal certainty and the '*novelty*' of the CMA's approach prevents the imposition of a (substantial) penalty in this case. As set out above, there is no legal uncertainty or '*novelty*' with respect to the CMA's case that puts the fact of excessiveness into doubt. In these circumstances, it would be wrong to conclude that the imposition of a substantial fine would be precluded.
- 10.125. Furthermore, it is well established that the '*novelty*' of an infringement alone is not sufficient to justify the imposition of a nominal penalty. The fact as such that conduct with the same features has not been examined in past decisions does not exonerate an undertaking where its conduct is manifestly contrary to competition on the merits.³⁶²⁴ The same must also apply to manifestly exploitative abuses where '*a diligent undertaking in the applicant's position could not at any time have been unaware of the consequences of its conduct.*'³⁶²⁵ The CMA has already found that Auden/Actavis knew or should have known the essential facts justifying the CMA's findings that it was imposing unfairly high prices by making use of the opportunities arising out of its position as the sole supplier of hydrocortisone tablets in the UK.
- 10.126. In contrast, in cases where the Commission has chosen to impose nominal fines there was genuine uncertainty as to whether the conduct would be anticompetitive or would be abusive.

b. Agreements

- 10.127. The Chapter I prohibition is clear and settled law: there is no uncertainty or '*novelty*' in relation to market sharing/market exclusion agreements, and there is nothing '*novel*' or particularly '*complex*' about the CMA's case (see also sections 6.D.III.b and c above). The CMA's comments in *Paroxetine* were made in the specific context of that case, the novelty of which is not mirrored here. As set out above, the Court of Justice has specifically rejected similar arguments in the *Lundbeck* appeals. The CMA therefore rejects AMCo's and Cinven's submissions with regard to novelty and their submission that no fine or a nominal fine is applicable.

³⁶²⁴ See the judgments in *Michelin v Commission* C-322/81 EU:C:1983:313, paragraph 107 and T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 901.

³⁶²⁵ See judgment in *Lucchini SpA v Commission* Case T-91/10 EU:T:2014:1033.

C. Calculation of the financial penalties: the CMA's approach

- 10.128. The remainder of this chapter sets out the penalties the CMA imposes in this case. Given the number of parties to which this Decision is addressed, corporate changes within each liable undertaking during the Infringements and the presence of multiple infringements, the analysis that follows is lengthy and detailed. This is necessary to ensure each addressee's liability is properly considered.
- 10.129. The parties' conduct was inherently serious in nature, both exploitative by charging excessive and unfair prices, and anti-competitive by excluding potential competitors from the market for hydrocortisone tablets. This conduct had a long-lasting and serious impact. The harm caused to the NHS runs in the hundreds of millions of pounds: in 2007 the NHS was spending around £500,000 per year on hydrocortisone tablets which rose to over £80 million per year in 2016. The financial benefits to the parties, as calculated by the CMA on a conservative basis in this section, run to more than £160 million. It is essential that the penalties in this case are set at a level that deters the undertakings involved and other undertakings considering similar conduct from engaging in these or similar infringements.^{3626, 3627}
- 10.130. On the basis of the evidence set out in this Decision, and for the reasons set out in this section, the CMA has made a decision that the following penalties are imposed on the parties:

³⁶²⁶ The CAT has recognised the essential role of the deterrence element in setting a penalty: in *Napp* the CAT explained: 'we agree with the thrust of the Director's Guidance that while the turnover in the products affected by the infringement may be an indicative starting point for the assessment of the penalty, the sum imposed must be such as to constitute a serious and effective deterrent, both to the undertaking concerned and to other undertakings tempted to engage in similar conduct. The policy objectives of the Act will not be achieved unless this Tribunal is prepared to uphold severe penalties for serious infringements.' (*Napp Pharmaceutical Holdings Limited v DGFT* [2002] CAT 1, paragraph 502).

³⁶²⁷ The CAT has recognised that 'the final penalty figure will depend on evaluation and judgment and the reasoning process will not lend itself to elaborate exposition. Ultimately the CMA has to select the figure which seems to it to be appropriate in all the circumstances. The CMA is not constrained to selecting the lowest figure in the band.' Additionally, the CAT confirmed that 'we do not consider that there is a legal principle that the CMA is restricted to imposing the lowest penalty that could reasonably be justified.' See *FP McCann Limited v CMA*, [2020] CAT 28, paragraph 347.

Table 10.1: Penalties for each Infringement³⁶²⁸

Infringement	Penalty	Attribution
10mg Unfair Pricing Abuse	£147.1 million	Allergan and Accord-UK jointly and severally: £74.3 million (due to Accord-UK's statutory cap of £28.4 million applied to the periods for which it is solely liable, Allergan will be solely liable for £74.3 million) Intas, Accord and Accord-UK jointly and severally: £44.4 million Accord-UK alone: £28.4 million
20mg Unfair Pricing Abuse	£8.1 million	Allergan and Accord-UK jointly and severally: £2.0 million Accord-UK alone: £6.1 million
10mg Agreement: Auden /Actavis	£63.2 million	Allergan and Accord-UK jointly and severally: £34.8 million (due to the application of Accord-UK's statutory cap, Allergan will be solely liable for £34.8 million) Accord-UK alone: £28.4 million
10mg Agreement: Waymade	£0.3 million	Waymade plc and Amdipharm UK Limited jointly and severally: £0.3 million (due to Amdipharm UK Limited's statutory cap of zero, Waymade plc is liable for £0.3 million)
10mg Agreement: AMCo	£42.8 million	Cinven Entities £35.1m, of which the Amdipharm Companies are jointly and severally liable for £14.2 million (Cinven will be solely liable for £21.0 million of the £35.1 million) Advanz and the Amdipharm Companies jointly and severally: £7.7 million
20mg Agreement: Auden /Actavis	£2.8 million	Accord-UK alone: £2.8 million
20mg Agreement: Waymade	£2.2 million	Waymade plc alone: £2.2 million

10.131. When setting the amount of a penalty, the CMA must have regard to the guidance on penalties in force at that time.^{3629,3630} The CMA penalties guidance establishes a six-step approach for calculating the penalty. The six steps and their application in this case are set out below.

³⁶²⁸ Penalties in this table are shown to the nearest £0.1million. The precise penalty amounts are provided in the workings below, and summary penalty calculations are provided in Annex E.

³⁶²⁹ S. 38(8) of the Act.

³⁶³⁰ Intas/Accord-UK has submitted that the CMA should not '*retrospectively*' apply the CMA penalties guidance in this case as a statement of objections and a DPS had already been issued in this case (Document 205802, Intas/Accord-UK's RDPS, paragraphs 46 and 47, see also Document 205813, Accord-UK's RDPS, paragraph 2.3). The CMA does not accept this representation. The CMA is required to have regard to the guidance in force at the time when setting the amount of the penalty to be imposed (see s. 38(8) of the Act and the CMA penalties guidance paragraph 1.10). The specific difference cited by Intas is that excessive pricing is now included as an example of a serious infringement. However, even under the old guidance it would be a serious infringement (see the CMA's approach in *Phenytoin*). In any case, the current penalty relates to the provisional case as set out in the SSO and DPS issued in 2020 and this current Decision, not any previous provisional decision by the CMA. In any event, the inclusion of excessive pricing as an example of a particularly serious infringement did not constitute a change in the CMA's approach but a mere clarification of its pre-existing views (see to this effect paragraph 1.10 of the CMA penalties guidance which notes that '*amendments made to the previous guidance (OFT423) are intended to be clarificatory and reflect recent CMA decisional practice*').

10.132. The CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.³⁶³¹ The CMA is not bound by its decisions in relation to whether to impose financial penalties or the calculation of any such penalties in previous cases under the Act. It makes assessments on a case-by-case basis,³⁶³² having regard to all relevant circumstances and the objectives of its policy on financial penalties. This is in line with statutory requirements and the twin objectives of the CMA's policy on financial penalties, as reflected in the CMA penalties guidance.³⁶³³ These objectives require the CMA to reflect the seriousness of the infringement and ensure the deterrence of the undertaking on which the penalty is imposed and to deter others from engaging in agreements or conduct that infringes any prohibition(s) under the Act.³⁶³⁴

10.133. The CMA has set out below the guiding principles it has applied when calculating the penalties which explain the CMA's overall approach to penalties in this case. These are set out below before the CMA has applied the six steps of the penalty calculation (by reference to the CMA penalties guidance) and *'in the round'*.

I. Liability to pay the financial penalties

10.134. As explained in section 9.B, the CMA has attributed liability for the Infringements to the legal entities which formed part of the Auden/Actavis undertaking, the AMCo undertaking and the Waymade undertaking during the periods of the Infringements.

10.135. In determining how the total penalty is distributed between entities which are liable for the Infringements in the different ownership periods the CMA has had regard to the principle that a penalty needs to be specific to the offender and the offence.³⁶³⁵ Where an infringing subsidiary is owned by successive

³⁶³¹ Provided that any penalty that the CMA imposes under the Act is within the range of penalties permitted by section 36(8) of the Act, calculated in accordance with The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (the 2000 Turnover Order), and calculated having regard to the CMA penalties guidance in accordance with section 38(8) of the Act. The CMA's margin of appreciation is referred to in, for example, *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 168, and *Umbro Holdings, Manchester United, JJB Sports and Allsports v OFT* [2005] CAT 22, paragraph 102. See also recently the CAT recognised that *'it may well be appropriate for the Tribunal to give weight to an evaluative assessment made by the CMA in relation to a matter of which the CMA has particular expertise, such as the need for deterrence of a particular type of infringement because of its current prevalence ... provided that this does not entail any reduction in the rigorous scrutiny to which the Tribunal is bound to subject the CMA's decision under appeal in reaching its own conclusions on the merits'* (*Roland (UK) Limited and Roland Corporation v CMA*, [2021] CAT 8, paragraph 36).

³⁶³² See, for example, *Kier Group and Others v OFT* [2011] CAT 3, paragraph 116: *'other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent'*. See also *Eden Brown, CDI and Hays v OFT* [2011] CAT 8, paragraph 97: *'[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case'*. See also the CMA penalties guidance, paragraph 2.6.

³⁶³³ The CMA penalties guidance, paragraph 1.3.

³⁶³⁴ The Act, section 36(7A); CMA penalties guidance, paragraph 1.3.

³⁶³⁵ C-247/11 P and C-253/11 P *Areva and Others v Commission*, EU:C:2014:257, paragraphs 127 and 131.

parents during the infringement period, each parent can be jointly and severally liable with that subsidiary only for the penalty in relation to its ownership period.³⁶³⁶

10.136. The CMA has ensured that any adjustments, including any aggravating or mitigating circumstances, only relate to the period of ownership of each relevant parent company.

10.137. The CMA's approach allows the penalty to be apportioned in a way that reflects the financial benefit obtained by the Addressees during their respective periods of liability as well as their respective size as set out further below. It also allows each successive parent company to know its own liability for the penalty which it is required to pay.³⁶³⁷ The CMA can also apply the statutory cap that sets the maximum penalty that the CMA can legally require an undertaking to pay³⁶³⁸ appropriately, as further explained in the relevant section below.

10.138. The remainder of this chapter describes the penalties by reference to the different ownership periods as defined in Table 10.2 below.

Table 10.2: ownership periods and liability for Infringements

Infringement	Undertaking(s)	Periods of liability	Attribution of liability
10mg Unfair Pricing	Auden/Actavis	1 October 2008 – 28 May 2015 ('Period A1')	Accord-UK
		29 May 2015 – 1 August 2016 ('Period A2')	Accord-UK Allergan
		2 August 2016 – 8 January 2017 ('Period A3')	Accord-UK
		9 January 2017 - 31 July 2018 ('Period A4')	Accord-UK Accord Intas
20mg Unfair Pricing	Auden/Actavis	1 October 2008 – 28 May 2015 ('Period B1')	Accord-UK
		29 May 2015 – 1 August 2016 ('Period B2')	Accord-UK Allergan

³⁶³⁶ C-247/11 P and C-253/11 P *Areva and Others v Commission*, EU:C:2014:257, paragraphs 126 to 142.

³⁶³⁷ C-247/11 P and C-253/11 P *Areva and Others v Commission*, EU:C:2014:257, paragraph 135.

³⁶³⁸ The Act, section 36(8); The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000, as amended; the CMA penalties guidance, paragraph 2.25. The applicable turnover of an undertaking is limited to the amounts derived by the undertaking from the sale of products and the provision of services falling within the undertaking's ordinary activities after deduction of sales rebates, value added tax and other taxes directly related to turnover (2000 Order, Schedule, paragraph 3). The business year based on which worldwide turnover is determined will be the one preceding the date on which the decision of the CMA is taken or, if figures are not available for that business year, the one immediately preceding it. The penalty will be adjusted if necessary to ensure that it does not exceed this maximum.

Infringement	Undertaking(s)	Periods of liability	Attribution of liability
		2 August 2016 – 8 January 2017 ('Period B3')	Accord-UK
10mg Agreement	Auden/Actavis	23 October 2012 – 28 May 2015 ('Period C1')	Accord-UK
		29 May 2015 – 24 June 2016 ('Period C2')	Accord-UK Allergan
	Waymade and AMCo	23 October 2012 – 30 October 2012 ('Period D1')	Amdipharm UK Limited Waymade plc
		31 October 2012 – 20 October 2015 ('Period D2')	Amdipharm Companies Cinven Entities
		21 October 2015 – 24 June 2016 ('Period D3')	Amdipharm Companies Advanz
20mg Agreement	Auden/Actavis	11 July 2011 – 30 April 2015	Accord-UK
	Waymade	11 July 2011 – 30 April 2015	Waymade plc

II. Specific deterrence and proportionality

10.139. Under the CMA penalties guidance, a penalty may be adjusted upwards or downwards to reflect the need to achieve specific deterrence and proportionality.³⁶³⁹ The need to deter the undertaking which committed an infringement finds its direct basis in the Act.³⁶⁴⁰ An increase in the penalty may be appropriate, among other things, if the CMA has evidence that the infringing undertaking has made an economic or financial benefit from the infringement that is above the level of penalty reached at the end of step 3.

10.140. The following features of the case are relevant and material to the CMA's approach to specific deterrence and proportionality:

- a. It is in the nature of the Infringements that the CMA has a good indication of the financial benefits the undertakings made from them;³⁶⁴¹
- b. Some of the current and former parent companies of the legal entities that were directly involved in the Infringements are of considerable size and/or derive a significant proportion of their turnover from outside the relevant market;³⁶⁴² and

³⁶³⁹ As set out in the CMA penalties guidance, paragraphs 2.20 to 2.24.

³⁶⁴⁰ The Act, section 36(7A).

³⁶⁴¹ As set out in the CMA penalties guidance at step 4 of the penalty calculation, paragraph 2.21.

³⁶⁴² As set out in the CMA penalties guidance at step 4 of the penalty calculation, paragraph 2.21.

- c. Some undertakings (and the legal entities that form or formed part of them) face multiple penalties.

10.141. The financial benefits obtained by the parties, and the parties' respective financial positions, have both played important roles at step 4 in the CMA's penalty calculations.

III. Financial benefits and deterrence

10.142. The financial benefits obtained by the parties have played an important role in the CMA's penalty calculation, as effective deterrence should ensure that an undertaking does not profit from infringing competition law. Simply asking a company to repay the minimum level of its unlawful direct gains (or a small percentage more) would not be enough to deter the company from taking the risk of committing the unlawful conduct again in future.³⁶⁴³ This is particularly the case given the possibility that future unlawful conduct may not be detected or subject to enforcement.

10.143. Further, the EU General Court has confirmed that a penalty 'imposed for infringement of the competition rules pursues not only a preventative but also a punitive objective' and that 'taking into account that punitive aspect, that a fine to be imposed for participation in a cartel in breach of the competition rules cannot be set at a level which merely negates the profits of the cartel'.³⁶⁴⁴

10.144. Taking these principles into account, any penalty imposed in relation to an Infringement should exceed the financial benefit from the relevant Infringement. The CMA has assessed the level at which the penalty should be set in order to be a meaningful deterrent where it is proportionate to do so given the size of the undertakings as they currently exist.³⁶⁴⁵

10.145. The CMA estimates that the financial benefits from the Unfair Pricing Abuses are as a minimum at the levels set out in the table below.

³⁶⁴³ See Case T-471/13 *Alpharma v Commission* EU:T:2016:460, paragraph 429: '*the purpose of a fine is not simply to remove the benefits that an undertaking has obtained through its anticompetitive conduct, but also to deter that undertaking and other undertakings from engaging in such conduct*' (paragraph 429), as upheld by the Court of Justice in Case C-611/16 P *Xellia Pharmaceuticals and Alpharma LLC v European Commission*.

³⁶⁴⁴ T-410/09 *Almamet v Commission*, paragraph 271, and the case law cited there. See also the Court of Justice: '*The deterrent effect of the fines would be diminished if undertakings which committed an infringement of competition law could expect that their conduct would be penalised by a fine of an amount lower than the profit which was likely to be derived from that conduct*' in case T-15/02 *BASF v Commission*, paragraph 227, citing Case T99/99 *HFB and Others v Commission* [2002] ECR II-1487, paragraph 456, confirmed on appeal by C-189/02 P *Dansk Rørindustri and Others v Commission*, paragraph 292.

³⁶⁴⁵ AMCo, Cinven, Accord-UK, Allergan and Intas/Accord-UK submitted that the CMA had no authority from the CMA penalties guidance to set a penalty above the level of a financial benefit. The CMA does not accept that representation for the reason set out above. See also Annex F.

Table 10.3: minimum financial benefits from the Unfair Pricing Abuses

Period	Revenue differential above £20 per pack (minimum financial benefit) ³⁶⁴⁶	Penalty prior to adjustment at step 4
10mg Unfair Pricing Abuse		
Periods A1 and A3 for which Accord-UK is solely liable	£77.5 million (Period A1) £10.2m (Period A3)	£40,643,592
Period A2 for which Accord-UK and Allergan are jointly and severally liable	£37.9 million	£6,755,168
Period A4 for which Accord-UK, Accord and Intas are jointly and severally liable	£12.5 million	£8,894,304
20mg Unfair Pricing Abuse		
Period B1 and B3 for which Accord-UK is solely liable	£4.8 million (Period B1) £0.4m (Period B3)	£6,082,119
Period B2 for which Accord-UK and Allergan are jointly and severally liable	£2.0 million	£1,015,120

10.146. The differential above £20 per pack would not have been accrued if it were not for the Unfair Pricing Abuses. Left unadjusted, the CMA's penalty calculation at step 3 would mean Auden/Actavis retained a significant, direct and foreseeable financial benefit from carrying out the Unfair Pricing Abuses.³⁶⁴⁷ Specifically with respect to the 10mg Unfair Pricing Abuse, for example, of the financial benefit that Auden/Actavis accrued from the 10mg Unfair Pricing Abuse, the penalty at the end of step 3 would represent only 41% of financial benefits when measured against the level of £20 per pack, and only 19% of total revenue from 10mg hydrocortisone tablets during the infringement period. This is a conservative estimate of the minimum, not actual, financial benefit (based on the £20 ASP below which the CMA has not prioritised investigating Auden/Actavis's prices). It is likely that the unadjusted penalty at step 3 would also leave Auden/Actavis in profit from the 20mg Unfair Pricing Abuse.

10.147. With respect to the Agreements, the only turnover AMCo and Waymade generated in the relevant market(s) during the time the agreements were in

³⁶⁴⁶ This is a conservative estimate of the minimum, not the actual financial benefit, based on profits relative to the £20 per pack ASP below which the CMA has not prioritised investigating Auden/Actavis's prices. If Auden/Actavis's profits are assessed against the costs of hydrocortisone tablets plus a reasonable rate of return (Cost Plus), Auden/Actavis's profits are closer to £270 million.

³⁶⁴⁷ See section 5.

place was from the sale of the heavily discounted packs that Auden supplied to them and additionally in Waymade's case through the Buyback under the 20mg Agreement.³⁶⁴⁸ Left unadjusted, the CMA's penalty calculation would mean AMCo and Waymade would have made a financial benefit from the Agreements in excess of the penalty arrived at before deterrence is considered, as set out in the table below.³⁶⁴⁹

Table 10.4: Financial benefits from the 10mg and 20mg Agreements³⁶⁵⁰

Period / Liability	Estimated financial benefit ³⁶⁵¹	Penalty prior to adjustment at step 4
10mg Agreement		
Period D1 (23 October 2012 – 30 October 2012) for which Waymade plc and Amdipharm UK Limited are jointly and severally liable	£70,000	£254,620
Period D2 (31 October 2012 – 20 October 2015) for which the Amdipharm Companies and the Cinven Entities are jointly and severally liable	£14.2 million	£8,783,674
Period D3 (21 October 2015 – 24 June 2016) for which the Amdipharm Companies and Advanz are jointly and severally liable	£6.5 million	£1,928,276
20mg Agreement		
Period F1 (11 July 2011 – 30 April 2015) for which Waymade plc is solely liable	£1.8 million	£1,135,682

10.148. Again, AMCo and Waymade would not have made these financial benefits but for the Agreements.

IV. Considerable size of some of the undertakings

10.149. In the specific circumstances of this case, even after financial benefits are exceeded by a material amount, the penalties represent only a very small

³⁶⁴⁸ The only exception is May and June 2016, when AMCo had independently entered the market and the 10mg Agreement came to an end.

³⁶⁴⁹ See European Commission decision in *Lundbeck*, paragraph 1370, and as upheld by the General Court in case T-471/13 *Alpharma v Commission*, paragraphs 429 to 433. AMCo and Cinven have submitted that the amount of the fine should not be based on the amount transferred to AMCo and Waymade, or alternatively that the CMA should conduct a counterfactual analysis or deduct the costs incurred by AMCo or Waymade in its efforts to enter the market independently. The CMA rejects this submission. The costs incurred by AMCo or Waymade were incurred independently of the infringement. The CMA penalties guidance states that the CMA may increase a penalty to take into account the economic or financial benefit from the infringement (see paragraph 2.21). This is therefore the relevant figure. See also Annex F.

³⁶⁵⁰ The CMA has not separately calculated the financial benefit Auden/Actavis generated from the Agreements, as any such benefit would already be incorporated in the financial benefits from the Unfair Pricing Abuses, and increasing the penalty for the financial benefits from the Agreements would therefore amount to double counting.

³⁶⁵¹ See section 6.D.II.b.i (20mg Agreement) and section 6.D.II.b.ii (10mg Agreement).

proportion of some Addressees' worldwide turnover. For this reason the CMA has applied a number of further uplifts for the specific deterrence of those undertakings.^{3652, 3653}

V. The CMA's decision to impose separate penalties for separate infringements

10.150. As a matter of law the CMA may impose separate penalties for different infringements of competition law in the same case.³⁶⁵⁴ The fact that multiple penalties would be imposed on an undertaking or legal entity at the same time would not of itself be a reason to apply downward adjustments to those proposed penalties.³⁶⁵⁵

10.151. The statutory cap of 10% of worldwide turnover applies individually to each separate penalty in respect of each Infringement.³⁶⁵⁶

10.152. As set out above, the CMA has reached a decision that the 10mg Unfair Pricing Abuse, the 20mg Unfair Pricing Abuse, the 10mg Agreement and the 20mg Agreement constitute separate infringements of the prohibitions imposed by (in each case as applicable) section 2(1) of the Act or section 18(1) of the Act.

10.153. With respect to the Auden/Actavis and Waymade undertakings, which have been found to have participated in multiple infringements, the CMA considers it necessary and appropriate to calculate a separate penalty in respect of each of the Infringements these undertakings were involved in, to reflect the fact that the Infringements, and the nature of the undertakings' participation in them, have different characteristics – specifically:

³⁶⁵² The CMA penalties guidance, paragraph 2.21.

³⁶⁵³ See also the CAT's endorsement of this approach in *Lexon v CMA*: '[the CMA] then had to consider whether a penalty of this amount would fulfil the purpose of dissuading Lexon from breaking the law in the future. This can only be assessed by reference to how significant such a sum would be in the light of an undertaking's other activities and its overall financial position.' ([2021] CAT 5, paragraph 276.)

³⁶⁵⁴ For example, the Commission's approach in cases T-71/03 *Tokai Carbon v Commission* EU:T:2005:220, paragraph 118 and Case T-15/02 *BASF v Commission* EU:T:2006:74, paragraph 70. In *BASF*, for example, the Commission imposed eight fines on that company for participating in 8 distinct worldwide cartels for vitamins A, B2, B5, C, D3, E, beta-carotene and carotinoids. As set out further below, the fact that there are multiple penalties imposed would not in itself be a reason to reduce the penalty amount.

³⁶⁵⁵ See *Vitamins* (Commission decision in case 37.512), as upheld by the General Court in T-15/02 *BASF v Commission*; *Freight forwarding* (Commission decision in case 39.462), as upheld by the General Court in T-267/12 *Deutsche Bahn v Commission* (upheld by the Court of Justice in C-264/16 *Deutsche Bahn v Commission*); and *Thread* (Commission decision in case 38.337) as upheld by the General Court in T-446/05 *Amann & Söhne and Others v Commission*.

³⁶⁵⁶ See for example: T-446/05 *Amann & Söhne and Others v Commission*, paragraph 94. Accord-UK submitted that the infringements should be considered together and Waymade submitted that the CMA should apply the statutory cap to the total amount of the penalty, which are considered in Annex F. The CMA does not accept these representations as the statutory cap applies to each infringement separately. As set out further below and in Annex F, the CMA has been mindful of possible overlaps between penalties where more than one penalty is imposed to avoid double counting and to recognise that infringements occurred on different product strengths and at different times.

- a. the different strengths of hydrocortisone tablets (10mg or 20mg) subject to each of the Agreements and each of the Unfair Pricing Abuses;
- b. the difference in conduct as between the 10mg and 20mg Unfair Pricing Abuses on one hand, which were exploitative in nature and commenced before the emergence of potential competition, and the 10mg and 20mg Agreements on the other, which were exclusionary in nature in seeking to prevent potential competitors from independently entering the relevant markets;
- c. that different prices are charged and separate pricing decisions taken with respect to the different strengths of hydrocortisone tablets;
- d. that the market has developed differently after there was competitive entry for the separate strengths of tablet, so the 10mg Unfair Pricing Abuse and the 20mg Unfair Pricing Abuse have different durations;
- e. the fact that the Agreements had shorter durations than the Unfair Pricing Abuses; and
- f. that each of the Agreements had different terms, counterparties, starting dates and durations, related to a different strength of hydrocortisone tablet, and each sustained a separate Unfair Pricing Abuse.

10.154. The CMA therefore considers it appropriate to calculate separate penalties for the Auden/Actavis and Waymade undertakings for each Infringement.

VI. Liability for multiple penalties for multiple infringements: avoiding 'double counting'

10.155. For Waymade and Auden/Actavis, the CMA has, however, taken into account that multiple penalties are being imposed for infringements that cover the same product and geographic markets and for which the duration of the infringements overlap. In particular, the CMA has avoided double counting the relevant financial benefits and specific deterrence uplifts across multiple infringements:

- a. After increasing the penalties for the Unfair Pricing Abuses for the Auden/Actavis undertaking on the basis of the financial benefits this undertaking accrued from those Infringements, the CMA has not applied any further uplift for financial benefits relating specifically to the Agreements.

- b. Where an undertaking was involved in two infringements of the same type, the CMA has only applied an uplift for deterrence above the level of the financial benefit for one of the two infringements. In particular:
 - i. Auden/Actavis was involved in the 10mg and 20mg Unfair Pricing Abuses and in the 10mg and 20mg Agreements, but the CMA has only applied such a further uplift for the 10mg version of each Infringement; and
 - ii. Waymade was involved in the 20mg and 10mg Agreements, but the CMA has only applied such a further uplift for the 20mg Agreement.
- c. Although the CMA finds that the relevant market only segmented into separate product markets for each strength of hydrocortisone tablets after competitive entry occurred, it has only used 10mg turnover in the calculation of the penalty for the 10mg Agreement, and 20mg turnover in the calculation of the penalty for the 20mg Agreement, thus again avoiding using the same relevant turnover twice.

10.156. The CMA's approach to these points ensures that the uplifts applied at step 4 do not include more than once the same analysis of financial benefit and specific deterrence for the relevant undertakings.

VII. Assessment of the penalties in aggregate

10.157. As well as ensuring that the individual step 4 analysis for each separate penalty is sensitive to the fact that there are multiple penalties, the CMA has also been mindful of the fact that it is imposing multiple penalties on these undertakings which amount to a total amount that will be imposed on the same day and in a single decision. The CMA has therefore assessed these total amounts against the factors it has already taken into account for individual penalties, and against the fact that these individual penalties relate to Infringements that had a severe impact. The CMA has concluded that no further adjustment is necessary, as the penalties it has imposed on each undertaking are, within the context of the serious and harmful Infringements committed, not excessive or disproportionate even in aggregate.³⁶⁵⁷

³⁶⁵⁷ The CMA has considered the relevant considerations of deterrence, culpability and the seriousness of the Infringements as the CAT has noted that '*whilst deterrence is a relevant consideration when assessing proportionality in this context, so equally is the culpability of the offender/seriousness of the offence [...]* Ultimately the question will be: *is the final penalty reasonable and proportionate having regard to the twin objectives set out in paragraph 1.4 of the Guidance.*' See *Kier Group and Others v OFT* [2011] CAT 3, paragraph 175.

10.158. Accord-UK, Waymade, AMCo and Allergan submitted that it was important that the CMA take a ‘*step back*’, citing the CAT’s judgment in *Kier*,³⁶⁵⁸ and assess whether the proposed penalty is proportionate ‘*in the round*’, and where relevant also stating that the CMA should assess this across multiple infringements.³⁶⁵⁹ Accord-UK, Allergan and Waymade also pointed to approaches taken by the CMA in some of its previous decisions where there were multiple infringements and/or overlaps in the product and geographic markets and the Commission’s approach its pharmaceutical cases such as *Servier*.³⁶⁶⁰

10.159. The CMA has taken such a ‘*step back*’ and considered whether the overall action it has taken is not disproportionate or excessive by reference to the total level of the penalties as they will fall to be paid by the Auden/Actavis and Waymade undertakings, and considering that these are serious infringements of competition law with a severe impact. The CMA has met the requirement of ensuring that its action in this case as a whole does not lead to a disproportionate or excessive outcome. In determining the appropriate approach in this case the CMA has also considered the approach of the European Commission to addressing overlaps between geographic and product markets concerned by multiple infringements and overlapping time periods.³⁶⁶¹ As explained above, the present case involves two separate strengths of hydrocortisone tablets, which form (post-entry) separate product markets. The multiple Infringements in this case are an Unfair Pricing Abuse for each strength and an anti-competitive agreement for each strength, and do not result, as in *Paroxetine*, from simply the characterisation of two agreements within the same product market as an infringement of both the Chapter I and II prohibitions.

10.160. The Unfair Pricing Abuses were underpinned by anticompetitive agreements in the same markets. This feature of the multiple infringements should not operate as a ‘mitigating’ factor requiring a reduction in the penalty because more than one penalty has been imposed for different, mutually reinforcing

³⁶⁵⁸ *Kier Group and Others v OFT* [2011] CAT 3, paragraph 166.

³⁶⁵⁹ Document 205791, Allergan’s RDPS, paragraphs 77, 96, and 97; Document 205799, Waymade’s RDPS paragraphs 3.70 to 3.71; Document 206661, Waymade’s RLOF, paragraph 9.5; Document 205813, Accord-UK’s RDPS paragraphs 5.2, 10.49 to 10.51; Document 205848, AMCo’s RDPS, paragraphs 2.4 and 7.3.

³⁶⁶⁰ Such as the CMA’s decisions in *Light Fittings*, *Drawer wraps* and *Drawer fronts*, and *Paroxetine*, and the European Commission’s decisions in its pharmaceutical case *Servier*. Document 205799, Waymade’s RDPS paragraphs 3.85 and 3.87; Document 205791, Allergan’s RDPS paragraph 96; Document 205813, Accord-UK’s RDPS paragraphs 1.15, 5.1 to 5.11, 10.49 to 10.51.

³⁶⁶¹ The parties do not however mention the European Commission’s approach in the *Vitamins* case (European Commission case 37.512), the *Freight Forwarding* case (European Commission case 39.462) and the *Industrial Threads* case (European Commission case 38.227) where the Commission imposed separate penalties for separate cartels which did not include an adjustment for the fact that there were multiple penalties imposed. The *Freight forwarding* and *Vitamins* decisions both apply deterrence uplifts for each individual penalty which has the effect of imposing multiple deterrence uplifts. These decisions were upheld on appeal (see paragraph 10.150 above).

infringements committed by the same undertaking.³⁶⁶² This would run counter to the rationale and statutory objectives for imposing penalties³⁶⁶³ and undermine their deterrent effect.³⁶⁶⁴

10.161. The approach to the common factors between the Infringements as set out in more detail above navigates these issues in the appropriate way given the specific facts of this case.

D. Penalty calculations

10.162. The CMA has applied the six-step approach set out in the CMA penalties guidance when calculating each of the penalties in this case. The results are set out below and the summary penalty calculation tables are in Annex E. Annex F contains the CMA's assessment of the case parties' representations on the CMA's approach at step 4.

I. Step 1: starting point

10.163. The starting point for determining the level of financial penalty which will be imposed is calculated with regard to the seriousness of the infringement and the turnover of the undertaking in the relevant product market and geographic market affected by the infringement in the undertaking's last business year (known as 'relevant turnover') except in exceptional circumstances.³⁶⁶⁵ The CMA will apply a percentage rate of up to 30% to the relevant turnover depending on the seriousness of the infringement. The remainder of this section refers to this as the 'standard approach'.

a. Relevant turnover

10.164. The CMA has determined the relevant turnover for each penalty in accordance with the standard approach described in paragraph 10.163 above, with the exception of Waymade's relevant turnover for the 10mg Agreement.

10.165. Waymade is liable for the 10mg Agreement for the period from 23 October 2012 to 30 October 2012 only. Under the standard approach, Waymade's

³⁶⁶² In *Paroxetine* the CAT agreed with the CMA's the calculation of separate penalties for two Agreements because 'in our view, the fact that GSK entered into two distinct infringing Agreements, almost eight months apart and with different generic companies, manifestly justifies a significantly higher penalty than if GSK had entered into only one of those Agreements' (see *Generics (UK) Limited and others v CMA* [2021] CAT 9, paragraph 190).

³⁶⁶³ As set out in s.36(7A) of the Act.

³⁶⁶⁴ CMA penalties guidance, paragraph 1.3 referring to s. 36(7A) of the Act that the twin objectives of the policy on financial penalties are: 'to impose penalties on infringing undertakings which reflect the seriousness of the infringement; and to ensure that the threat of penalties will deter both the infringing undertakings and other undertakings that may be considering anti-competitive activities from engaging in them.'

³⁶⁶⁵ CMA penalties guidance, paragraphs 2.3 to 2.15. Paragraph 2.11 provides that the undertaking's last business year is the financial year preceding the date when the infringement ended.

relevant turnover would be calculated by reference to Waymade's financial year ending 31 December 2011, before the 10mg Agreement commenced. This would not reflect the '*real economic situation*' and true scale of Waymade's activities in the market at the time of the 10mg Agreement.³⁶⁶⁶ Instead, the CMA has calculated Waymade's relevant turnover for the 10mg Agreement by reference to its total revenue from the sale of 10mg hydrocortisone tablets in the UK during the 12-month period from 1 November 2011 to 31 October 2012.³⁶⁶⁷ This reference year most accurately reflects the real economic situation at the time Waymade committed the infringement of entering into the 10mg Agreement. It is a more representative period of Waymade's business for calculating the starting point.

10.166. Cinven and AMCo submitted that the CMA should depart from the standard approach in order to calculate AMCo's relevant turnover at step 1 of the penalty calculation for the 10mg Agreement. In Cinven's view the relevant turnover for the penalty for which it is held jointly and severally liable should be based on its period of ownership only. AMCo urged the CMA to use an average of turnover generated during the Infringement, rather than the last business year before the Infringement ended (since its turnover in that year was materially higher than in previous years).³⁶⁶⁸

10.167. The CMA rejects Cinven's contention: the CMA's guidance is clear that the undertaking's last business year before the Infringement ended is the appropriate reference year to calculate the undertaking's relevant turnover. The CMA has found that AMCo constituted an undertaking of which Cinven formed part until it sold its stake in the undertaking.³⁶⁶⁹ Consistent with this finding and the CMA's penalties guidance, the CMA has calculated the relevant turnover figure based on that undertaking's last business year before the infringement ended (the financial year ending 31 December 2015). Doing so would not discriminate against Cinven when compared to Waymade,³⁶⁷⁰ because Waymade was not part of the AMCo undertaking.

³⁶⁶⁶ See *Kier Group plc and others v OFT* [2011] CAT 3, paragraphs 126, 132 and 138. See also the *Balmoral* judgment [2017] CAT 23, paragraph 141, in particular the CAT's reference to the need to reflect '*the infringer's position on the market*', and the *Paroxetine* judgment (*Generics (UK) Limited and others v CMA* [2021] CAT 9) paragraph 159. A similar approach has been adopted in EU case law prior to IP completion day, see for example Case T 334/94 *Sarrió v Commission* [1998] II 1439, paragraph 397.

³⁶⁶⁷ Waymade submitted that this is not an exceptional case warranting a departure from the CMA penalties guidance (Document 205799, Waymade's RDPS, paragraphs 3.25 to 3.30). The CMA does not accept this submission for the reasons set out in paragraph 10.165. There is no definitive list of circumstances in which a departure from the guidance may be appropriate in the CMA penalties guidance or otherwise, as recently confirmed by the CAT in *FP McCann* [2020] CAT 28.

³⁶⁶⁸ Document 205805, Cinven's RDPS, paragraphs 1.24, 3.3 to 3.9; Document 205848, AMCo's RDPS, paragraphs 2.16, 4.45 to 4.47, 7.4 to 7.8.

³⁶⁶⁹ See section 9: Undertakings and attribution of liability.

³⁶⁷⁰ Document 205805, Cinven's RDPS, paragraph 3.8.

10.168. The CMA also rejects AMCo's request that the CMA depart from its guidance. The trajectory of AMCo's relevant turnover does not show such volatility or exponential growth that the application of the guidance may need to be modified to arrive at a more accurate reflection of its position on the market.³⁶⁷¹ The fact that AMCo's turnover in 2015 was higher than in previous years is the result of the consistently increasing prices that AMCo charged its customers for the hydrocortisone tablets it procured at heavily discounted rates from Auden/Actavis. This does not require the CMA to depart from the CMA penalties guidance.

10.169. Finally, the relevant turnover for the 10mg Unfair Pricing Abuse is considerably lower than the annual turnover that Auden/Actavis generated in the relevant product market and geographic market in most years during the Infringement. This is a result of the drop in prices and volumes that followed after independent entry in the market was observed. Rather than treating this as an exceptional case at step 1, this has been taken into account at step 4.

10.170. The relevant turnover of each undertaking for each Infringement is therefore as follows:

Table 10.5: relevant turnover for each infringement

Infringement	Undertaking	Relevant turnover
10mg Unfair Pricing	Auden/Actavis	£17,058,504
20mg Unfair Pricing	Auden/Actavis	£2,606,883
10mg Agreement	Auden/Actavis	£48,464,781
	Waymade ³⁶⁷²	£738,030
	AMCo	£8,347,516
20mg Agreement	Auden/Actavis	£2,120,095
	Waymade	£822,958

b. Seriousness

10.171. Taking into account the nature of the Infringements, the specific circumstances of the case, and the need for general deterrence³⁶⁷³ the CMA

³⁶⁷¹ The CAT's decision in *FP McCann* [2020] CAT 28, paragraph 180.

³⁶⁷² The Waymade undertaking comprised Waymade plc and Amdipharm-UK for Period D1 (23 October 2012 - 30 October 2012) and Waymade plc only thereafter.

³⁶⁷³ CMA penalties guidance, paragraphs 2.6 to 2.9. Contrary to Accord-UK's, AMCo's and Waymade's representations, the CMA has approached the penalty calculations on a case-by-case basis with reference to the

considers that each of the Infringements is so serious that the maximum starting point of 30% of relevant turnover should be applied for each of the penalties.

10.172. With respect to **all Infringements**, the following factors are relevant to the CMA's assessment of their seriousness:³⁶⁷⁴

- a. Likelihood of the Infringements, by their nature, to harm competition. Market sharing and excessive and unfair pricing are both recognised in the CMA's penalties guidance as the types of infringement which are most likely by their very nature to harm competition.³⁶⁷⁵ This is further discussed for each of the Unfair Pricing Abuses and the Agreements below.
- b. Nature of the product. Hydrocortisone tablets are an essential medication used by approximately 95% of all UK patients who suffer from adrenal insufficiency.³⁶⁷⁶ The NHS has no choice but to fund the prescription of hydrocortisone tablets to those patients. As a result of the price increases for hydrocortisone tablets, CCGs would have had to reallocate funding from other services and treatments. Hydrocortisone tablets are a very old product which is long off-patent and in the third stage of the drug lifecycle, and the prices charged by Auden/Actavis were clearly excessive and unfair.³⁶⁷⁷ The CMA has borne in mind that the demand for hydrocortisone tablets is from patients who suffer from a very serious condition. The abusively high prices charged for this product did not affect the level of demand during the relevant period, which reflects the essential nature of the product and the lack of affordable alternatives.
- c. Structure of the market. Auden/Actavis was the sole supplier of hydrocortisone tablets during the majority of the Infringements and retained a significant market share even after independent entry.³⁶⁷⁸ Its position as the sole supplier allowed Auden/Actavis to increase and maintain prices for hydrocortisone tablets to very high levels. As

specific facts of the case, in accordance with the CMA penalties guidance paragraph 2.6 (Document 205813, Accord-UK's RDPS, paragraphs 6.3 to 6.9; Document 205848, AMCo's RDPS, paragraphs 4.48 to 4.54 and 7.13 to 7.15; Document 205799, Waymade's RDPS, paragraphs 3.3 to 3.8)

³⁶⁷⁴ The CMA has considered the seriousness of the Agreements for the purposes of the penalty calculations, notwithstanding the fact that, since the CMA has found that the Agreements are object infringements, it is not required to make a formal assessment of the actual harm caused for the purposes of establishing an infringement (joined cases C-56/64, C-58/64, p. 342 *Consten and Grundig v Commission*, see also *Cityhook Limited v OFT* [2007] CAT 18, paragraph 269).

³⁶⁷⁵ CMA penalties guidance, paragraph 2.6.

³⁶⁷⁶ See section 3.C.II.

³⁶⁷⁷ See section 3.B.VII and section 5.

³⁶⁷⁸ See section 4.C.II.b.i and 4.C.II.c.i.

discussed in section 4.C the CMA has concluded that Auden/Actavis held a dominant position that enabled it to act to an appreciable extent independently of customers, competitors and ultimately consumers in the markets for hydrocortisone tablets in the UK. Auden/Actavis's substantial market power was strengthened by the orphan designation with respect to the 10mg tablet strength which acted as a barrier to expansion.³⁶⁷⁹ The Agreements had the object of delaying the emergence of effective competition for hydrocortisone tablets, thereby enabling Auden/Actavis to sustain both its position as sole supplier and abusively high prices.³⁶⁸⁰ In these circumstances, there was no effective competitive pressure to bring hydrocortisone tablet prices down to competitive levels.

- d. Harm to end customers. Auden/Actavis's abusively high prices for hydrocortisone tablets, which were sustained by the Agreements, had a direct and substantial effect on the NHS and CCGs. In particular, they increased costs to the NHS and ultimately the taxpayer. The abusively high prices were not the result of any innovation, development, additional commercial risks or a material change in costs and brought no additional benefits for patient welfare.³⁶⁸¹
- i. The NHS budget is constrained and legitimate demands for healthcare tend to exceed its capacity, so that unnecessary additional costs for medicines make it even harder to fulfil its functions of meeting patient needs.
- ii. Auden/Actavis's prices have resulted in the NHS paying significantly more for hydrocortisone tablets when compared, for example, to the prices that the NHS was paying prior to April 2008. In the last full year that hydrocortisone tablets were supplied by MSD (2007), the NHS's annual spend on hydrocortisone tablets was approximately £0.5 million. By contrast, during the period in which hydrocortisone tablets were supplied by Auden/Actavis, the NHS's annual spend on the product increased from £7.8 million in 2008 to a peak of nearly £84 million in 2016 (before it began falling thereafter, with an annual spend of £62 million in 2017, approaching £40 million in 2018 and down to just under £10 million in 2020).³⁶⁸²

³⁶⁷⁹ See section 4.C.II.c.iii.

³⁶⁸⁰ See section 4.C.II.b.iii, and section 6.

³⁶⁸¹ See section 5.D.II.b.

³⁶⁸² See section 5.D.II.e.

- iii. Due to these increased costs, CCGs had to commit additional funds to the supply of hydrocortisone tablets that could have been used for other healthcare services.³⁶⁸³ Therefore, the harm caused by the Unfair Pricing Abuses is not restricted to hydrocortisone tablets.
 - iv. Without material investment or innovation, Auden/Actavis' genericised hydrocortisone tablets have added no benefits to patients beyond those available in MSD's branded Hydrocortone product since 1955.
- e. General deterrence. Section 36(7A) of the Competition Act 1998 requires the CMA to set penalties in particular to deter other undertakings from engaging in similar infringements.³⁶⁸⁴ Unfairly high pricing, by definition, tends to directly create significant excess profits for undertakings which engage in such conduct. Since the potential gains from such conduct are so great, and so certain, the CMA considers that a high starting point is appropriate in order to ensure that other dominant firms are deterred from engaging in such conduct in the future.
 - i. Market exclusion agreements are very likely, by their nature, to cause harm to competition. The EU Court of Justice has consistently held market exclusion agreements to be a particularly serious breach of the competition rules.³⁶⁸⁵ The CMA therefore considers that a high starting point is appropriate to ensure that other undertakings are deterred from concluding market exclusion agreements in the future.
 - ii. The Unfair Pricing Abuses and the Agreements are not isolated examples of such conduct within the pharmaceutical sector in the UK. Indeed, there are other cases involving similar conduct that have been, or are being, investigated by the European Commission, in the UK and other EU Member States.³⁶⁸⁶

³⁶⁸³ See paragraphs 5.362 to 5.364.

³⁶⁸⁴ CMA penalties guidance, paragraphs 2.4 and 2.9.

³⁶⁸⁵ See section 6.D.I.b.i

³⁶⁸⁶ See, for example, CMA Decision finding unfair pricing in respect of the supply of phenytoin sodium capsules in the UK, Case CE/9742-13. See also the CMA's open case into alleged excessive and unfair pricing in relation to liothyronine tablets (case 50395). See also the decision taken by the Autorità Garante della Concorrenza e del Mercato in case A480 against the multinational pharmaceutical company Aspen on 29 September 2016 ([AGCM - Autorita' Garante della Concorrenza e del Mercato](#)).

10.173. It is important to note that all of the foregoing factors, taken in the round, informed the CMA's assessment of the harm to competition in the specific circumstances of this case.

10.174. In addition to the factors set out in paragraph 10.172 above, the very nature of the **Unfair Pricing Abuses** in this case contributes to their seriousness.

- a. The Unfair Pricing Abuses are by their nature likely to have serious exploitative effects. Protecting customers against exploitation is one of the underlying purposes of competition law: unfair pricing is expressly prohibited by section 18(2)(a) of the Act. Unfair pricing, by its very nature, goes to the heart of one of the key harms that competition law is designed to address – namely, consumers being exploited by supra-competitive prices. Whereas other types of abuse of dominance (i.e. exclusionary conduct such as predatory pricing) and cartels seek to restrict competition with a view to the infringing parties being able to charge supra-competitive prices, unfair pricing directly and deliberately imposes such prices.
- b. The CMA has found that the Unfair Pricing Abuses resulted in Auden/Actavis's prices being considerably higher than those which might usually be achieved through other forms of anti-competitive conduct. Where the structure of the relevant market is conducive to a supplier imposing unfair prices, the harmful effects of this abuse may – absent intervention – also be more sustainable. These effects tend to persist for longer than other forms of serious anticompetitive practice – indeed, the Unfair Pricing Abuses both have a longer duration than any other since the Act came into force.

10.175. In addition to the factors set out in paragraph 10.172 above, the very nature of the **Agreements** in this case contributes to their seriousness.

- a. Market exclusion agreements are very likely, by their nature, to cause harm to competition. They eliminate competition between the parties. Such agreements may be more effective than horizontal price fixing from the cartel's point of view, because the expense and difficulties of fixing common prices are avoided: the agreement means that there will be no price competition anyway. Market-sharing and market exclusion agreements are among the most serious restrictions of competition expressly referred to in the Chapter I prohibition.³⁶⁸⁷

³⁶⁸⁷ Case T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 765 (appeal dismissed: Case C-591/16 P EU:C:2021:243). See also section 6.D.I.b.i.

- b. In this case, the Agreements were intended to maintain Auden/Actavis's 100% market share in 10mg and 20mg hydrocortisone tablets and to delay true competition by paying potential competitors not to enter the market independently of Auden/Actavis.³⁶⁸⁸ Waymade and AMCo used their position as potential competitors as leverage to agree with Auden/Actavis not to enter the market independently in exchange for significant monthly payments. In the absence of the Agreements, independent entry would be expected to reduce prices in order to win (or retain) business. The aim of the Agreements was to disrupt the competitive process and delay the emergence of true generic competition for these products. The consequence was that a dominant supplier was able to charge prices which were excessive and unfair, with the further consequence that the NHS (and thus the taxpayer) had to pay abusively high prices for a generic, essential drug.³⁶⁸⁹

10.176. In the light of the factors identified in paragraphs 10.171 to 10.175 above, the CMA considers that the maximum starting point of 30% of relevant turnover is necessary and appropriate in respect of each of the Infringements for the purposes of reflecting their seriousness and achieving general deterrence.

10.177. All the case parties argued that the 30% starting point is too high by reference to: (i) the specific facts of the case; (ii) the factors that the CMA has cited when assessing seriousness (including that similar factors have historically led to lower starting points); (iii) the DHSC's powers to regulate prices and (iv) the '*uncertainty*' in the law the parties assert was present at the time of the Infringements.³⁶⁹⁰ Accord-UK, Allergan, AMCo and Cinven also argued that the maximum starting point is not required in order to achieve general deterrence in the pharmaceutical sector, as this has already been achieved by the CMA's and European Commission's recent and ongoing investigations.³⁶⁹¹

10.178. The CMA does not accept these submissions, for the following reasons.

³⁶⁸⁸ See section 6.

³⁶⁸⁹ For example, as summarised in section 1.B.

³⁶⁹⁰ Document 205813, Accord-UK's RDPS, paragraphs 3.1 to 3.14, 6.8 to 6.20; Document 205848, AMCo's RDPS, paragraphs 2.17 to 2.18, 4.51 to 4.66, and 7.9 to 7.16; Document 205791, Allergan's RDPS, paragraphs 33 to 44, and 91 to 93; Document 205805, Cinven's RDPS, paragraphs 3.11 to 3.26; Document 205802, Intas/Accord-UK's RDPS, paragraphs 44 to 56; Document 205799, Waymade's RDPS, paragraphs 3.8 to 3.24; Document 206661, Waymade's RLOF, paragraph 9.3.

³⁶⁹¹ Document 205813, Accord-UK's RDPS, paragraphs 6.8 to 6.10, 6.21 to 6.23; Document 205848, AMCo's RDPS, paragraphs 2.17 to 2.18, 7.17 to 7.29; Document 205791, Allergan's RDPS, paragraph 41; Document 205802, Intas/Accord-UK's RDPS, paragraph 52.

- 10.179. The CMA has ensured that it has performed an evaluative assessment of seriousness³⁶⁹² by considering the factors set out in paragraphs 10.171 to 10.175 above based on the facts of this particular case. The Infringements are inherently serious infringements which have been prevalent in the pharmaceutical sector and which has a harmful effect on the NHS. Moreover, the starting point is not out of line with the starting point adopted by the CMA in other decisions involving similar conduct.³⁶⁹³
- 10.180. The CMA rejects the case parties' contention that the starting point should be lower on the basis of comparisons with other CMA and Commission cases. The CMA assesses penalties on a case-by-case basis and is not bound by previous decisional practice, and in any case there are significant differences between this case and those cited by the case parties.³⁶⁹⁴ As set out above, the CMA considers the Infringements to be particularly serious infringements for which the maximum starting point is appropriate.
- 10.181. As set out in section 10.B.III above (*Legal certainty*), there was no uncertainty as to whether the conduct was anti-competitive at the time of the Infringements that would suggest that the Infringements should be considered as less serious.
- 10.182. The existence of DHSC powers does not reduce the need for general deterrence. As discussed in response to the parties' representations on the powers of the DHSC³⁶⁹⁵ the DHSC's powers are not aimed at deterring and punishing illegal activity (as the CMA's powers under section 36 of the Act are). Further, the need to impose a penalty for a breach of competition law does not, and should not, depend on whether the DHSC could intervene to bring down an unduly high generic drug price. Further still, having regard to its resources, capabilities and powers, it is neither realistic nor appropriate to expect the DHSC to identify opportunistic price exploitation (and associated conduct, including market sharing) and seek to use its powers to prevent such conduct from occurring in a sufficiently timely manner. In any event, the existence of DHSC powers does not, and should not, absolve parties of their obligation to comply with competition law or preclude the imposition of an appropriate penalty designed to achieve general deterrence (which, by

³⁶⁹² CMA penalties guidance, paragraphs 2.4 to 2.10.

³⁶⁹³ For example, the starting point of 30% applied in the CMA's *Phenytoin* decision and the starting point of 27% in the CMA's decision in *'Anti-competitive agreement with respect to fludrocortisone acetate 0.1mg tablets'*.

³⁶⁹⁴ The CAT recently confirmed that limited assistance can be obtained from previous OFT and CMA decisions when assessing seriousness, since seriousness depends on a number of factors and each case is very different (see decision in *Generics (UK) Limited and others v CMA* [2021] CAT 9, paragraph 151, and *Roland v CMA*, [2021] CAT 8, paragraphs 87 and 90 on the value of previous decisional practice and the individual assessment of case-specific factors).

³⁶⁹⁵ See Annex F.

definition, is not confined to a specific sector):³⁶⁹⁶ it is important to deter infringing conduct of the kind engaged in by the undertaking on which the penalty is being imposed across the economy in the UK.

10.183. The fact that there have been and continue to be a number of investigations in the pharmaceutical sector by the CMA and the European Commission does not detract from the seriousness of the Infringements set out in this Decision. It cannot be accepted that, in circumstances where the CMA detects infringements in a sector that has already been subject to such scrutiny, there is no need for setting the starting point at a level that achieves general deterrence. The fact that the Infringements have been identified in these circumstances of itself demonstrates that general deterrence *is* still necessary.

10.184. Cinven, AMCo and Waymade submitted that the CMA has failed to apply equal treatment principles by applying the same starting point for all the Infringements.³⁶⁹⁷ This mischaracterises the approach the CMA has taken to assessing seriousness: the CMA has considered each of the Infringements individually and concludes that each warrants the maximum starting point under the guidance for the reasons set out above.

10.185. In conclusion on step 1, the CMA considers that each of the Infringements concern the most serious type of infringing activity. There is a clear need to ensure general deterrence with respect to these types of infringements, including within the pharmaceutical industry.³⁶⁹⁸ Where a penalty is not recognised by other undertakings as sufficiently high to have a real impact on the infringing undertaking, other undertakings may form the view that the risk of penalties for competition infringements is not a significant business

³⁶⁹⁶ See, for example, *Ping Europe Limited v CMA* [2018] CAT 13, paragraph 241: ‘*The CMA was also correct to consider deterrence on Ping, other golf club manufacturers and other manufacturers and wholesalers in retail sectors more generally*’.

³⁶⁹⁷ Document 205799, Waymade’s RDPS, paragraphs 3.15 to 3.22; Document 205805, Cinven’s RDPS, paragraphs 3.87 to 3.89; Document 205848, AMCo’s RDPS, paragraphs 2.17, 7.15.

These parties also asserted that the CMA should distinguish between the conduct of each party to the Agreements at this step. However, the CMA penalties guidance is clear that in the case of infringements involving more than one undertaking, the assessment will be consistent for each undertaking since the starting point is intended to reflect the seriousness of the infringement at issue, rather than the particular circumstances of each undertaking’s unlawful conduct, which are taken into account at other steps (CMA penalties guidance, paragraph 2.10).

Similarly Allergan (Document 205791, Allergan’s RDPS, paragraphs 33 and 37) and Intas/Accord-UK (Document 205802, Intas/Accord-UK’s RDPS, paragraphs 44 and 56) submitted that the CMA’s assessment of seriousness does not reflect the circumstances of their ownership periods. However, the starting point is intended to reflect the seriousness of the infringement as a whole, rather than the involvement of a particular undertaking or entity, which are taken into account at other steps (CMA penalties guidance, paragraph 2.10).

³⁶⁹⁸ As noted above, the CMA and the European Commission continue to investigate anti-competitive conduct in the pharmaceuticals sector: see for example the CMA’s ongoing investigations into the supply of nitrofurantoin and into the supply of prochlorperazine 3mg buccal tablets, and the CMA’s recently concluded investigation into market sharing for fludrocortisone acetate 0.1mg tablets in the UK. See also for example the European Commission’s infringement finding against Teva and Cephalon on 26 November 2020 for delaying the entry of a generic drug.

risk to which their management (including their top-level management) should give attention. This would undermine the effectiveness of competition law.

II. Step 2: adjustment for duration

10.186. The starting point under step 1 may be increased or, in exceptional circumstances, decreased to take account of the duration of an infringement. Where the total duration of an infringement is more than one year, the CMA may round up part years to the nearest quarter year where the total duration is more than one year.³⁶⁹⁹

a. Auden/Actavis

10.187. The CMA finds that:

- a. the duration of the 10mg Unfair Pricing Abuse was from 1 October 2008 to 31 July 2018 (9 years and 10 months) and a duration multiplier of 10 is therefore applicable;
- b. the duration of the 20mg Unfair Pricing Abuse was from 1 October 2008 to 8 January 2017 (8 years and 3 months) and a duration multiplier of 8.25 is therefore applicable;
- c. the duration of the 10mg Agreement was from 23 October 2012 to 24 June 2016 (3 years, 8 months and 1 day) and a duration multiplier of 3.75 years is therefore applicable; and
- d. the duration of the 20mg Agreement was from 11 July 2011 to 30 April 2015 (3 years and 10 months) and a duration multiplier of 4 is therefore applicable.

10.188. The CMA only holds Allergan, Accord and Intas jointly and severally liable with Accord-UK for their respective distinct periods of ownership. The penalties imposed on the Auden/Actavis undertaking will therefore be apportioned by reference to the entities' periods of ownership as explained further in the penalty calculation.

b. Waymade

10.189. The CMA finds that the duration of the 20mg Agreement was from 11 July 2011 to 30 April 2015 (3 years, 10 months). The CMA has therefore applied

³⁶⁹⁹ CMA penalties guidance, paragraph 2.16. Though Cinven submitted that the CMA penalties guidance does not require the starting point to be increased for duration, nor that the duration multiplier is required to reflect the full duration of the infringement (Document 205805, Cinven's RDPS, paragraph 3.27), the CMA nevertheless considers there are no circumstances which would make it appropriate to depart from the guidance in this case.

a duration multiplier of 4. The CMA concludes that the duration of Waymade's liability for the 10mg Agreement was from 23 October 2012 to 30 October 2012 (1 week) and therefore does not consider it necessary to adjust the penalty at step 2.³⁷⁰⁰

c. AMCo

10.190. The CMA concludes that the duration of AMCo's liability for the 10mg Agreement (Periods D2 and D3) was 31 October 2012 to 24 June 2016 (3 years and 8 months). The CMA has therefore applied a duration multiplier of 3.75.

10.191. The CMA only holds the Cinven Entities and Advanz jointly and severally liable with the Amdipharm Companies for their respective distinct periods of ownership. The duration multiplier will therefore be apportioned by reference to their respective periods of ownership as explained further in the penalty calculation.

10.192. Accord-UK, Allergan, AMCo, Cinven and Waymade have submitted that the penalties imposed by the CMA do not accurately reflect the duration of their involvement in the Infringements.³⁷⁰¹ The CMA does not accept these representations which relate to the parties' liability for the Infringements: the CMA's calculation of duration is in accordance with the CMA penalties

³⁷⁰⁰ CMA penalties guidance, paragraph 2.16. Waymade submitted that the penalty for the 10mg Agreement ought to be adjusted downwards at step 2 in order to reflect the short duration of the infringement (Document 205799, Waymade's RDPS, paragraphs 3.35 to 3.38). The CMA does not accept that the short period of infringement constitutes '*exceptional circumstances*' as outlined in paragraph 2.16 of the CMA penalties guidance. Short duration of an infringement does not necessarily mean it should be considered less serious, and the CMA has found that Waymade instigated the 10mg Agreement which was continued by AMCo for several years.

³⁷⁰¹ Accord-UK submitted that it was not dominant in the supply of 10mg hydrocortisone tablets beyond March 2016 or the supply of 20mg hydrocortisone tablets beyond December 2015, and therefore argued that the CMA is not entitled to fine Accord-UK for these periods. It further argued that Accord-UK could not have been aware of any unwritten anticompetitive terms agreed during the negotiation of the 10mg Agreement therefore the CMA should not hold it liable or impose for the period following 29 May 2015 (Document 205813, Accord-UK's RDPS, paragraphs 7.1 to 7.9).

Allergan contested its liability for the period up to 1 September 2015 when Auden was responsible for marketing, sale and distribution of hydrocortisone tablets; it submitted that the Akzo presumption is rebutted as it had already agreed to sell the Actavis Generics business to Teva prior to September 2015; and it argued that even if the Akzo presumption were not rebutted, it should not be held liable for the Hold-Separate Period commencing on 10 March 2016 (Document 205791, Allergan's RDPS, paragraphs 45 to 46 and 91).

AMCo submitted that the CMA has not shown that the 10mg Agreement persisted unbroken for the entire infringement period and stated that the CMA's approach was inconsistent with its finding that save Amdipharm UK, AMCo is not found liable for the 10mg Agreement before 1 January 2013 (Document 205848, AMCo's RDPS, paragraph 7.30).

Cinven argued that the duration multiplier should be lower as AMCo was at least six to eight months away from being able to enter the market during the infringement period, during which time any anticompetitive agreement had no effect on AMCo's independent entry (Document 205805, Cinven's RDPS, paragraph 3.28).

Waymade submitted that its efforts to commercialise its 20mg hydrocortisone tablets show that the 20mg Agreement should end in August 2013, and argued that its liability for the 10mg Agreement amounts only to 12 days, and that it is disproportionate to treat this as a full year at step 2 (Document 205799, Waymade's RDPS, paragraphs 3.31 to 3.34).

The CMA does not accept any of these arguments, which are based on incorrect assessments of liability.

guidance and its findings of liability for the Infringements as established in this Decision.

III. Step 3: adjustment for aggravating and mitigating factors

10.193. The financial penalty at the end of step 2 may be increased to reflect aggravating factors and/or decreased where there are mitigating factors.³⁷⁰²

a. Aggravating factors – involvement of directors or senior management

10.194. The CMA has concluded that the involvement of directors and senior management within the Auden/Actavis, Waymade and AMCo undertakings in the design and implementation of the Infringements should be considered as an aggravating factor at step 3.^{3703, 3704}

i. Auden/Actavis

The Unfair Pricing Abuses

10.195. In relation to the Unfair Pricing Abuses, the following directors and senior management were involved: [Auden Senior Employee 1] and [Auden Senior Employee 5], [Auden Senior Employee 2]; and [Auden Senior Employee 4] from Auden; and [Actavis Senior Employee 1]³⁷⁰⁵ and [Actavis Senior Employee 3] from Actavis.³⁷⁰⁶

³⁷⁰² A non-exhaustive list of aggravating and mitigating factors is set out in the CMA penalties guidance, paragraphs 2.17 to 2.19.

³⁷⁰³ Accord-UK, the Cinven Entities and Advanz submitted that the involvement of senior management in negotiating significant commercial agreements, acquisitions and in product development and strategy is unavoidable and in the ordinary course of business for most companies. They submit that the CMA's approach therefore '*punishes normal decision-making*', especially in smaller companies such as Auden and AMCo, and amounts to an '*automatic*' uplift rather than being a genuine aggravating factor (Document 205848, AMCo's RDPS, paragraph 7.32.2; Document 205813, Accord-UK's RDPS, paragraphs 8.6 to 8.24; and Document 205805, Cinven's RDPS, paragraphs 1.16 and 3.36). This representation cannot be accepted: the CMA's objection is to senior involvement in anticompetitive infringements, not the ordinary course of business. Differences in size of undertaking are corrected for in the proportionality adjustments at Step 4.

³⁷⁰⁴ Accord-UK submitted that the CMA has not provided sufficient justification to treat director involvement as an aggravating factor, and has not provided sufficient reasoning to apply an uplift for director involvement during the period of Auden's involvement or Allergan's ownership (Document 205813, Accord-UK's RDPS, paragraphs 8.7 and 8.11). As set out above, the CMA has a number of reasons to consider that directors and senior management played a key role in infringing conduct. The CMA has found that senior involvement went beyond knowledge of the infringements but also involved instigating and maintaining the conduct in question, as well as doing nothing to discontinue conduct when under investigation. The uplift is applied in relation to the entire infringement period, and not considered with reference to different ownership periods.

³⁷⁰⁵ [Actavis Senior Employee 1] [REDACTED]. See Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 8, lines 2 to 3; Document 02238, response to question 1, Intas and Accord-UK's UK's response to the CMA's section 26 notice dated 20 December 2017.

³⁷⁰⁶ [Actavis Senior Employee 3] [REDACTED]. See Document 02238, response to question 1, Intas and Accord-UK's UK's response to the CMA's section 26 notice dated 20 December 2017; and Document 203353, transcript of [Actavis Senior Employee 3] interview dated 22 July 2019, page 7, lines 3 to 10.

10.196. In particular, at all stages of the infringement period, directors and senior management were involved in price setting for hydrocortisone tablets:

- a. From 2008 to 2010, [Auden Senior Employee 1] and [Auden Senior Employee 5] were responsible for setting the price of hydrocortisone tablets.³⁷⁰⁷
- b. From 2011 to 2015, [Auden Senior Employee 2], and later [Auden Senior Employee 4], were responsible for setting hydrocortisone tablet prices, periodically briefing [Auden Senior Employee 1].³⁷⁰⁸
- c. From 1 September 2015 onwards (during both the Allergan and the Intas ownership periods), prices for hydrocortisone tablets were set at meetings organised by the Commercial Team's senior management and chaired by [X] (first [Actavis Senior Employee 3] and subsequently by [X]).³⁷⁰⁹ [Actavis Senior Employee 1] said he had 'sign off'³⁷¹⁰ over price changes while [X] (a position subsequently held by [Actavis Senior Employee 3]).³⁷¹¹

10.197. The pricing of hydrocortisone tablets was a key issue for the senior management of Auden/Actavis throughout the infringement periods. This remained true when Auden was acquired by Allergan and subsequently Intas:

- a. Prior to Allergan's acquisition of Auden, the pricing of hydrocortisone tablets was closely scrutinised by senior management: [Actavis Senior Employee 1] acknowledged that assessments of the price of hydrocortisone tablets had formed part of the due diligence process, and had been built into the '*modelling[...]* for the overall acquisition value.'³⁷¹²

³⁷⁰⁷ [X].

³⁷⁰⁸ Document 00725, Witness Statement of [X] dated 12 September 2016, paragraph 1.5.

³⁷⁰⁹ Document 01941, response to question 1, Accord-UK's response to the CMA's section 26 notice dated 29 August 2017; and Document 02238, response to question 1, Intas and Accord-UK's response to the CMA's section 26 notice dated 20 December 2017. In this response, Accord-UK stated that they were introducing a Commercial Product Management team that would take an overview responsibility for products including hydrocortisone tablets, and had appointed [X], to the team. This team would have a key input, but '*pricing decisions will still be made according to the existing procedures and mechanisms (such as at the monthly Generics Commercial Meeting)*'.

³⁷¹⁰ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 12, line 7.

³⁷¹¹ Intas submitted that the CMA's reasoning on [Actavis Senior Employee 1]'s involvement in the infringement during the Intas period (signing off prices and attending meetings) is not sufficient to warrant an uplift (Document 205802, Intas/Accord-UK's RDPS, paragraph 59). On the basis of the evidence set out here showing [Actavis Senior Employee 1]'s clear oversight of price setting decisions the CMA does not accept this representation.

³⁷¹² Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 12, lines 24 to 26; page 13, lines 1 to 4.

- b. [Actavis Senior Employee 1] stated in interview that hydrocortisone tablets were ‘a key important product’ that ‘would have got a lot more focus than others’ in pricing meetings.³⁷¹³
- c. [Actavis Senior Employee 1] attended State of Play meetings on behalf of Accord-UK at which the CMA outlined its concerns over unfair and excessive pricing of hydrocortisone tablets in May and September 2016.³⁷¹⁴ A Statement of Objections outlining the CMA’s provisional conclusions that hydrocortisone tablets were (and continued to be) excessively and unfairly priced in breach of competition law was issued in December 2016. Nevertheless, the ASPs for hydrocortisone tablets remained above £55 per pack for 10mg tablets and £40 per pack for 20mg tablets throughout 2016, while cost of goods was £1.02 and £1.35 per pack respectively.³⁷¹⁵
- d. Before its acquisition of Accord-UK, Intas carried out due diligence identifying various product business cases, including hydrocortisone tablets.³⁷¹⁶ Prior to the completion of the sale, in October 2016 the CMA contacted Intas to make it aware of the investigation into Auden/Actavis’s alleged excessive and unfair pricing of hydrocortisone tablets,³⁷¹⁷ and shortly after met with Intas, including [X], to discuss the investigation. Nevertheless, after its acquisition by Intas and Accord, despite its knowledge of the CMA’s investigation and provisional conclusions, Accord-UK continued to operate under the same management and with the same price setting mechanisms as outlined above at 10.196.c.

10.198. As set out in Sections 5.C (*Auden/Actavis’s prices were excessive*) and 5.D (*Auden/Actavis’s prices were unfair*), the CMA has found that the prices Auden/Actavis charged for hydrocortisone tablets throughout the infringement periods were excessive and unfair. The non-exhaustive examples listed above demonstrate that directors and senior management of Auden/Actavis were directly involved in the 10mg Unfair Pricing Abuse and 20mg Unfair Pricing Abuse, including in price setting and monitoring

³⁷¹³ Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 13, lines 15 to 17.

³⁷¹⁴ Document 00746, note of state of play meeting on 12 May 2016; Document 00747, note of state of play meeting on 7 September 2016 (at this meeting the CMA provided a detailed slide presentation with its provisional views on the case – see Document 00748).

³⁷¹⁵ See Figure 5.6: Auden/Actavis’s ASPs for 10mg and 20mg hydrocortisone tablets, and Tables 5.8 and 5.9: Auden/Actavis’s direct costs per pack of 10mg and 20mg hydrocortisone tablets.

³⁷¹⁶ Document 03006, transcript of CMA hearing with Intas Pharmaceuticals Limited / Accord Healthcare Limited / Actavis UK Limited on Friday 15 December 2017, page 47, lines 6 to 22.

³⁷¹⁷ Document 03006, transcript of CMA hearing with Intas Pharmaceuticals Limited / Accord Healthcare Limited / Actavis UK Limited on Friday 15 December 2017, page 57, lines 14 to 25; page 58, lines 1 to 2. The sale was completed on 9 January 2017.

throughout the relevant period. Given this involvement, the CMA concludes that an uplift of 15% for director/senior management involvement is appropriate.

The 10mg Agreement

10.199. In relation to the 10mg Agreement, the following directors and senior management were involved: [Auden Senior Employee 1], [Auden Senior Employee 2] and [Actavis Senior Employee 1].

10.200. As set out in Sections 3.F.III (Facts relevant to the 10mg Agreement) and 6.D (Agreements restricting competition by object):

- a. Senior figures at Auden/Actavis understood that the low supply price in the 10mg Agreement was agreed in return for the non-entry of its potential competitor (Waymade, then AMCo) with its own product and with the objective of protecting its market share.
- b. The 10mg Agreement started in October 2012 as an extension of the 20mg Agreement, and was established by the same individuals, including [Auden Senior Employee 1], on similar terms.³⁷¹⁸
- c. [Auden Senior Employee 1] led further negotiations on the 10mg Agreement with senior figures at AMCo in November and December 2012 and January 2013.³⁷¹⁹ He also led discussions with AMCo in 2013 when they decided to formalize the unwritten supply agreement,³⁷²⁰ and played a key role in forming and negotiating the Second Written Agreement.³⁷²¹
- d. [Actavis Senior Employee 1] personally reviewed the Second Written Agreement as part of due diligence prior to Actavis's acquisition of Auden.³⁷²² Following the acquisition, Actavis continued to supply AMCo on the same terms as the Second Written Agreement until the Agreement expired on 24 June 2016. Senior figures were not only aware of the 'very low'³⁷²³ price and limited volumes supplied to AMCo,

³⁷¹⁸ See in particular paragraphs 6.552 to 6.587.

³⁷¹⁹ See in particular paragraph 3.448 to 3.451.

³⁷²⁰ See in particular paragraphs 3.455 to 3.461 and 3.465 to 3.471.

³⁷²¹ See in particular paragraphs 3.555 to 3.576.

³⁷²² SSO, paragraphs 3.624 to 3.625; See paragraph 6.762 and in particular Document 203378, transcript of [Actavis Senior Employee 1] interview dated 22 July 2019, page 16, lines 21 to 26; page 17, lines 1, 6 to 7 and 11 to 12; page 29, line 1.

³⁷²³ Document 02329, email from [X] to [Actavis Senior Employee 2] dated 4 September 2015.

they also approved the continuation of the agreed terms when they were flagged as unusual by colleagues.³⁷²⁴

The 20mg Agreement

10.201. In relation to the 20mg Agreement, the following directors and senior management were involved: [Auden Senior Employee 1] and [Auden Senior Employee 2].

10.202. As set out in Sections 3.F.II (*Facts relevant to the 20mg Agreement*) and 6 (*The Agreements*):

- a. Senior figures at Auden/Actavis understood that the '*special price*'³⁷²⁵ in the 20mg Agreement was agreed in return for the non-entry of Waymade with its own product and to protect its market share.³⁷²⁶
- b. [Auden Senior Employee 1] and [Auden Senior Employee 2] were closely involved in the negotiations for the 20mg Agreement in June and July 2011.³⁷²⁷ [Auden Senior Employee 1] proposed specific terms, including the 'RAMA' clause, which ensured the Agreement would only continue as long as it protected Auden's market exclusivity.³⁷²⁸
- c. Senior management involvement in the 20mg Agreement continued throughout the entire period of the infringement: for example, in March 2013 [Auden Senior Employee 1] emailed [Waymade Senior Employee 1] to propose an increase in the number of packs supplied and subject to the 'Buyback' arrangement.³⁷²⁹ [Auden Senior Employee 1] was also contacted directly by [X] [Waymade Senior Employee 1] and [Waymade Senior Employee 2] with regards to the 20mg Agreement in March 2014 and March 2015 when chasing Auden for payment.³⁷³⁰

10.203. Given the direct involvement of Auden/Actavis's most senior directors and management in the 10mg Agreement and 20mg Agreement, which included negotiating, instigating and maintaining the terms of the 20mg Agreement

³⁷²⁴ See in particular paragraphs 3.683 to 3.687.

³⁷²⁵ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

³⁷²⁶ See in particular paragraphs 6.931 to 6.932.

³⁷²⁷ See paragraphs 6.412 to 6.478.

³⁷²⁸ See in particular paragraphs 6.468 to 6.478.

³⁷²⁹ See in particular paragraphs 3.376 to 3.377.

³⁷³⁰ See in particular paragraphs 3.383 to 3.390.

throughout the relevant period, the CMA concludes that an uplift of 15% for director/senior management involvement is appropriate.³⁷³¹

ii. Waymade

The 20mg Agreement

10.204. The CMA concludes that the involvement of directors and senior management within the Waymade undertaking in the design, implementation, continuation and escalation of the 20mg Agreement should be considered as an aggravating factor at step 3.³⁷³² This included the [X] [Waymade Senior Employee 1], [Waymade Senior Employee 4], [Waymade Employee] and [Waymade Senior Employee 3]:

10.205. As set out in Sections 3.F.II and 6.D.II.C.i:

- a. Senior management, including [Waymade Senior Employee 1] and [Waymade Senior Employee 3], clearly understood that Waymade's 20mg MA was used as '*leverage*'³⁷³³ to secure favourable supply terms from Auden/Actavis, and that the '*special price*'³⁷³⁴ in the 20mg Agreement was agreed in return for Waymade's non-entry with its own product.
- b. Waymade's senior management strategically considered the timing of its negotiations with Auden/Actavis in light of the development of its own 20mg hydrocortisone tablets (which it used as the '*leverage*' described above),³⁷³⁵ and were aware of the link between Waymade's own development of 20mg tablets and the negotiations with Auden.³⁷³⁶

³⁷³¹ Accord-UK submitted that the 15% uplift for director involvement is inconsistent with the approach adopted by the CMA in previous cases relating to similar behaviour in the pharmaceutical sector, for example *Paroxetine*. Accord-UK further submitted that the 15% uplift is inconsistent with its own approach in the 2017 DPS, where the CMA applied only a 10% uplift for director involvement, and that the CMA does not sufficiently explain its reason for increasing the uplift (Document 205813, Accord-UK's RDPS, paragraphs 8.5 to 8.6). The CMA does not accept this representation: the CMA is not bound by previous decisional practice, and determines uplifts for aggravating factors on a case-by-case basis. The relevant considerations for this case are set out here, which are sufficient to justify a 15% uplift rather than the factors considered relevant in a previous provisional decision. A 15% is not unprecedented in any case: a 15% increase for director and senior management was applied in the CMA's decision in '*supply of products to the construction industry (pre-cast concrete drainage products)*' (dated 23 October 2019). Though this specific point was not appealed this decision was upheld by the CAT in *FP McCann v CMA* [2020] CAT28.

³⁷³² CMA penalties guidance, paragraph 2.18.

³⁷³³ Document 301315, transcript of [Waymade Senior Employee 3] interview dated 27 March 2018, part 3, page 12, line 14 to page 13, line 7.

³⁷³⁴ Document 300619, email from [Waymade Senior Employee 4] to [Auden Senior Employee 2] dated 11 July 2011.

³⁷³⁵ See Section 3.F.II.b (*Waymade enters into a supply agreement with Auden for 20mg hydrocortisone tablets and 'freezes' its 20mg product*).

³⁷³⁶ See in particular paragraphs 3.367 to 3.374 and 6.178.

- c. During June and July 2011, senior figures at Waymade including [Amdipharm Senior Employee], [Waymade Employee] and [Waymade Senior Employee 4] were involved in the negotiations for the 20mg Agreement. The 20mg Agreement, including the 'Buyback' and the 'RAMA clause', was confirmed by [Waymade Senior Employee 4] after discussions with other senior Waymade colleagues.³⁷³⁷
- d. [Waymade Senior Employee 1] oversaw the renegotiation of the 20mg Agreement in 2013,³⁷³⁸ and monitored orders closely, intervening on a number of occasions to ensure the 20mg Agreement was upheld.³⁷³⁹

The 10mg Agreement

10.206. The CMA similarly concludes that the involvement of directors and senior management within the Waymade undertaking in the design and implementation of the 10mg Agreement should be considered as an aggravating factor at step 3. This includes [Waymade Senior Employee 1] and [Amdipharm Senior Employee].

10.207. As set out at Sections 3.F.III (Facts relevant to the 10mg Agreement) and 6.D.II.c.ii (The 10mg Agreement):

- a. The 10mg Agreement started in October 2012 as an extension of the 20mg Agreement, established by the same senior individuals.
- b. [Amdipharm Senior Employee] negotiated a 97% reduction on the price Waymade paid Auden for 10mg hydrocortisone tablets following Waymade obtaining its 10mg MA on 27 September 2012.³⁷⁴⁰
- c. [Amdipharm Senior Employee] and [Waymade Senior Employee 1] understood that, following the pattern established by the 20mg Agreement, their 10mg MA could be used as leverage to secure a common understanding with Auden that sufficient payment would buy off Waymade's competitive threat and prevent Waymade's entry.

10.208. Given the non-exhaustive examples of direct involvement of Waymade directors and senior management in the 20mg and 10mg Agreements listed

³⁷³⁷ See paragraphs 6.412 to 6.478.

³⁷³⁸ See paragraph 3.377.

³⁷³⁹ Document 300238, email from [Waymade Senior Employee 1] to [X], [Waymade Senior Employee 4] and [Amdipharm Senior Employee] dated 21 May 2012. See also paragraphs 3.389; Document 301697, emails between [Waymade Senior Employee 2], [Waymade Senior Employee 1] and [Auden Senior Employee 3] dated 7 March 2014; Document 301928, email from [Waymade Senior Employee 1] to [Waymade Senior Employee 2] dated 17 March 2015; and Document 301929, email from [X] to [Waymade Senior Employee 2] and emails between [Waymade Senior Employee 1] and [Waymade Senior Employee 2] dated 17 March 2015.

³⁷⁴⁰ See paragraphs 6.557, 3.336 to 3.449, and 6.554 to 6.555.

above, the CMA concludes that an uplift of 15% for director/senior management involvement is appropriate.

iii. AMCo

10.209. The CMA concludes that the involvement of directors and senior management within the AMCo undertaking during Periods D2 and D3 in the design, implementation, continuation and escalation of the 10mg Agreement should be considered as an aggravating factor at Step 3.³⁷⁴¹ This included [Amdipharm Senior Employee]; [AMCo Senior Employee 1]; [AMCo Senior Employee 8]; [AMCo Senior Employee 2]; [AMCo Senior Employee 3] and [AMCo Senior Employee 5].

10.210. As set out in Sections 3.F.III and 6.D.II.c.ii:

- a. Having established the 10mg Agreement, Waymade transferred the 10mg MA, the 10mg product development and certain senior staff involved in the 10mg Agreement (including [Amdipharm Senior Employee]) to AMCo. AMCo continued the 10mg Agreement from 31 October 2012 onwards. From that date, [Amdipharm Senior Employee], under the supervision of [AMCo Senior Employee 1], was in charge of negotiating an increase in the monthly volume of 10mg hydrocortisone tablets available to AMCo from Auden at the £1 supply price.³⁷⁴²
- b. Subsequent negotiations to formalise the terms of supply with Auden Mckenzie during 2013 were primarily led by [Amdipharm Senior Employee], [AMCo Senior Employee 1] and [AMCo Senior Employee 8] from AMCo.³⁷⁴³
- c. In 2014, [AMCo Senior Employee 1] and [AMCo Senior Employee 8] led further negotiations with Auden. [AMCo Senior Employee 1] used the threat of the launch of AMCo's own Aesica-manufactured 10mg hydrocortisone tablets to secure terms under the Second Written Agreement.³⁷⁴⁴

³⁷⁴¹ Advanz submitted that the CMA has 'double counted' director involvement by utilising the maximum starting point at Step 1 and then uplifting for director involvement at Step 3, as it submitted that the situations that the penalties guidance suggest warrant the selection of 30% as the starting point (eg cartel activity, predatory or excessive pricing) can only take place with the knowledge of senior management (Document 205848, AMCo's RDPS, paragraphs 7.32.3). The CMA does not engage in double counting by applying a high starting point at Step 1 and an uplift for director involvement at Step 3. Seriousness of infringement and involvement of directors are separate criteria. It is not accurate to say that cases meriting a 30% starting point will always involve senior staff. In this case, the CMA considers that the involvement of senior individuals in designing and sustaining the infringements is sufficiently significant to warrant a 15 % uplift.

³⁷⁴² See in particular Section 3.F.III.e (*AMCo succeeds Waymade as counterparty to the 10mg Agreement*) and paragraphs 6.604 to 6.611.

³⁷⁴³ See in particular Section 3.F.III.f (*AMCo moves to formalise the 10mg supply arrangement*).

³⁷⁴⁴ See in particular paragraph 3.262.

- d. At an internal PPRM meeting held on 25 June 2014 and attended by senior management, including [AMCo Senior Employee 1], [AMCo Senior Employee 2] and [AMCo Senior Employee 5], it was agreed that AMCo would not launch its own Aesica-manufactured 10mg hydrocortisone tablets following the signing of the Second Written Agreement.³⁷⁴⁵ AMCo's senior management therefore understood that AMCo would not launch its Aesica product in exchange for further payments from Auden under the Second Written Agreement.
- e. [AMCo Senior Employee 3], [AMCo Senior Employee 2] and [AMCo Senior Employee 1] were involved in AMCo's strategy of using a Focus pipeline project to develop hydrocortisone tablets with Lamda as further leverage with Auden to obtain an increase in supply volumes of hydrocortisone tablets under the 10mg Agreement.³⁷⁴⁶

10.211. Given the direct involvement of AMCo directors and senior management in the 10mg Agreement, which included negotiating, maintaining and escalating the terms of the Agreement throughout Periods D1-D3, the CMA concludes that an uplift of 15% for director/senior management involvement is appropriate.

10.212. The case parties have submitted representations that the CMA has not provided sufficient justification for its uplifts and that the directors' involvement does not justify an uplift.³⁷⁴⁷ The CMA does not accept this representation: for the reasons set out above, the CMA has found on the basis of extensive evidence that senior management were involved in the negotiation, implementation and continuation of the Infringements and an uplift of 15% for each infringement is appropriate.

10.213. The case parties submitted that the level of the 15% uplift is inappropriate: Accord-UK³⁷⁴⁸ stated that the uplift of 15% is not appropriate for Chapter II conduct (by reference to the examples in the CMA penalties guidance), and Accord-UK,³⁷⁴⁹ Intas/Accord-UK,³⁷⁵⁰ Waymade³⁷⁵¹ and Cinven³⁷⁵² submitted that the Agreements are not equivalent to 'secret cartel' behaviour (citing

³⁷⁴⁵ See paragraph 3.592.

³⁷⁴⁶ See Section 3.F.III.o ('AMCo acquires another hydrocortisone tablets portfolio');

Document 200151, draft responses to questions on Cinven's sale of the AMCo group, attached to document 200150; and Document 202830, email from [AMCo Senior Employee 3] to [X] dated 3 December 2015.

³⁷⁴⁷ Document 205813, Accord-UK's RDPS, paragraphs 8.7, 8.12 to 8.16, and 8.21 to 8.24; Document 205805, Cinven's RDPS, paragraphs 3.32 to 3.35; Document 205848, AMCo's RDPS, paragraphs 7.32 to 7.33; and Document 205802, Intas/Accord-UK's RDPS, paragraphs 59 to 60. Intas makes this representation specifically with respect to [Actavis Senior Employee 1]'s involvement.

³⁷⁴⁸ Document 205813, Accord-UK's RDPS, paragraphs 8.2 to 8.5.

³⁷⁴⁹ Document 205813, Accord-UK's RDPS, paragraphs 8.4 and 8.19.

³⁷⁵⁰ Document 205802, Intas/Accord-UK's RDPS, paragraphs 61 to 62.

³⁷⁵¹ Document 205799, Waymade's RDPS, paragraphs 3.40 to 3.45

³⁷⁵² Document 205805, Cinven's RDPS, paragraph 3.33.

Ping).³⁷⁵³ Accord-UK further referred to the CMA's approach in *Paroxetine* where no uplift for director involvement was applied.³⁷⁵⁴ Furthermore, Accord-UK³⁷⁵⁵ and Waymade³⁷⁵⁶ submitted that uplifts for director involvement disproportionately impact smaller companies, whose directors are more likely to be involved in key decisions, and Cinven submitted that as senior managers are often involved in negotiating contracts, such involvement should not merit an uplift.³⁷⁵⁷

10.214. These representations cannot be sustained. Directors were very closely involved in both pricing and negotiation of the agreements; this was not just '*knowledge*' of the infringements but active participation in and instigation of arrangements which the CMA has found to infringe competition law. This is a misrepresentation of the CAT judgment in *Ping*, where the CAT said that '*an example*' where director level involvement would be an aggravating factor would be a secret cartel, but the CAT was not exhaustive in giving that example. The CAT also held that an uplift should be reserved for '*more reprehensible behaviour*' and gave weight to the fact that the infringement in *Ping* was characterised as '*less serious*'.³⁷⁵⁸ The Infringements in this case involve excessive pricing and market exclusion agreements in relation to an essential drug, which the CMA has characterised as serious infringements for which the highest starting point is appropriate. Those are the circumstances in which, if senior management are involved in the infringements, an uplift is appropriate. Furthermore, the CMA is not bound by previous decisional practice and the CMA penalties guidance is not limited to uplifts for Chapter I infringements.

b. Mitigating factors

10.215. The case parties have submitted that the CMA should take the following mitigating factors into consideration.

i. Compliance activities

10.216. The CMA may decrease the penalty at step 3 where an undertaking can show that adequate steps have been taken to ensure compliance with competition law.³⁷⁵⁹

³⁷⁵³ *Ping Europe Limited v CMA* [2020] CAT 13.

³⁷⁵⁴ Document 205813, Accord-UK's RDPS, paragraph 8.5.

³⁷⁵⁵ Document 205813, Accord-UK's RDPS, paragraph 8.8.

³⁷⁵⁶ Document 205799, Waymade's RDPS, paragraphs 3.41 to 3.42.

³⁷⁵⁷ Document 295805, Cinven's RDPS, paragraph 1.16.

³⁷⁵⁸ *Ping Europe Limited v CMA* [2020] CAT 13, paragraph 247.

³⁷⁵⁹ CMA penalties guidance, footnote 33.

10.217. All of the parties submitted that they have a strong culture of competition law compliance. The parties also submitted representations on their competition law compliance programmes and argued that these merit a discount at step 3.³⁷⁶⁰

10.218. For the reasons set out below, the CMA has granted a 5% discount to Allergan, Accord-UK, Accord, Intas, and Advanz and the Amdipharm Companies.

Accord-UK, Accord and Intas

10.219. Submissions from Accord-UK, Accord and Intas show that, since the CMA opened its investigations in Case 50277, Accord and Accord-UK³⁷⁶¹ have:

- a. Reviewed and enhanced its competition compliance programme, which includes:
 - i. The provision of compulsory training on competition law for all non-operational staff;³⁷⁶²
 - ii. Additional targeted training for relevant Accord-UK staff;³⁷⁶³
 - iii. A system for reporting and reviewing competition issues;³⁷⁶⁴ and
 - iv. The adoption of a specific competition compliance policy as a supporting policy to the Accord Code of Conduct.³⁷⁶⁵
- b. Established new regional and cluster head Compliance Committees, which report regularly to the Accord Healthcare Board and are

³⁷⁶⁰ Document 205813, Accord-UK's RDPS, paragraph 9.8; Document 205802, Intas/Accord-UK's RDPS, paragraphs 70 to 72; Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021; Document 205791, Allergan's RDPS, paragraph 52 and Document 206495, Allergan's response to the CMA's request for information dated 9 April 2021; Document 205805, Cinven's RDPS, paragraphs 1.17 and 3.39 to 3.42 and Document 206429, Cinven's response to the CMA's request for information dated 9 April 2021; Document 205848, AMCo's RDPS, paragraphs 7.35 to 7.45, and Document 206433, Advanz's response to the CMA's request for information dated 9 April 2021; Document 205799, Waymade's RDPS, 3.51 to 3.53, and Document 206421, Waymade's response to the CMA's request for information dated 9 April 2021.

³⁷⁶¹ Accord-UK, Accord and Intas submitted that Intas's compliance activities are structured by region, with Accord and its subsidiaries (including Accord-UK) responsible for compliance in Europe. The CMA has therefore focussed on the compliance activities of Accord and Accord-UK as the relevant entities in the undertaking. See Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April, paragraph 2.

³⁷⁶² Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 4.iii and 23.

³⁷⁶³ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 17 to 23.

³⁷⁶⁴ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 7 to 14. See also Document 206525, Accord-UK's compliance report for the period 4th March 2020 to 3rd March 2021, submitted as Annex 1 of Accord's response.

³⁷⁶⁵ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 12 to 16.

supported by a Director of Compliance and dedicated compliance officers;³⁷⁶⁶

- c. Made a clear public commitment to compliance with competition law on its website;³⁷⁶⁷ and
- d. Operated a confidential and independent whistleblowing service for reports of compliance or competition concerns.³⁷⁶⁸

10.220. Furthermore, Accord-UK's compliance activities were assessed as sufficient to merit a compliance discount in *Nortriptyline (Market sharing)*.³⁷⁶⁹ Pursuant to that discount, [X].³⁷⁷⁰

10.221. However, Accord-UK, Accord and Intas did not provide some of the underlying documentation necessary for the CMA fully to assess its compliance activities and programme.³⁷⁷¹

10.222. In addition, the CMA penalties guidance is clear that an undertaking that seeks to obtain a discount in recognition of its compliance activities needs to present evidence on the steps it took to review its compliance activities, and change them as appropriate, in light of the events that led to the investigation at hand.³⁷⁷² Accord-UK, Accord and Intas however told the CMA that Accord-UK and Accord did not review their compliance activities in light of the specific events that led to the investigation in the present case, but that developments in its compliance programme instead reflected a general and long-running emphasis on compliance (including its engagement with the CMA's investigations).³⁷⁷³

10.223. Having carefully considered the evidence presented of Accord-UK and Accord's compliance activities and the factors set out at paragraphs 10.221

³⁷⁶⁶ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 7 to 9.

³⁷⁶⁷ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraph 26. See also [Accord's web statements on competition law compliance](#) and screenshots provided as Document 206526 and Document 206527 (Annexes 2 and 3 of Accord's response).

³⁷⁶⁸ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 24 to 25.

³⁷⁶⁹ See CMA's Decision in Case 50507.2, [Nortriptyline Tablets \(Market sharing\)](#), paragraphs 8.37 to 8.42.

³⁷⁷⁰ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraph 31; and Document 206525, Accord-UK Ltd's compliance report for the period 4th March 2020 to 3rd March 2021 submitted as Annex 1 of Accord's response.

³⁷⁷¹ For example, Accord, Accord-UK and Intas did not provide a copy of their competition law compliance policies or Code of Conduct as part of its submission on compliance to Case 50277. Furthermore, it only provided cover pages and high-level descriptions of training materials. See Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, Table 1 and Document 206528, Document 206529 and Document 206530, provided as Annexes 4, 5 and 6 of Accord, Accord-UK and Intas's response.

³⁷⁷² CMA penalties guidance, footnote 33.

³⁷⁷³ Document 206524, Accord, Accord-UK and Intas's response to the CMA's request for information dated 9 April 2021, paragraphs 28 to 30.

and 10.222 above, the CMA has concluded that a compliance discount of 5% to the penalties attributed to Accord-UK, Accord and Intas is warranted.

Allergan

10.224. Submissions from Allergan, which is now part of Abbvie, show that Abbvie has comprehensive global and UK-specific compliance programmes, which include:

- a. The provision of mandatory training on compliance issues, including antitrust, for relevant staff;³⁷⁷⁴
- b. A system for reporting and reviewing competition issues;³⁷⁷⁵
- c. An established Office of Ethics and Compliance led by a Chief Ethics and Compliance Officer who regularly reports on compliance matters to the CEO, Board of Directors and Public Policy Committee;³⁷⁷⁶
- d. A Global Compliance Insights Forum and a UK-specific Affiliate Compliance Insights Forum, which are composed of senior-level management, and review and oversee Abbvie's compliance programs and policies;³⁷⁷⁷
- e. Clear public statements of commitment to ethics and compliance, including compliance with competition law, on its website;³⁷⁷⁸ and

³⁷⁷⁴ Document 206497, Witness statement from [REDACTED], AbbVie Office of Ethics and Compliance, paragraphs 5.6 to 5.7, provided as an Annex to Document 206495, Allergan's response to the CMA's request for information dated 9 April 2021. See also Document 206495A, The Focus of Abbvie's [Global] Ethics and Compliance Programme, page 1; and Document 206495B, The Focus of [Abbvie's UK] Ethics & Compliance Programme, page 2, provided as Annexes to Document 206495.

³⁷⁷⁵ Document 206497, Witness statement from [REDACTED], AbbVie Office of Ethics and Compliance, provided as an Annex to Allergan's response, paragraphs 4.4 to 4.5 and 5.3 to 5.8.

³⁷⁷⁶ Document 206497, Witness statement from [REDACTED], AbbVie Office of Ethics and Compliance, provided as an Annex to Allergan's response, paragraph 5.3.

³⁷⁷⁷ Document 206497, Witness statement from [REDACTED], AbbVie Office of Ethics and Compliance, provided as an Annex to Allergan's response, paragraphs 5.4 to 5.5; See also Document 206495A, The Focus of Abbvie's [Global] Ethics and Compliance Programme, page 1; and Document 206495B, The Focus of [Abbvie's UK] Ethics & Compliance Programme, page 1, provided as Annexes to Document 206495.

³⁷⁷⁸ This includes Abbvie's Code of Business Conduct, and a public summary of the focus of Abbvie's Ethics and Compliance Programme, both of which are publicly accessible on Abbvie's webpages.

[Abbvie's Code of Business Conduct](#) includes a foreword from Abbvie's Chairman of the Board and Chief Executive Officer expressing the importance of adhering to the Code of Business Conduct and highlighting the Office of Ethics and Compliance and its reporting hotline. An 'Integrity in the Marketplace' section includes a commitment to complying with competition law (stating 'We follow antitrust laws' and 'we support fair and honest competition'), which stresses the importance of 'fair pricing' for Abbvie's products. Document 206495D, provided as an annex to Document 206495, page 50. Abbvie's public summary of its compliance programme includes statements on the importance of strong leadership, clear written standards, effective lines of communication, relevant training, accountability and continuous improvement. See: <https://www.abbvie.co.uk/our-company/ethics-and-compliance.html>

- f. A 24-hour Ethics and Compliance helpline providing resources for employees wishing to raise or report compliance issues³⁷⁷⁹

10.225. However, Allergan submitted that it was not able to identify specific steps which had been taken to review and develop Allergan's compliance activities in light of the CMA's investigation, due to Allergan no longer being active in the relevant product markets; the passage of time before Allergan was involved in the CMA's investigation; and the fact that Abbvie only acquired Allergan in 2020.³⁷⁸⁰

10.226. Allergan also did not provide some of the underlying documentation necessary for the CMA fully to assess its compliance activities and programme.³⁷⁸¹

10.227. Having carefully considered the evidence presented of Allergan's compliance activities and the factors set out at paragraphs 10.225 and 10.226 above, the CMA has concluded that a compliance discount of 5% to the penalties attributed to Allergan is warranted.

Advanz and the Amdipharm Companies

10.228. Submissions from Advanz and the Amdipharm Companies show that, since the infringement period, Advanz has:

- a. introduced a revised competition compliance programme, which includes:
 - i. the provision of training for all staff;³⁷⁸²
 - ii. additional training for Advanz's UK commercial team and legal team;³⁷⁸³

³⁷⁷⁹ Document 206495, Allergan's response to the CMA's request for information dated 9 April 2021; Document 206497, Witness statement from [§], AbbVie Office of Ethics and Compliance, provided as an Annex to Allergan's response, paragraphs 4.4 to 4.5.

³⁷⁸⁰ Document 206495, Allergan's response to the CMA's request for information dated 9 April 2021, pages 1 to 2.

³⁷⁸¹ For example, Allergan did not provide its 'Compliance with Antitrust Laws' policy (referred to in Document 206495D, Abbvie's Code of Business Conduct, p.50) or any of its competition law training materials to the CMA.

³⁷⁸² Document 206433, AMCo's response to the CMA's request for information, setting out the current compliance activities of Advanz and the Amdipharm Companies, dated 9 April 2021; paragraphs 1.79 to 1.80. See also Document 206456, Advanz's competition law compliance policy dated 11 August 2020, page 2, and Document 206457, NAVEX Global course script for Antitrust & Competition Law training, provided as Annexes 5 and 6 to AMCo's response.

³⁷⁸³ Document 206433, AMCo's response to the CMA's request for information, setting out the current compliance activities of Advanz and the Amdipharm Companies, dated 9 April 2021; paragraphs 1.81 to 1.83. See also Documents 206458, Document 206459 and Document 206460, provided as Annexes 7, 8, and 9 to AMCo's response.

- iii. a system for reporting and reviewing competition issues;³⁷⁸⁴
- b. created a new Global Compliance Officer role;³⁷⁸⁵
- c. made a clear public commitment to compliance with competition law on its website;³⁷⁸⁶ and
- d. introduced a whistleblowing hotline for anonymous reports of violations or suspected violations of Advanz's Code of Conduct or the law.³⁷⁸⁷

10.229. However, the materials provided by Advanz in support of its submission raise some doubt as to the mandatory nature of Advanz's competition compliance training for all staff.³⁷⁸⁸

10.230. Further, Advanz has not offered to provide an annual update to the CMA confirming its ongoing commitment to, and periodic review of compliance activities.³⁷⁸⁹

10.231. Having carefully considered the evidence presented of Advanz's compliance activities and the factors set out at paragraphs 10.229 and 10.230 above, the CMA has concluded that a compliance discount of 5% to the penalties attributed to Advanz and the Amdipharm Companies is warranted.

³⁷⁸⁴ Document 206433, AMCo's response to the CMA's request for information, setting out the current compliance activities of Advanz and the Amdipharm Companies, dated 9 April 2021; paragraphs 1.78 and 1.84. See also Document 206455, Advanz's Code of Conduct dated 11 August 2020, provided as Annex 4 to AMCo's response to the CMA's request for information dated 9 April 2021, paragraphs 6.2 to 6.3.

³⁷⁸⁵ Document 206433, AMCo's response to the CMA's request for information, setting out the current compliance activities of Advanz and the Amdipharm Companies, dated 9 April 2021; paragraph 1.80.

³⁷⁸⁶ [Advanz's Code of Conduct](#) published 11 August 2020; see Document 206455, Annex 4 of AMCo's response to the CMA's request for information dated 9 April 2021; and Document 206433, AMCo's response to the CMA's request for information dated 9 April 2021; paragraph 1.78.

³⁷⁸⁷ Document 206455, Advanz's Code of Conduct dated 11 August 2020, provided as Annex 4 to AMCo's response to the CMA's request for information dated 9 April 2021, paragraphs 6.2 to 6.3.

³⁷⁸⁸ For example, the Foreword of Advanz's updated competition law policy, written by [AMCo Senior Employee 3], states that compliance documents and training sessions are available for eligible employees. It states that for anyone who is invited, the training sessions are mandatory. In section 2, it states that '*everyone has access to continuous training and legal assistance*' but does not mention it being mandatory for everyone. See Document 206456, Advanz's competition law compliance policy dated 11 August 2020, provided as Annex 5 to AMCo's response to the CMA's request for information dated 9 April 2021, page 2.

³⁷⁸⁹ As set out in paragraph 2.19 and footnote 33 of the CMA penalties guidance, in order to merit a discount, an undertaking's compliance activities will generally be expected to include '*conducting period review of its compliance activities, and reporting that to the CMA*'.

Cinven

10.232. [REDACTED].³⁷⁹⁰ [REDACTED].³⁷⁹¹ [REDACTED].

10.233. [REDACTED].

10.234. [REDACTED]³⁷⁹² [REDACTED].

10.235. [REDACTED].

10.236. Having carefully considered the evidence presented of the Cinven Entities' compliance activities, the CMA concludes that no discount to their penalty is warranted.

Waymade

10.237. Submissions from Waymade indicate that employees at Waymade [REDACTED].³⁷⁹³
[REDACTED].³⁷⁹⁴

10.238. There is also no statement signalling Waymade's commitment to competition law compliance on its website and Waymade has not offered to report back to the CMA with periodic reviews.

10.239. More generally, the CMA is not satisfied that Waymade has taken adequate steps to review their compliance activities, and change them as appropriate, in the light of the events that led to the current investigation. [REDACTED].

10.240. [REDACTED].³⁷⁹⁵

³⁷⁹⁰ For example, since the CMA's investigation was opened, the Cinven Entities submitted that they have developed a dedicated Legal and Compliance team, including a Compliance Manager (Document 206429, Cinven's response to the CMA's request for information dated 9 April 2021, paragraph 3) and outline a process for identifying, assessing, mitigating and reviewing competition law risk in its portfolio companies pre- and post-acquisition (Document 206429, Cinven's response to the CMA's request for information dated 9 April 2021, paragraphs 6 to 31; see also Document 206430I, Cinven ESG Questionnaire for portfolio companies, provided as Annex 2 to Cinven's response, which asks portfolio companies to identify and provide any code of conduct for competition law, and Document 206430O, template competition law compliance policy, provided as Annex 8 of Cinven's response). Notably the Cinven Entities do not provide any competition law compliance policy of their own.

³⁷⁹¹ Document 206429, Cinven's response to the CMA's request for information dated 9 April 2021, paragraphs 21 to 23. The exception in this gap was the attendance of members of the Legal and Compliance Team at general counsel roundtable training sessions (see footnote 10).

³⁷⁹² See, for example, Document 206430C, a competition law policy for LGC; Document 206430D, a competition law compliance policy for Stada; Document 206430E, antitrust guidelines on participation in trade associations for Stada; and Document 206430O, template antitrust compliance guidelines for portfolio companies, provided as Annexes to Document 206429, Cinven's response to the CMA's request for information dated 9 April 2021. Cinven did not provide copies of its own competition law compliance policies.

³⁷⁹³ Document 206421, Waymade's response to the CMA's request for information dated 9 April 2021, paragraph 3. See also Document 206422 and Document 206423, provided as Annexes to Waymade's Response.

³⁷⁹⁴ Document 205799, Waymade's RDPS, paragraph 3.51.

³⁷⁹⁵ Document 205799, Waymade's RDPS, paragraphs 3.51 to 3.53.

10.241. The CMA penalties guidance is clear that in order to obtain a compliance discount, an undertaking must demonstrate that ‘adequate steps, appropriate to the size of the business concerned, have been taken to achieve a clear and unambiguous commitment to competition law compliance [X] the undertaking (from the top down).’³⁷⁹⁶ [X].

10.242. Having carefully considered the evidence presented of the Waymade’s compliance activities, the CMA concludes that no discount to its penalties is warranted.

ii. Other mitigating factors

10.243. Accord-UK, Intas, Allergan and Advanz argued they have cooperated fully with the CMA’s investigation.³⁷⁹⁷ The CMA does not accept this representation: to be considered mitigating, cooperation must be ‘over and above’ simply complying with the CMA’s requests (as set out in the CMA penalties guidance)³⁷⁹⁸ and in this case the CMA does not consider the parties’ cooperation sufficient to meet the threshold for mitigation.

10.244. Waymade and Cinven submitted that the termination of the infringements prior to or immediately following the CMA’s intervention should be considered a mitigating factor.³⁷⁹⁹ The Agreements each continued for several years, delaying the development of effective competition; their termination before intervention by the CMA should not be considered a mitigating factor. AMCo ended the 10mg Agreement because of independent entry (which undermined the rationale of the 10mg Agreement), not because of the CMA’s investigation.

10.245. The CMA does not accept that there is any uncertainty as to the application of the Chapter I prohibition to the 10mg Agreement or around the facts of the unfair pricing infringements. The parties’ arguments on legal uncertainty,³⁸⁰⁰ their submissions on lack of intention or negligence³⁸⁰¹ and AMCo’s legal advice³⁸⁰² have been addressed on the law and the facts (see section

³⁷⁹⁶ CMA penalties guidance, footnote 33.

³⁷⁹⁷ Document 205813, Accord-UK’s RDPS, paragraph 9.6; Document 205802, Intas/Accord-UK’s RDPS, paragraph 69; Document 205791, Allergan’s RDPS, paragraph 52; Document 205848, AMCo’s RDPS, paragraphs 7.53 to 7.55. Accord also points out that the CMA used Macfarlanes’ in-house e-discovery, document recovery and review platform during follow-up inspections of Accord-UK documents in 2017 and that a cooperation discount was granted on that basis in the digital keyboards decision (Document 205813, Accord-UK’s RDPS, paragraph 9.7).

³⁷⁹⁸ CMA penalties guidance, footnote 35.

³⁷⁹⁹ Document 205805, Cinven’s RDPS, paragraphs 1.17 and 3.46.

³⁸⁰⁰ Document 205805, Cinven’s RDPS, paragraphs 1.17; 3.44 to 3.45.

³⁸⁰¹ Document 205791, Allergan’s RDPS, paragraphs 47 to 50.

³⁸⁰² Document 205805, Cinven’s RDPS, paragraphs 1.16 to 1.17 and 3.32 to 3.35; Document 205848, AMCo’s RDPS, paragraphs 7.32 to 7.33 and 7.46 to 7.49. AMCo and Cinven argued in particular that senior management involvement in seeking legal advice should be a mitigating factor and that senior management had no basis to

10.B.II.e.iv above) or in the CMA's substantive findings on the case. The CMA has considered the facts of those arguments elsewhere and these cannot be upheld as mitigating factors at step 3.

10.246. The parties have made further representations which go to the factual assessment of the case.³⁸⁰³ For example, AMCo submitted that AMCo was acting under duress as a victim of Auden's exclusionary conduct by reference to Project Guardian.³⁸⁰⁴ The CMA does not accept that AMCo's conduct in continuing the 10mg Agreement was under 'severe duress' to merit a discount: this decision finds that AMCo was a willing participant in the 10mg Agreement. AMCo also submitted that it was actively pursuing competitive conduct on the market, which should be considered a mitigating factor.³⁸⁰⁵ This representation cannot be sustained: this Decision has found that the 10mg Agreement was a market exclusion agreement, among the most serious infringements of competition law.

10.247. Intas/Accord-UK argued that prices falling during its period of ownership should act as a mitigating factor.³⁸⁰⁶ The CMA does not accept this representation: the infringement is assessed as a whole, rather than by ownership period and the prices remained at a level found to be excessive and unfair. The falling prices during the Intas period followed sustained growth in prices for several years, which Accord-UK benefitted from.

10.248. Accord-UK and Intas/Accord-UK argued that the CMA should consider the benefits of the undertaking's business model in mitigation.³⁸⁰⁷ The CMA does not accept these submissions: this Decision finds that these infringements

know that they were committing an infringement of competition law. For the reasons set out at section 10.B.II.e.iv above, this cannot be sustained.

³⁸⁰³ Accord-UK submitted that the case requires a number of terms to be inferred into the Agreement which Accord-UK was not aware of (Document 205813, Accord-UK's RDPS, paragraph 8.18). The CMA does not accept this characterisation of the infringement, and evidence demonstrates that [Actavis Senior Employee 1] was aware of the terms of the 10mg Agreement as demonstrated in the evidence as set out above. A further example is Cinven submitting that AMCo only inherited the 10mg Agreement and that the arrangement was required for AMCo to remain on the market (Document 205805, Cinven's RDPS, paragraph 3.32). The CMA does not accept this representation on the facts of the case: AMCo was a potential competitor and could have entered the market within 6-8 months, and the AMCo senior management were involved in negotiating and prolonging the 10mg Agreement as set out above. A further example is Accord-UK's arguments about the lack of intervention by the DH, that it inherited the prevailing market prices and that [Actavis Senior Employee 1] was signing off on price decreases (Document 205813, Accord-UK's RDPS, paragraphs 8.12 to 8.24). The CMA does not accept these representations as set out in the findings of this decision.

³⁸⁰⁴ Document 205848, AMCo's RDPS, paragraphs 7.56 to 7.57.

³⁸⁰⁵ Document 205848, AMCo's RDPS, paragraph 7.58.

³⁸⁰⁶ Document 205802, Intas/Accord-UK's RDPS, paragraphs 65 to 66, and submitting that [Actavis Senior Employee 1] was signing off on price decreases (Document 205802, Intas/Accord-UK's RDPS, paragraph 60).

³⁸⁰⁷ For example, Accord-UK argued that its continued supply of an essential drug for the benefit of patients and the NHS should be considered in mitigation (Document 205813, Accord-UK's RDPS, paragraph 9.6), and Intas's submissions about its role during the COVID-19 pandemic and its investment in developing new and existing products (Document 205802 Intas/Accord-UK's RDPS paragraphs 73 to 74).

caused sustained and significant harm to patients and the NHS to the sums of hundreds of millions of pounds.

c. Application of adjustments for aggravating and mitigating factors

10.249. An uplift of 15% for director involvement is to be applied to the penalty for all parties.

10.250. A discount of 5% is to be applied to the parts of the penalties for which Accord-UK, Accord Healthcare, Intas, Allergan, the Amdipharm Companies and Advanz are liable.

IV. Step 4: adjustment for specific deterrence and proportionality

- 10.251. Adjustments to the penalty at step 4 may result in either an increase or a decrease to the penalty. The assessment of the need to adjust the penalty either upwards or downwards³⁸⁰⁸ will be made on a case-by-case basis for each individual undertaking on which the CMA imposes penalties.
- 10.252. The penalty reached after step 3 may be increased to ensure that the penalty to be imposed on the relevant undertaking(s) will deter it from breaching competition law in the future, given its size and financial position – as at the time the penalty is being imposed³⁸⁰⁹ – and any other relevant circumstances of the case. Specific deterrence increases will generally be limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market, or where the CMA has evidence that the undertaking has made an economic or financial benefit from the infringement that exceeds the penalty reached at the end of step 3.³⁸¹⁰
- 10.253. In considering the appropriate level of any adjustment for specific deterrence, the CMA will ensure that it does not result in a disproportionate or excessive penalty. The CMA will have regard to the undertaking's size and financial position at the time the penalty is being imposed, the nature of the infringement, the role of the undertaking in the infringement and the impact of its infringing activity on competition.³⁸¹¹
- 10.254. As set out in section 10.C above, in the step 4 assessment the CMA has been guided first by whether an undertaking obtained financial benefits from the relevant Infringement in excess of the penalty after the first three steps of the calculation. The CMA has then assessed whether the penalty should be increased above the level of financial benefit received to ensure that the undertaking is deterred from breaching competition law in the future by reference to the overall size and financial position of the undertaking as it currently exists, subject to the CMA's consideration of the overlaps between the infringements.³⁸¹² The CMA has also considered whether the penalty

³⁸⁰⁸ CMA penalties guidance, paragraph 2.24.

³⁸⁰⁹ CMA penalties guidance, paragraph 2.20. See also C-408/12 *YKK v Commission*, paragraph 91 : *'the objective of pursuing a deterrent effect through the financial penalty is essentially to control, in the future, the conduct of the economic entity to which the [CMA] decision is addressed. Such an effect must necessarily be produced on the undertaking in the state [in] which it exists at the time when that decision is adopted'*. In that case, the infringing subsidiary no longer existed as an independent economic entity at the time the contested decision was adopted, having been acquired by the YKK group. The Court of Justice held that *'Consequently, the pursuit of a deterrent effect by means of the fine had necessarily to apply to the YKK group, of which [the subsidiary] was now part, regardless of the fact that [the parents] had not participated in the infringement in the period [prior to the acquisition of the subsidiary]'* (paragraph 92).

³⁸¹⁰ CMA penalties guidance, paragraph 2.21.

³⁸¹¹ CMA penalties guidance, paragraph 2.24.

³⁸¹² Unless stated otherwise, the CMA has based its assessment on:

should be decreased at the end of step 3 to ensure the level of the penalty is not disproportionate or excessive, and in applying any uplifts has taken into account whether the resulting penalty is not disproportionate or excessive having regard to the undertaking's size and financial position and the nature of the infringement.

10.255. As explained in section 10.C.I above a parent company can only be held liable for an Infringement for its period of ownership of its infringing subsidiary, and in determining how a total penalty is distributed between entities which are liable in different ownership periods the CMA has had regard to the principle that a penalty needs to be specific to the offender and the offence.³⁸¹³

10.256. The penalties are therefore calculated on a per-Period basis from step 4 onwards, in each case starting with the apportionment of the penalty after step 3 between the relevant Periods. A summary of each penalty calculation can be found in Annex E.

10.257. The parties have submitted representations on the CMA's approach to step 4. Where appropriate, these have been referenced and responded to in the

Financial information for Accord-UK and Intas: Accord-UK's financial statements for the financial year ending 31 March 2020, lodged at Companies House on 22 October 2020; Document 205297, Consolidated balance sheet and consolidated statement of profit and loss for Intas Pharmaceuticals Ltd for the financial years ending 31 March 2018, 31 March 2019 and 31 March 2020, provided in response to the CMA's section 26 notice dated 7 August 2020. Figures have been converted from US dollars into sterling using the Bank of England's annual average and year end spot exchange rates over that period. Averages have been calculated over the three-year period ending 31 March 2020.

Financial information for Allergan: publicly available financial information for Allergan taken from accounts consolidated at the level of AbbVie. See: [Abbvie's Annual Report on Form 10-K and 2021 Proxy Statement](#). Averages have been calculated over the three-year period ending 31 December 2020. Figures have been converted from US dollars into sterling using the Bank of England's annual average and year end spot exchange rates over that period.

Financial information for the Cinven Entities: Document LIO6539.2, Annex 1 of Cinven's response to the CMA's section 26 notice dated 15 May 2018; Document 206470, Annex 1 of Cinven's response to the CMA's section 26 notice dated 14 April 2021; Document 206471, Annex 2 of Cinven's response to the CMA's section 26 notice dated 14 April 2021. Averages have been calculated over the three-year period ending 31 December 2019.

Financial information for Advanz: Advanz's [publicly available financial information](#), comprising consolidated annual financial statements for the financial years ending 31 December 2018, 31 December 2019 and 31 December 2020; Advanz's 2019 Annual Management's Discussion and Analysis, dated 25 March 2020; and Advanz's 2020 Annual Management's Discussion and Analysis, dated 17 March 2021. Figures have been converted from US dollars into sterling using the Bank of England's annual average and year end spot exchange rates over that period. Averages have been calculated over the three-year period ending 31 December 2020.

Financial information for Waymade: Waymade is a wholly owned subsidiary of Waymade Holdings Ltd, which is a non-trading Jersey private company which is not required to prepare accounts. Consolidated accounts are available only at a Waymade level. Financial information for Waymade and Waymade Holdings Limited has been taken from the consolidated financial statements for Waymade plc for the financial year ending 31 December 2020 (Document 207009, Waymade plc's Annual Report and Financial Statements for the financial year ending for the financial year ending 31 December 2020, provided in response to the CMA's section 26 notice dated 9 June 2021); Waymade plc's Annual Report and Financial Statements for the financial year ending 31 December 2019 lodged at Companies House on 6 October 2020; and management accounts for Waymade Holdings Limited for the financial year ending 2020 (Document 206690, Waymade's response to the CMA's section 26 notice dated 9 June 2021) and the financial year ending 31 December 2019 (Document 205345, provided in response to the CMA's section 26 notice dated 7 August 2020). Averages have been calculated over the three-year period ending 31 December 2020.

³⁸¹³ C-247/11 P and C-253/11 P *Areva and Others v Commission*, EU:C:2014:257, paragraphs 127 and 131.

analysis set out below. The remaining representations are responded to in Annex F.

a. Auden/Actavis

i. 10mg Unfair Pricing Abuse

Apportionment of penalties and financial benefits

10.258. The penalty at the end of step 3 is £56,293,063.

10.259. The table below sets out how the total duration of the 10mg Unfair Pricing Abuse is apportioned to each specific period of ownership at the end of step 3.

Table 10.6: Apportionment of step 3 penalty for the 10mg Unfair Pricing Abuse

Period	Duration-based apportionment ³⁸¹⁴	Entities liable	Step 3 penalty
Period A1 (1 October 2008 – 28 May 2015)	72% (7.22 years)	Accord-UK	£40,643,592
Period A2 (29 May 2015 – 1 August 2016)	12% (1.20 years)	Accord-UK	£6,755,168
		Allergan	
Period A3 (2 August 2016 – 8 January 2017)	[See Period A1]	Accord-UK	[See Period A1]
Period A4 (9 January 2017 – 31 July 2018)	16% (1.58 years)	Accord-UK	£8,894,304
		Accord	
		Intas	

10.260. The CMA has considered whether the penalty should be adjusted by reference the need for specific deterrence. As set out in section 10.C.III above, the CMA has first had regard to the financial benefits generated by the undertakings involved in the Infringements. Table 10.7 sets out the

³⁸¹⁴ The CMA has allocated the Auden/Actavis undertaking's penalty at the end of step 3 (£56,293,063) to the different ownership periods in accordance with the percentage of the total step 2 duration of 10 years.

estimated financial benefit that can be attributed to each period of ownership with respect to the 10mg Unfair Pricing Abuse committed by Auden/Actavis.

Table 10.7: the CMA's estimate of the financial benefits obtained by Auden/Actavis from the 10mg Unfair Pricing Abuse

Period	Entities liable	Step 3 Penalty	Revenue differential above £20 per pack (minimum financial benefit) ³⁸¹⁵	Differential above Cost Plus	Range
Period A1 (1 October 2008 – 28 May 2015)	Accord-UK	£40.6 million	£77.5 million	£168.7 million	£77.5 – £168.7 million
Period A2 (29 May 2015 – 1 August 2016)	Accord-UK	£6.8 million	£37.9 million	£52.2 million	£37.9 – £52.2 million
	Allergan				
Period A3 (2 August 2016 – 8 January 2017)	Accord-UK	[See Period A1]	£10.2 million	£14.6 million	£10.2 – £14.6 million
Period A4 (9 January 2017 – 31 July 2018)	Accord-UK	£8.9 million	£12.5 million	£27.0 million	£12.5 – £27.0 million
	Accord				
	Intas				

The penalty should be increased at step 4: financial benefit

10.261. The penalties at the end of step 3 should be increased as Auden/Actavis obtained significant financial benefits from the 10mg Unfair Pricing Abuse throughout its nearly 10-year duration.

10.262. As set out in section 10.C.III above, any penalty imposed in relation to the 10mg Unfair Pricing Abuse should exceed the financial benefit from the 10mg Unfair Pricing Abuse by a material amount in order to be a meaningful deterrent. However, the penalties at the end of step 3 are significantly less

³⁸¹⁵ As explained in paragraphs 10.145 to 10.146, this is a conservative estimate of the minimum, not the actual financial benefit, based on profits relative to the £20 per pack price charged in July 2018. The Differential is provided by way of comparison.

than even the minimum financial benefit that Auden/Actavis accrued from the 10mg Unfair Pricing Abuse as set out in the table above.

10.263. While some of the financial benefits over Cost Plus of £263 million will have been profit that Auden/Actavis could have legitimately accrued but for the 10mg Unfair Pricing Abuse, the differential above £20 per pack of £138 million would not have been accrued absent the 10mg Unfair Pricing Abuse.³⁸¹⁶ For each of the Periods A1-A4 Auden/Actavis would therefore retain a significant, direct and foreseeable financial benefit from having carried out the 10mg Unfair Pricing Abuse if the penalty is not adjusted at step 4.

10.264. Of the total financial benefit that Auden/Actavis accrued from the 10mg Unfair Pricing Abuse, the penalty at the end of step 3 would represent only 41% when measured against the incremental benefit above the CMA's prioritisation level of £20 per pack.³⁸¹⁷ For Periods A1-A4, the financial benefits are as follows:

- a. for Periods A1 and A3, for which Accord-UK is solely liable, the step 3 penalty of £40,643,592 would represent 46% of financial benefits when measured against £20 per pack;
- b. for Period A2, for which Allergan and Accord-UK are jointly and severally liable, the step 3 penalty of £6,755,168 would represent 18% of financial benefits when measured against £20 per pack;³⁸¹⁸ and
- c. for Period A4, for which Intas and Accord-UK are jointly and severally liable, the step 3 penalty of £8,894,304 would represent 71% of financial benefits when measured against £20 per pack.

³⁸¹⁶ See paragraphs 5.220 to 5.227.

³⁸¹⁷ Accord and Allergan argued that the Unfair Pricing Infringements are more heavily penalised than the other infringements because the CMA can assess likely profits derived from the infringement in a way that they may not be able to for cartels and other types of infringement (Document 205813, Accord RDPS paragraph 1.15.5, paragraph 10.42; Document 205791, Allergan's RDPS, paragraph 55f). The CMA does not accept this representation. In cases where there is evidence of financial benefit it is important that such benefits are accounted for in any penalty imposed, taking into account the specific circumstances of the case. This accords with the CMA penalties guidance, paragraph 2.21. Indeed, the fact that profits from the infringement can more readily be assessed also means such profits are easier to predict for an undertaking considering similar conduct. If the penalties leave profits from the infringements unaddressed then an undertaking considering such conduct would not be deterred, particularly taking into account the low likelihood of getting caught. In different types of infringement where the benefits are also clear, competition authorities have based penalties on financial benefits and this has been sanctioned by the EU Courts (CMA penalties guidance, paragraph 2.20).

³⁸¹⁸ Allergan argued that the basis on which the CMA has calculated financial benefit for both the 10mg and 20mg Unfair Pricing penalties is flawed, and therefore accepts neither the methodology (ie Cost Plus) or the numbers, disputing in particular the inclusion of financial benefit attributable to the Hold-Separate Period (Document 205791, Allergan's RDPS, paragraphs 60 to 62). This goes to the facts of the case and is dealt with in sections 5 (The Unfair Pricing Abuses) and 9 (Undertakings and Attribution of Liability).

The penalty should reflect the nature and impact of the Infringement

10.265. In addition, the penalties at the end of step 3 do not reflect the serious nature and severe impact of the 10mg Unfair Pricing Abuse.

10.266. First, the 10mg Unfair Pricing Abuse amounts to a serious abuse of a dominant position, which is among the most serious infringements of competition law. Such infringements should attract significant financial penalties, reflecting the CMA's twin policy objectives of imposing penalties that reflect the seriousness of the infringement, and deterring both the infringing undertaking and other undertakings from engaging in anticompetitive activities.³⁸¹⁹

10.267. Second, the 10mg Unfair Pricing Abuse had a severe impact on the NHS.³⁸²⁰

- a. As set out in section 5.D.II.e above, the Unfair Pricing Abuses resulted in the NHS's annual expenditure on hydrocortisone tablets increasing from approximately £0.5 million in 2007 to a peak of nearly £84 million in 2016, (before falling thereafter, with an annual spend of £62 million in 2017 and approaching £40 million in 2018). This led to an adverse effect on the NHS and on patient welfare as CCGs were forced to compromise other healthcare services in order to fund the supply of hydrocortisone tablets to patients.³⁸²¹
- b. Auden/Actavis's prices were charged for a drug that has been on the market since 1955 and did not reflect any innovation or product-specific risks.³⁸²²

10.268. Third, as explained above, Auden/Actavis engaged in the 10mg Unfair Pricing Abuse over a sustained period of time, for the majority of which it was the sole supplier of 10mg hydrocortisone tablets.³⁸²³

³⁸¹⁹ CMA penalties guidance, paragraph 1.3.

³⁸²⁰ Accord-UK submitted that the impact on the NHS should not affect the CMA's analysis, citing previous decisional practice and the NHS's recourse to damages actions. The CMA rejects this submission: the CMA is not bound by previous decisional practice. In any case the CMA's decision in Case 50455 (Anticompetitive agreement with respect to fludrocortisone acetate 0.1mg tablets) took into consideration that the prices to the NHS had been artificially increased at step 1. In seeking to draw a comparison between a private damages action and the appropriate level of a penalty, Accord-UK does not appreciate the different roles that private and public enforcement of competition law play. Accord-UK also repeated arguments that had Accord-UK not increased the price of the product that MSD may have exited the market, imposing additional cost on the NHS, which wholly contradict the special responsibility of a dominant undertaking and the significant impact its pricing strategy had on the NHS (Document 205813, Accord-UK's RDPS, paragraph 10.47).

³⁸²¹ See section 5.D.II.e.

³⁸²² See section 5.D.II.b.i.

³⁸²³ Accord-UK is liable for this full period, either as the economic successor of AM Pharma or as the legal entity directly involved in the 10mg Unfair Pricing Abuse.

Further factors relating to Period A2 (Accord-UK and Allergan joint and several liability): specific deterrence

10.269. As set out in paragraphs 10.251 to 10.253 additional factors may support an increase to the penalty after step 3 to ensure this will deter the undertaking from breaching competition law in the future. There are such additional factors relating to the undertakings liable for Period A2, as follows.³⁸²⁴

Size and financial position

10.270. Allergan and Accord-UK are jointly and severally liable for the penalty for the infringement committed by Auden/Actavis during Period A2 as they were part of that undertaking at the time of the infringement. Since they no longer form part of the same undertaking today, the CMA has separately considered for each of Allergan and Accord-UK whether the penalty that relates to Period A2 is set at a level that would deter each of them.

10.271. The CMA has had regard to the size and financial position of the entities. In the absence of the statutory cap applied at step 5 for Accord-UK the CMA would have considered whether a further uplift would be required to take into account the considerable size of the Accord undertaking as it currently exists to ensure that the penalty is a meaningful deterrent, and would have considered – consistent with the calculations for the other penalties - that the penalty should materially exceed the financial benefit. However, since the penalty for Period A1 for which Accord-UK is solely liable already exceeds Accord-UK's statutory cap (exacerbated if Period A3 is added), it is not necessary to consider the exact level to which its penalty for Period A2 needs to be further increased to take into account its size. With respect to Allergan, the CMA has had regard to the financial indicators of Allergan and its corporate group at the time the penalty is imposed.³⁸²⁵ For the reasons set out below, the penalty in respect of Period A2 should be further increased to deter Allergan.

10.272. Allergan is currently owned by AbbVie and forms part of an undertaking of considerable size. For the financial year ending 31 December 2020, AbbVie reported revenue of USD 45.8 billion (£35.7 billion), profit after tax of USD 4.6 billion (£3.6 billion), and a net asset position of £9.6 billion.³⁸²⁶ The penalty at the end of step 3 (£6,755,168), even following adjustment at step 4 to reflect the financial benefits accrued during Period A2, would represent

³⁸²⁴ CMA penalties guidance, paragraph 2.21.

³⁸²⁵ CMA penalties guidance, paragraph 2.20. Accord-UK will have its own 10% statutory cap applied to it for this period, which is lower than the penalty arrived at after step 3, such that it is not necessary to consider whether its penalty should be increased at this step.

³⁸²⁶ AbbVie Annual Report on Form 10-K and 2021 Proxy Statement: [Annual report & proxy | AbbVie](#)

less than 0.1% of Abbvie's worldwide turnover for the financial year ending 31 December 2020, average annual worldwide turnover, profit after tax, and dividends over its last three financial years.³⁸²⁷ A financial penalty that forms such a small proportion of worldwide turnover is unlikely to deter the undertaking from committing infringements of competition law again in future, when considered together with the other case specific factors.

Turnover outside the relevant market

10.273. In addition, during its period of ownership (Period A2) Allergan had a significant proportion of its turnover outside the relevant market, and since the end of its ownership period it generated all its turnover outside the relevant market.³⁸²⁸

Other relevant factors

10.274. The relevant turnover used at step 1 of this penalty calculation does not accurately reflect the scale of the infringement during Allergan's period of ownership given the evolution of prices and market shares.³⁸²⁹

10.275. The relevant turnover at step 1 relates to the end of the infringement period and is therefore based on lower ASPs and a lower volume of sales than those during Allergan's ownership period.³⁸³⁰ The monthly ASP for 10mg hydrocortisone tablets reached its highest level, at £72.14 in March 2016, during Period A2 under Allergan's ownership.³⁸³¹ Had the 10mg Unfair Pricing Abuse ended at the end of Period A2, the relevant turnover used at step 1 would have amounted to circa £48.5 million,³⁸³² and the penalty for Period A2 after step 3 to circa £19.2 million rather than the current £6.8 million.

10.276. Although Allergan's liability covers just under one and a half years of the total duration of the 10mg Unfair Pricing Abuse, prices reached their zenith during this period. The CMA conservatively estimates Allergan generated profits in excess of £50m from a single product which accounts for less than 0.1% of its worldwide revenues,³⁸³³ the proceeds of which will have been

³⁸²⁷ CMA calculations based on Allergan data.

³⁸²⁸ Since Allergan sold Accord-UK in August 2016 it has not had any activities in the relevant market.

³⁸²⁹ It is not the case that any variation in turnover across time should result in an adjustment to the penalty at step 4, but material variations must be taken into account by the CMA when assessing whether a penalty is appropriate. This results in a higher increase at step 4 as compared to the uplift had the Infringement ended when Allergan divested Accord-UK.

³⁸³⁰ Relevant turnover for the 10mg Unfair Pricing Abuse during the last full business year of the period for which Allergan was jointly liable was £48.5 million, compared with £17.1 million at the end of the infringement period.

³⁸³¹ See section 3.E.V.a.i above.

³⁸³² Relevant turnover for the financial year ending 31 December 2015.

³⁸³³ Financial benefit at Cost Plus for the period June 2015-July 2016, compared with Allergan's worldwide revenues for the financial year ending 31 December 2015.

available to profitably reinvest within its business. While some of these earnings will have been profit that Allergan could legitimately have accrued, the penalty should exceed Allergan's financial benefit by a material amount to achieve a deterrent effect. As parent of Accord-UK exercising decisive influence, Allergan did not act to discontinue its abusive behaviour.

10.277. A significant uplift is therefore required for the penalty for which Allergan is liable to address the financial benefit, to provide a deterrent effect, and to address the scale of the infringement during Allergan's period of ownership.³⁸³⁴

Further factors relating to Period A4 (Intas, Accord and Accord-UK joint and several liability): specific deterrence

10.278. There are also additional factors relating to the undertakings liable for Period A2 which support an increase to the penalty after step 3 to ensure this will deter the undertaking from breaching competition law in the future, as follows.

Size and financial position

10.279. Intas, Accord and Accord-UK currently form part of a single undertaking, a large corporate group headed by Intas, and are jointly and severally liable for the penalty for Period A4. In assessing whether the penalty in respect of Period A4 after step 3 produced a sufficient deterrent effect, the CMA has had regard to the financial indicators of Intas and its corporate group at the time the penalty is imposed.³⁸³⁵

10.280. This undertaking is of considerable size.³⁸³⁶ In the financial year ending 31 March 2020, Intas reported revenue of INR 148.5 billion (£1.65 billion), profit after tax of INR 16.4 billion (£182 million) and reported a net asset position of £1.0 billion.³⁸³⁷ The penalty at the end of step 3 (£8,894,304), even following adjustment at step 4 to reflect the financial benefits accrued during Period A4, represents less than 1% of Intas's worldwide turnover for the financial year ending 31 March 2020, its average worldwide turnover over its last three financial years and the sum of its net assets for the financial year

³⁸³⁴ Accord-UK argued that the CMA had already accounted for financial benefit as ASP is included in relevant turnover at step 1 (Document 205813, Accord-UK's RDPS, paragraph 10.48). The CMA does not accept this representation. In the specific circumstances of an excessive pricing case like the 10mg Unfair Pricing Abuse, only part of the financial benefit would be captured by applying a 30% starting point to relevant turnover. The purpose of step 4 is to look at deterrence in the round and where necessary to adjust the penalty accordingly. The penalty is adjusted for the reasons set out here.

³⁸³⁵ CMA penalties guidance, paragraph 2.20.

³⁸³⁶ Accord-UK itself generated annual turnover of over £280 million in the most recent financial year, profit after tax of £39 million and paid dividends of £54 million (Accord-UK's financial statements for the financial year ending 31 March 2020 lodged at Companies House on 22 October 2020.)

ending 31 March 2020. It represents just 5.7% of its average annual profit after tax over its last three financial years. A financial penalty that forms such a small proportion of worldwide turnover and average annual profits is, in the CMA's view, unlikely to deter the undertaking from committing infringements of competition law again in future when considered together with the other case specific factors.

Turnover outside the relevant market

10.281. This undertaking has a significant proportion of its turnover outside the relevant market.³⁸³⁸

Other relevant factors

10.282. By the time Intas acquired Accord-UK (through its 100% subsidiary Accord) in January 2017, the CMA's investigation into the Unfair Pricing Abuses had been open for approximately nine months. The CMA made Intas aware of the investigation prior to the acquisition but Intas nonetheless failed to discontinue the conduct.³⁸³⁹ The existence of the CMA's investigation and the potential liability that would attach to a continuation of the alleged infringement was therefore insufficient to deter Intas from continuing that infringement.

10.283. A significant uplift is therefore required for the penalty for which Intas, Accord and Accord-UK are jointly and severally liable to address the financial benefit and provide a deterrent effect.

Adjustments at step 4

10.284. The penalty after step 4 should both exceed financial benefit and be set at a level which in the CMA's assessment would also have a deterrent effect on the undertaking as it currently exists, as well as taking into account the specific factors of the case.³⁸⁴⁰ The CMA considers that the following penalties are appropriate.

³⁸³⁸ Over [X] of Intas's worldwide turnover is generated outside the relevant market; and over [X] of Accord-UK's turnover is generated outside the relevant market.

³⁸³⁹ Accord-UK and Intas/Accord-UK made submissions as to the relevance of this factor to the penalty calculation. These are discussed in more detail in paragraph 10.25.g above. Allergan sought to distinguish its knowledge of the investigation and unfair pricing enforcement activity during its ownership period with that of Intas, to argue that the penalty for which it is liable is disproportionate when compared with that of Intas (Document 205791, Allergan's RDPS, paragraphs 87 to 90). The CMA rejects this representation: each penalty has been assessed on a case-by-case basis with particular reference to the financial benefit, financial indicators and other relevant circumstances.

³⁸⁴⁰ Intas argued that its penalty at the end of step 3 is already too high, and more than sufficient for deterrence, but the CMA does not accept this for the reasons outlined in section 10.C.III, the step 4 analysis and in Annex F (Document 205802, Intas/Accord-UK's RDPS, paragraph 80).

- 10.285. For Periods A1 and A3, for which Accord-UK is solely liable, the penalty should first be increased to £87.65 million. As set out above at paragraph 10.270, although the CMA considers that the penalty should in principle *exceed* this financial benefit, a penalty of £87.65 million already significantly exceeds Accord-UK's statutory cap of £28.4 million. It is therefore not necessary to conclude on the exact amount by which Accord-UK's penalty should exceed the financial benefit and the penalty is not increased further at step 4 than £87.65 million.
- 10.286. For Period A2, for which Accord-UK and Allergan are jointly and severally liable, the penalty should first be increased to exceed the considerable financial benefit made by the undertaking of which both entities were part during this period, which amounts to £37.9 million.
- 10.287. Because Accord-UK's penalty for the 10mg Unfair Pricing Abuse already exceeds its cap at this level,³⁸⁴¹ it is not necessary to conclude whether a further uplift to the penalty for Period A2 is required to reflect Accord-UK's size and financial position.
- 10.288. However, the same does not apply to Allergan. The penalty should be uplifted to take into account not only the need for the penalty to materially exceed the financial benefit of £37.9 million that is specific to Period A2, but also the significant size and financial position of Allergan,³⁸⁴² and the other relevant case specific considerations identified above at paragraphs 10.270 to 10.277. The CMA has therefore applied an uplift to increase the total penalty for Period A2 for which Allergan is liable to £74.3 million. Allergan is an undertaking of considerable size (see paragraph 10.271 above) and a penalty of £74.3 million represents approximately:
- a. 0.2% of Allergan's worldwide turnover in the financial year ending 31 December 2020;
 - b. 0.3% of its average annual worldwide turnover over its last three financial years;
 - c. 1.6% of Allergan's average annual profit after tax over its last three financial years; and
 - d. 1.5% of Allergan's average dividends over its last three financial years.

³⁸⁴¹ As explained at step 5, its penalty for Period A2 is in fact reduced to zero.

³⁸⁴² Indeed, the benefit at £20 per pack is a conservative estimate of the minimum financial benefit (see also Table 10.7 which contrasts this benefit against the benefits above Cost Plus). Merely recouping the benefits obtained over and above the £20 per pack prioritisation level would not provide sufficient deterrence.

10.289. The CMA considers that a penalty at this level provides an effective yet proportionate deterrent to Allergan, having regard to Allergan's size and financial position; the nature of the 10mg Unfair Pricing Abuse; the role of the undertaking of which Allergan formed part in the 10mg Unfair Pricing Abuse and the impact of the 10mg Unfair Pricing Abuse on competition.

10.290. For Period A4, for which Accord-UK, Accord and Intas are jointly and severally liable, the penalty should be uplifted for specific deterrence to take into account not only the need for the penalty to materially exceed the financial benefit of £12.5 million for Period A4,³⁸⁴³ but also the significant size and financial position of Intas and other relevant case specific considerations set out at paragraphs 10.279 to 10.283 above, and including in particular Intas' status as the current parent company of Accord-UK and its failure to discontinue the conduct during the entirety of Period A4 despite having been made aware of the investigation by the CMA. The CMA has therefore applied an uplift to increase the penalty for Period A4 for which Accord-UK, Accord and Intas are jointly and severally liable to £44.4 million.³⁸⁴⁴

10.291. A penalty of this size represents:

- a. 3% of Intas's annual worldwide turnover for the financial year ending 31 March 2020, and its average annual worldwide turnover over its last three financial years;
- b. 24% of Intas's annual profit for the financial year ending 31 March 2020;
- c. 29% of Intas's average annual profit after tax over its last three financial years; and
- d. 4% of the sum of Intas's net assets for the financial year ending 31 March 2020.

10.292. The CMA considers that a penalty at this level provides an effective yet proportionate deterrent to the undertaking consisting of Intas, Accord and Accord-UK for their involvement in the 10mg Unfair Pricing Abuse during

³⁸⁴³ As for Allergan, the benefit of £20 per pack is a conservative estimate of the minimum financial benefit (see also Table 10.7). Merely recouping the benefits obtained over and above the £20 per pack prioritisation level would not provide sufficient deterrence.

³⁸⁴⁴ Allergan and Intas have each made representations that the uplifts imposed for Periods A2 and A4 are disproportionately high relative to each other. For example, Allergan argued that the uplift imposed for Period A2 at step 4 is disproportionately high when compared with the percentage uplift for Period A4 set out in the Draft Penalty Statement, while Intas argued that the penalty at step 4 is disproportionately high relative financial benefit for Period A4 relative to Period A2. However, as explained above, each penalty was determined by the CMA having regard to the level of financial benefit, each party's individual size and financial position, and other case specific factors and the CMA considers the uplifts for both Allergan and Intas to be appropriate. Moreover, simple comparisons in percentage uplift terms are not meaningful in this case.

Period A4, having regard to their collective size and financial position; Intas's position as Accord-UK's current parent company and its failure to discontinue the conduct of its subsidiary; the nature of the 10mg Unfair Pricing Abuse; the role of the undertaking in the 10mg Unfair Pricing Abuse; and the impact of the 10mg Unfair Pricing Abuse on competition.³⁸⁴⁵

10.293. Accord-UK is currently part of the same undertaking as Intas and Accord. The CMA is mindful of the fact that as a result, that undertaking not only bears liability for the penalty attributable to Period A4, but also the penalty attributable to the periods for which Accord-UK is liable, even though its current parent companies cannot be held jointly and severally liable for those periods. The CMA has therefore assessed whether the total of the penalties for which Accord-UK is solely liable and the penalty for which it is jointly and severally liable with Accord and Intas is disproportionate or excessive when considered against the financial position of the undertaking consisting of Accord-UK, Accord and Intas.³⁸⁴⁶ The CMA has not included the amount for which Accord-UK is liable with respect to Period A2 of the 10mg Unfair Pricing Abuse, because that amount is reduced to zero at step 5 (see below). This assessment therefore focusses on the penalties attributable to Periods A1, A3 and A4.

10.294. The penalty of £132.05 million (ie £87.65 million + £44.4 million) attributable to Periods A1, A3 and A4 represents approximately:

- a. 8% of Intas's worldwide turnover for the financial year ending 31 March 2020;
- b. 9% of Intas's average annual worldwide turnover over its last three financial years;
- c. 73% of Intas's annual profit for the financial year ending 31 March 2020
- d. 85% of Intas's average annual profit after tax over its last three financial years;

³⁸⁴⁵ Intas argued that it was disproportionate for the penalty for period A4 to be a materially higher proportion of financial metrics than Allergan's penalty for period A2 (Document 205802, Intas/Accord-UK's RDPS, paragraph 92-93). However, the CMA considers the penalty proportionate to the specific circumstances of the case for the reasons set out above. The CMA also notes that because revenues from the sale of 10mg hydrocortisone tablets accounted for a larger proportion of Intas's global revenues than for Allergan, and penalty equivalent to 5% of 3 year average profit after tax would be required just to increase the penalty to the level of financial benefit at £20 per pack. Further, although Allergan and Intas are both large undertakings, Allergan is significantly bigger than Intas, such that it is not appropriate to seek to set penalties at precisely the same percentage of a certain financial metric for each of them. Instead, the CMA has in exercising its judgment ensured that the differences between the undertakings are not overlooked and that the penalties are set at levels that would provide an effective yet proportionate deterrent for each, while not discriminating against one undertaking when compared to another.

³⁸⁴⁶ CMA penalties guidance, paragraph 2.24.

- e. 13% of the sum of Intas's net assets for the financial year ending 31 March 2020.³⁸⁴⁷

10.295. The CMA concludes that the aggregated penalty for Periods A1, A3 and A4 is not disproportionate or excessive, having regard to the considerable financial benefits attributable to these periods (£100 million on a conservative basis, ie based on benefits above the prioritisation level of £20 per pack); Accord-UK, Accord and Intas's size and financial position; Intas' position as Accord-UK's current parent company and its failure to discontinue the conduct of its subsidiary; the nature of the 10mg Unfair Pricing Abuse; the role of the undertaking of which Accord-UK formed part in the 10mg Unfair Pricing Abuse and the impact of the 10mg Unfair Pricing Abuse on competition.³⁸⁴⁸ While it has not had an impact on the conclusion that the total penalty of £132.05 million would not be disproportionate or excessive when considered against the financial indicators of the undertaking consisting of Intas, Accord and Accord-UK, it should also be noted that this total amount is reduced to £72.8 million at the end of the next step of the penalty calculation (see below).

10.296. The total penalty for periods A1, A2, A3 and A4 at the end of step 4 is therefore £206,350,000, of which:

- a. Accord-UK is liable for £87,650,000 for periods A1 and A3,
- b. Allergan is liable for £74,300,000 for period A2; and
- c. Accord-UK, Accord and Intas are jointly and severally liable for £44,400,000 for period A4.

ii. 20mg Unfair Pricing Abuse

10.297. As for the 10mg Unfair Pricing Abuse, the CMA has taken into account the financial benefits accrued by Accord-UK and Allergan through the 20mg Unfair Pricing Abuse to assess whether the penalty is an effective deterrent and whether a further increase is required (see paragraph 10.254).³⁸⁴⁹

³⁸⁴⁷ As set out at step 5 below the penalty amount that Intas will be liable for will be significantly lower than £132 million due to the application of the statutory cap to Periods A1 and A3. The maximum amount that Accord-UK, Accord and Intas are liable for in relation to the 10mg Unfair Pricing Abuse is approximately £72.8 million (£28.4 million + £44.4 million), or 4% of Intas' most recent worldwide turnover.

³⁸⁴⁸ Accord-UK submitted that some of the factors the CMA cites in step 4 are already taken into account at earlier steps. (Document 205813, Accord-UK's RDPS, paragraph 10.47). There is no double counting of deterrence between step 4 and earlier steps (although there may be common facts that are relevant both to seriousness and sanctions for seriousness, i.e. whether the sanction is appropriate). Allergan argued that the CMA had taken a formulaic approach (Document 205791, Allergan's RDPS, paragraph 96). The CMA rejects this argument and notes that the proportionality adjustment envisaged in step 4 is a method to correct any otherwise disproportionate result arising after the first three penalty steps. That, however, does not indicate that the CMA is wrong to follow the approach set out in the CMA penalties guidance in relation to those first three steps.

³⁸⁴⁹ See also section 10.D.IV.a.i above.

However, as set out in section 10.C.VI the CMA has not applied a further uplift for specific deterrence for the 20mg Unfair Pricing Abuse on the basis of the size of the undertakings involved, as a specific deterrence uplift has already been applied for the same type of conduct in the penalty for the 10mg Unfair Pricing Abuse.

Apportionment of penalties and financial benefits

10.298. The penalty at the end of step 3 is £7,097,239.

10.299. The penalties are calculated on a per-Period basis from step 4 onwards. Table 10.8 below sets out how the total duration of the 20mg Unfair Pricing Abuse is apportioned to each specific period of ownership.

Table 10.8: apportionment of step 3 penalty for the 20mg Unfair Pricing Abuse

Date	Duration based apportionment ³⁸⁵⁰	Undertaking	Step 3 penalty
Period B1 (1 October 2008 – 28 May 2015)	86% (7.07 years)	Accord-UK	£6,082,119
Period B2 (29 May 2015 – 1 August 2016)	14% (1.18 years)	Accord-UK	£1,015,120
		Allergan	
Period B3 (2 August 2016 – 8 January 2017)	[See Period B1]	Accord-UK	[See Period B1]

10.300. The CMA has considered whether the penalty should be adjusted by reference the need for specific deterrence. The CMA has first had regard to the financial benefits generated by the undertakings involved in the Infringements. Table 10.9 below sets out the financial benefit that can be attributed to each period of ownership.

³⁸⁵⁰ The CMA has allocated the Auden/Actavis undertaking's penalty at the end of step 3 (£7,097,239) to the different ownership periods in accordance with the percentage of the total step 2 duration of 8.25 years.

Table 10.9: the CMA's estimate of financial benefits obtained by Auden/Actavis from the 20mg Unfair Pricing Abuse

Date	Undertaking	Step 3 Penalty	Revenue differential above £20 per pack (minimum financial benefit) ³⁸⁵¹	Differential above Cost Plus	Range
Period B1 (1 October 2008 – 28 May 2015)	Accord-UK	£6.1 million ³⁸⁵²	£4.8 million	£9.7 million	£4.8 – £9.7 million
Period B2 (29 May 2015 – 1 August 2016)	Accord-UK	£1.0 million	£2.0 million	£2.7 million	£2.0 – 2.7 million
	Allergan				
Period B3 (2 August 2016 – 8 January 2017)	Accord-UK	[See Period B1]	£0.4 million	£0.7 million	£0.4 – £0.7 million

The penalty should be increased at step 4: financial benefit

10.301. The penalty for Period B2 at the end of step 3 should be increased to ensure effective deterrence as Auden/Actavis obtained significant financial benefits from the 20mg Unfair Pricing Abuse during that period which would be left unaddressed if the penalty at the end of step 3 is not adjusted.

10.302. As set out in Table 10.9 above the penalties at the end of step 3 for Periods B1 and B3 already exceed the financial benefit by reference to the CMA's prioritisation level at £20 per pack, so a further increase is not required and the penalty at the end of step 4 remains £6,082,119.

10.303. For Period B2, the penalty must be increased above the level of financial benefit. The CMA considers that an uplift to £2,000,000 is appropriate.

10.304. Of the total figure of £8,082,119 for Periods B1, B2 and B3, Accord-UK is solely liable for £6,082,119 and jointly and severally liable with Allergan for £2,000,000. The CMA has assessed the proportionality of the penalties for which Accord-UK is liable against the financial position of the undertaking

³⁸⁵¹ As explained in paragraphs 10.145 to 10.146, this is a conservative estimate of the minimum, not the actual financial benefit, based on profits relative to the £20 per pack price charged in July 2018. The Differential is provided by way of comparison.

³⁸⁵² Step 3 penalty is for Period B1 and Period B3 combined.

consisting of Accord-UK, Accord and Intas. The total penalty represents less than 1% of Intas's most recent worldwide turnover, average annual worldwide turnover over its last three financial years, and net assets in its last financial year. It represents 5.2% of Intas's average annual profit after tax over its last three financial years.³⁸⁵³

10.305. The CMA considers that this is an effective yet proportionate deterrent to the Auden/Actavis undertaking as it exists today, having regard to Accord-UK, Accord and Intas's size and financial position; the nature of the 20mg Unfair Pricing Abuse;³⁸⁵⁴ the role of the undertaking of which Accord-UK formed part in the 20mg Unfair Pricing Abuse; the impact of the 20mg Unfair Pricing Abuse on competition; the fact that it addresses the financial benefit derived from the 20mg Unfair Pricing Abuse, and the fact that specific deterrence for this type of conduct has been applied in respect of the 10mg Unfair Pricing Abuse (as set out at paragraph 10.297 above).

10.306. Of the total figure of £8,082,119, Allergan is jointly and severally liable with Accord-UK for £2,000,000. This represents less than 0.1% of Allergan's worldwide turnover in its last financial year, average annual worldwide turnover, average annual profit after tax and average dividends over its last three financial years.

10.307. The CMA considers that this is an effective yet proportionate deterrent having regard to Allergan's size and financial position; Allergan's position as Accord-UK's parent company exercising decisive influence and its failure to act to discontinue the conduct of its subsidiary; the nature of the 20mg Unfair Pricing Abuse;³⁸⁵⁵ the role of the undertaking of which Allergan formed part in the 20mg Unfair Pricing Abuse; the impact of the 20mg Unfair Pricing Abuse on competition;³⁸⁵⁶ the fact that this penalty addresses the financial benefit derived by the undertaking during Period B2, and the fact that specific deterrence for excessive and unfair pricing has been applied in respect of the 10mg Unfair Pricing Abuse (as set out at paragraph 10.297 above).

³⁸⁵³ With respect to the 20mg Unfair Pricing Abuse the CMA has assessed the proportionality of the total penalty for which Accord-UK is liable whether solely or jointly and severally with Allergan. This differs from the assessment for the 10mg Unfair Pricing Abuse, since the penalty for Periods A1 and A3 for which Accord-UK is solely liable already materially exceeds its statutory cap, such that the part of the penalty for which Accord-UK is liable for Period A2 is reduced to zero for Accord-UK (but not for Allergan). For this reason the CMA did not conduct a proportionality assessment with respect to Accord-UK's liability for Period A2.

³⁸⁵⁴ The CMA considers that the factors set out at section 10.D.IV.a.i at '*The penalty should reflect the nature and impact of the Infringement*' apply equally to the 20mg Unfair Pricing Abuse.

³⁸⁵⁵ The CMA considers that the factors set out at section 10.D.IV.a.i at '*The penalty should reflect the nature and impact of the Infringement*' apply equally to the 20mg Unfair Pricing Abuse.

³⁸⁵⁶ Allergan submitted that the penalty is disproportionate on the basis that it is being fined in its capacity as a parent company (Document 205791, Allergan's RDPS, paragraphs 4 to 5). This is addressed in Annex F.

10.308. The total penalty for Periods B1, B2 and B3 at the end of step 4 is therefore £8,082,119, of which:

- a. Accord-UK is liable for £6,082,119 for periods B1 and B3, and
- b. Accord-UK and Allergan are jointly and severally for £2,000,000 for Period B2.

iii. 10mg Agreement

Apportionment of penalties

10.309. The penalty at the end of step 3 is £59,975,166.

10.310. The penalties are calculated on a per-Period basis from step 4 onwards.

Table 10.10 below sets out how the total duration of the 10mg Agreement is apportioned to each specific period of ownership.

Table 10.10: apportionment of the step 3 penalty for the 10mg Agreement for Auden/Actavis

Period	Duration based apportionment ³⁸⁵⁷	Entities liable	Step 3 penalty
Period C1 (23 October 2012 – 28 May 2015)	71% (2.66 years)	Accord-UK	£42,542,385
Period C2 (28 May 2015 – 24 June 2016)	29% (1.09 years)	Accord-UK	£17,432,782
		Allergan	

No uplift for financial benefit

10.311. As an uplift has been applied to account for financial benefits in respect of the 10mg Unfair Pricing Abuse, the CMA has not taken any financial benefits obtained by Auden/Actavis into account at this stage of the penalty for the 10mg Agreement because any benefits attributable to the Agreement are captured in the financial benefits relating to the 10mg Unfair Pricing Abuse.

10.312. The CMA has however considered whether an uplift is required for specific deterrence on other grounds (as set out in paragraphs 10.251 to 10.254) and whether any decreases are required to ensure the penalty is not disproportionate or excessive.

³⁸⁵⁷ The CMA has allocated the Auden/Actavis undertaking's penalty at the end of step 3 (£59,975,166) to the different ownership periods in accordance with the percentage of the total step 2 duration of 3.75 years.

The penalty should reflect the nature and impact of the Infringement

10.313. The 10mg Agreement is a market exclusion agreement, which is among the most serious infringements of competition law which should attract significant financial penalties.³⁸⁵⁸

10.314. The 10mg Agreement also had a significant impact on competition and ultimately the NHS. The Auden /Actavis undertaking engaged in the 10mg Agreement for almost four years in order to exclude independent entry from competitors and sustain its position as the sole supplier of 10mg hydrocortisone tablets and therefore its high prices, resulting in the effects outlined in paragraph 10.171.

10.315. Further, it launched 'Project Guardian' as it sought to protect its market share and preserve its commercial advantage as the sole supplier of 10mg hydrocortisone tablets at a time when it anticipated that AMCo may independently enter the market.³⁸⁵⁹

No uplift required for Period C1

10.316. A penalty of £42.54 million already significantly exceeds Accord-UK's statutory cap of £28.4 million. It is therefore not necessary to conclude on whether an uplift is required to the penalty at the end of step 3 for specific deterrence and proportionality for Accord-UK for the period for which it is solely liable (Period C1).

10.317. The penalty for Period C1, £42,542,385, would represent less than 5% of Intas's most recent worldwide turnover, its average annual worldwide turnover over its last three financial years, and the sum of Intas's net assets in its last financial year. It would represent 28% of its average annual profit after tax over its last three financial years. The CMA considers that a penalty at this level will provide an effective deterrent to the undertaking consisting of Accord-UK, Accord and Intas, having regard to Accord-UK, Accord and Intas's size and financial position; the nature of the 10mg Agreement; the role of the undertaking of which Accord-UK formed part in the 10mg Agreement and the impact of the 10mg Agreement on competition.

Further factors relating to Period C2: specific deterrence

10.318. Accord-UK is liable for the penalties attributable to Periods C1 and C2. However, as the penalty for Period C1 already exceeds its statutory maximum, the amount for which Accord-UK is liable with respect to Period

³⁸⁵⁸ CMA penalties guidance, paragraph 1.3.

³⁸⁵⁹ See section 3.F.III.h

C2 of the 10mg Agreement is reduced at the end of step 5 to zero (see below). Consistent with the approach taken with respect to the 10mg Unfair Pricing Abuse, the CMA has therefore not assessed the proportionality of the penalty for Period C2 specifically against Accord-UK's own financial indicators.

10.319. However, the same does not apply to Allergan, which is also liable for Period C2. The CMA considers that factors relating to Allergan indicate that the penalty attributable to that period should be increased beyond £17,432,782.

Size and financial position, and turnover outside the relevant market

10.320. The CMA has had regard to the financial indicators of Allergan and its corporate group at the time the penalty is imposed.³⁸⁶⁰ For the reasons set out below, the penalty in respect of Period C2 should be further increased to deter Allergan.

10.321. As set out at paragraph 10.271 Allergan is an undertaking of considerable size and during the relevant time it had a significant proportion of its turnover outside the relevant market, and has had no turnover in that market since the end of its ownership period. The penalty at the end of step 3 (£17,432,782) would represent less than 0.1% of Allergan's most recent and average worldwide turnover over its last three financial years, and 0.4% of Allergan's average annual profit after tax and 0.4% of its average dividends over its last three financial years.³⁸⁶¹

Other relevant factors

10.322. As set out above, at the time when the 10mg Agreement delayed the emergence of competition into the market for 10mg hydrocortisone tablets, the monthly ASP for 10mg hydrocortisone tablets reached its highest level, at £72.14 in March 2016 (during Period C2 under Allergan's ownership as set out at paragraph 10.275). As parent of Accord-UK exercising decisive influence, Allergan did not act to discontinue its behaviour.

Adjustments at step 4 for Period C2

10.323. For the reasons described at paragraphs 10.320 to 10.322 above, the CMA considers that an uplift should be applied to the penalty in respect of Period C2 for Allergan to achieve specific deterrence, resulting in a penalty of

³⁸⁶⁰ CMA penalties guidance, paragraph 2.20.

³⁸⁶¹ CMA calculations based on Allergan data.

£34,800,000. As discussed at paragraphs 10.318 to 10.319 above, the uplift is specific to Allergan and is not applicable to Accord-UK.³⁸⁶²

10.324. Allergan is an undertaking of considerable size. A penalty of £34,800,000 would represent approximately 0.1% of Allergan's worldwide turnover for the financial year ending 31 December 2020, and its average annual worldwide turnover over its last three financial years. It would also represent approximately 0.7% of Allergan's average annual profit after tax and its average dividends over its last three financial years.

10.325. The CMA considers that uplifting the penalty to at least this level is necessary for the purpose of deterrence and yet proportionate, having regard to Allergan's size and financial position; the nature of the 10mg Agreement; the role of the undertaking of which Accord-UK formed part in the 10mg Agreement; the impact of the 10mg Agreement on competition; the fact that it addresses the conduct associated with the 10mg Agreement, and the fact that the financial benefits have already been addressed in the 10mg Unfair Pricing Abuse penalty (see section 10.D.IV.a.i and assessment in paragraphs 10.261 to 10.263 above).

10.326. The total penalty for periods C1, C2 and C3 at the end of Step 4 is therefore £59,975,166, of which:

- a. Accord-UK is solely liable for £42,542,385 for Periods C1 and C3, and
- b. Allergan is liable for £34,800,000, for which Accord-UK is jointly and severally liable for £17,432,782 for Period C2.

iv. 20mg Agreement

10.327. The penalty at the end of step 3 for which Accord-UK is liable is £2,798,525.

No uplift for financial benefits

10.328. For the same reasons as set out with respect to the 10mg Agreement, the CMA has not taken any financial benefits obtained by Auden/Actavis into account at this stage of the penalty for the 20mg Agreement.

³⁸⁶² As explained at step 5 below, the amount for which Accord-UK is liable is reduced to zero following the application of the statutory cap.

No uplift for specific deterrence

- 10.329. Further, in light of the deterrence uplift in relation to the 10mg Agreement, and consistent with section 10.C.VI above, it is not necessary to apply a further specific deterrence uplift for the 20mg Agreement.
- 10.330. The penalty of £2,798,525 represents 0.2% of the turnover of the Accord-UK undertaking.
- 10.331. This penalty is an effective deterrent to the Auden/Actavis undertaking as it exists today and yet proportionate, having regard to Accord-UK, Accord and Intas's size and financial position; the nature of the 20mg Agreement; the role of the undertaking of which Accord-UK formed part in the 20mg Agreement and the impact of the 20mg Agreement on competition;³⁸⁶³ the fact that it addresses the financial benefit derived by the undertaking as a result of the 20mg Unfair Pricing Abuse, and the fact that specific deterrence for this type of conduct has been applied in respect of the 10mg Agreement (see section 10.D.IV.a.iii (*10mg Agreement*) above).
- 10.332. The penalty at the end of step 4 is £2,798,525 for which Accord-UK is liable.

b. AMCo

i. 10mg Agreement

Apportionment of penalties and financial benefits

- 10.333. At the end of step 3, the penalty must be adjusted to take into account of the 15% director uplift and 5% compliance discount. As the compliance discount has only been granted to AMCo and not to Waymade and the Cinven Entities, this must be adjusted for after the penalty is apportioned between all of the parties:
- a. For Period D1, the step 3 penalty includes a 15% director uplift. It also includes a 5% compliance discount which applies to Amdipharm UK Limited only. Waymade's liability for the Period D1 penalty is discussed separately in section 10.D.IV.c (*Waymade*) below.
 - b. For Period D2, the step 3 penalty includes a 15% director uplift. It also includes 5% compliance discount which applies to the Amdipharm Companies only. The penalty for Period D2 at the end of step 3 is £8,783,674 after taking into account the 15% director uplift. The

³⁸⁶³ The CMA considers that the factors set out at section 10.D.IV.a.iii at '*The penalty should reflect the nature and impact of the Infringement*' at paragraph 10.313 and 10.314 apply equally to the 20mg Agreement.

amount of this step 3 penalty which the Amdipharm Companies are jointly and severally liable for is a lower amount of £8,401,775, because the penalty for the Amdipharm Companies also includes a 5% compliance discount.

- c. For Period D3, the step 3 penalty includes a both 15% director uplift and a 5% compliance discount. The penalty at the end of step 3 is £2,015,925.

10.334. Table 10.11 below sets out the apportionment of the total duration of the 10mg Agreement between each specific period of ownership and the application of the step 3 adjustments.

Table 10.11: apportionment of the AMCo step 3 penalty

Period	Duration-based apportionment ³⁸⁶⁴	Entities liable	Apportioned penalty after application of step 3 adjustments ³⁸⁶⁵
Period D1 (23 October 2012 – 30 October 2012)	n/a	Waymade plc Amdipharm UK Limited	£254,620 (of which Amdipharm UK Limited is jointly and severally liable for £243,550) ³⁸⁶⁶
Period D2 (31 October 2012 – 20 October 2015)	81% (3.05 years)	The Amdipharm Companies ³⁸⁶⁷ The Cinven Entities	£8,783,674 (of which the Amdipharm Companies are jointly and severally liable for £8,401,775)
Period D3 (21 October 2015 – 24 June 2016)	19% (0.70 years)	The Amdipharm Companies Advanz	£2,015,925

³⁸⁶⁴ Consistent with the CMA's findings on attribution of liability for the Infringements, at the time the penalty for the infringement is imposed (ie at the date of this Decision), there are two entities which will be liable to pay the penalty for Period D2 and D3 in different proportions. For the purpose of step 4, the CMA has therefore allocated the AMCo undertaking's share of the penalty for Period D2 and Period D3 at the end of step 3 (£10,711,950) to the different ownership periods in accordance with the percentage of the total step 2 duration for Periods D2 and D3 of 3.75 years, and then consider uplifts on the specifics of step 4.

³⁸⁶⁵ Step 3 adjustments for the 10mg Agreement for Waymade and AMCo comprise a 15% uplift which has been applied to all parties (see Section 10.D.III.a above) and a 5% discount for recent compliance activities which has been applied to the Amdipharm Companies and Advanz only (see Section 10.D.III.b.i above).

³⁸⁶⁶ As explained at step 5 below, the part of the penalty which Amdipharm UK Limited is liable to pay is in any case reduced to £0 after step 5.

³⁸⁶⁷ In the case of Amdipharm Limited, liability is only from 1 January 2013.

Uplift for financial benefit

10.335. The CMA has considered whether the penalty should be adjusted by reference to the need for specific deterrence. As set out in section 10.C.III above, the CMA has first had regard to the financial benefits generated by the undertakings involved in the Infringements. Table 10.12 below sets out the financial benefit that can be attributed to each period of ownership with respect to AMCo's involvement in the 10mg Agreement.

Table 10.12: the CMA's estimate of the financial benefits accrued to Waymade and AMCo from the 10mg Agreement

Period	Entities liable	Estimated financial benefit ³⁸⁶⁸
Period D1 (23 October 2012 – 30 October 2012)	Waymade plc Amdipharm UK Limited	£70,000
Period D2 (31 October 2012 – 20 October 2015)	The Amdipharm Companies ³⁸⁶⁹ The Cinven Entities	£14.2 million
Period D3 (21 October 2015 – 24 June 2016)	The Amdipharm Companies Advanz	£6.5 million

No uplift for Amdipharm UK for Period D1:

10.336. A penalty of £243,550 already exceeds Amdipharm UK Limited's statutory cap as well as the estimated financial benefit. It is therefore not necessary to conclude on whether an uplift is required to the penalty at the end of step 3 for specific deterrence and proportionality for Amdipharm for Period D1.³⁸⁷⁰

The penalty should be increased at step 4 for Periods D2 and D3: financial benefit

10.337. The CMA has found that Auden/Actavis paid AMCo at least £20.6 million during Periods D2 and D3, with the payments increasing significantly over time.³⁸⁷¹ As set out in the introduction, effective deterrence should ensure that an undertaking does not profit from infringing competition. The penalties at the end of step 3 for Periods D2 and D3 are significantly less than the

³⁸⁶⁸ See Section 6.D.II.b.ii.

³⁸⁶⁹ In the case of Amdipharm Limited, liability is only from 1 January 2013.

³⁸⁷⁰ Waymade's liability for the Period D1 penalty is discussed separately in section c (Waymade) below.

³⁸⁷¹ See section 6.D.II.b.ii.

financial benefits derived from the Infringement by AMCo and must therefore be increased for this reason alone.

The penalty should reflect the nature and impact of the Infringement

10.338. The 10mg Agreement is a market exclusion agreement which should attract severe financial penalties.³⁸⁷²

10.339. As set out in paragraph 10.171 and 10.174.b the CMA considers that the 10mg Agreement, in which Waymade/AMCo agreed it would not enter the market for 10mg hydrocortisone tablets, also had a significant impact on competition and ultimately the NHS.

Further factors relating to Periods D2 and D3: specific deterrence

10.340. Additional factors relating to Periods D2 and D3 justify further increasing the penalty attributable to those periods, as follows.³⁸⁷³

Size and financial position

Period D2

10.341. The Cinven Entities and the Amdipharm Companies³⁸⁷⁴ are jointly and severally liable for the penalty for the infringement committed by AMCo during Period D2 as they were part of that undertaking at the time of the infringement. Since they no longer form part of the same undertaking today, the CMA has separately considered for each of the Cinven Entities and the Amdipharm Companies whether the penalty that relates to Period D2 is set at a level that would deter each of them.

The Cinven Entities

10.342. For the purpose of determining whether the penalty is set at a level that would deter the Cinven Entities, the CMA has had regard to the financial indicators of the Cinven Entities as at the time the penalty is imposed.³⁸⁷⁵ The CMA must ensure that any penalty the Cinven Entities are required to pay is not negligible in light of their financial capacity.³⁸⁷⁶

³⁸⁷² CMA penalties guidance, paragraph 1.3.

³⁸⁷³ CMA penalties guidance, paragraph 2.20.

³⁸⁷⁴ In the case of Amdipharm Limited, liability is only from 1 January 2013.

³⁸⁷⁵ CMA penalties guidance, paragraph 2.20.

³⁸⁷⁶ See for example C-511/11 *Versalis v Commission*, paragraph 102.

10.343. The Cinven Entities are of considerable size. The Cinven Entities generated [X].³⁸⁷⁷

10.344. The penalty imposed on the Cinven Entities at the end of step 3 for Period D2 (£8,783,674), even following adjustment at step 4 to reflect the financial benefits accrued during Period D2, would represent [X] of the Cinven Entities' average and most recent worldwide turnover and [X] of their net assets for the financial year ending 31 December 2019. A financial penalty that forms such a small proportion of worldwide turnover is unlikely to deter the undertaking from committing infringements of competition law again in future, when considered together with other case specific factors.

The Amdipharm Companies

10.345. The Amdipharm Companies and Advanz currently form part of a single undertaking. For the purposes of assessing whether the penalty in respect of Period D2 after the first three steps of the calculation produces a sufficient deterrent effect, the CMA has had regard to that undertaking as it currently exists. The CMA has therefore had regard to the financial indicators of Advanz and its corporate group as at the time the penalty is imposed.³⁸⁷⁸

10.346. The Advanz corporate group is an undertaking of considerable size. Advanz reported revenue of USD 526 million (£409 million), Adjusted EBITDA of USD 233 million (£181 million), and a loss after tax of £58 million for the financial year ending 31 December 2020.³⁸⁷⁹ Advanz generated cash flow from operating activities of USD 166 million (£129 million), and reported a net asset position of USD 7.6 million (£5.6 million) in its last financial year.³⁸⁸⁰

10.347. The penalty to be imposed on the Amdipharm Companies at the end of step 3 for Period D2 (£8,401,775) only represents:

- a. 2.1% of Advanz's worldwide turnover for the financial year ending 31 December 2020;
- b. 2.2% of Advanz's average annual worldwide turnover over its last three financial years;

³⁸⁷⁷ Document 205490C, financial information for the Cinven Group, provided as Annex 1 of Cinven's response to the CMA's section 26 notice dated 1 October 2020.

³⁸⁷⁸ CMA penalties guidance, paragraph 2.20.

³⁸⁷⁹ The CMA has referenced Advanz's own Adjusted EBITDA metric, as defined in Advanz's 2020 Annual Management's Discussion Analysis, where it was cited as a '*non-IFRS measure*'.

³⁸⁸⁰ Advanz's consolidated annual financial statements for the financial year ending 31 December 2020 and Advanz's 2020 Annual Management's Discussion and Analysis, dated March 17 2021: see Advanz's [publicly available financial information](#).

- c. 4.6% of its average annual Adjusted EBITDA over the last 3 financial years; and
- d. 6.6% of its average annual cash flow from operating activities over the last 3 financial years.³⁸⁸¹

Period D3

10.348. For the purposes of assessing whether the penalty in respect of Period D3 after the first three steps of the calculation produces a sufficient deterrent effect, the CMA has had regard to the Advanz undertaking as it currently exists. The CMA has therefore had regard to the financial indicators of Advanz and its corporate group as at the time the penalty is imposed.³⁸⁸²

10.349. The penalties to be imposed on Advanz and the Amdipharm Companies at the end of step 3 for Period D3 (£1,928,276) only represent:

- a. 0.5% of Advanz's worldwide turnover for the financial year ending 31 December 2020, and its average worldwide turnover over the last 3 financial years;
- b. 1.0% of Advanz's average annual Adjusted EBITDA over the last 3 financial years; and
- c. 1.5% of its average annual cash flow from operating activities over the last 3 financial years.

Turnover outside the relevant market

10.350. During their periods of ownership (Periods D2 and D3 respectively) the Cinven Entities and the Advanz Group³⁸⁸³ had a significant proportion of their turnover outside the relevant market.

³⁸⁸¹ Advanz reported losses after tax of £154 million and £58 million respectively in 2019 and 2020 but reported a very high profit after tax of £1.1 billion in 2018. The CMA does not consider profit after tax to be a meaningful financial metric for assessing the proportionality of Advanz's penalty, because of the inclusion of significant non-operational costs for Advanz specifically, such as: finance costs, large non-cash costs such as amortisation charges that relate to the value of intangible assets acquired by Advanz in Advanz Pharma Group's income statement, and exceptional items such as the \$1.9 billion (£1.4 billion) gain on debt settlement when the company underwent a restructuring in 2018. These costs do not reflect the profitability of the assets of the business. The CMA considers Adjusted EBITDA and cashflow from operations as relevant profit measures for Advanz. Advanz's adjusted EBITDA has been broadly consistent and positive over the last three years (between £180 million and £190 million per year).

The CMA also considers that, in the circumstances of this case, the net assets reported in Advanz's financial statements are not relevant for the assessment of proportionality, as they are directly related to the profit after tax measure discussed above.

³⁸⁸² CMA penalties guidance, paragraph 2.20.

³⁸⁸³ [REDACTED]

10.351. In relation to the Cinven Entities, all of their current turnover comes from outside the hydrocortisone market.³⁸⁸⁴

Other relevant factors

10.352. As explained above, not only did AMCo benefit financially in return for not entering the market with its own product, the 10mg Agreement continued for nearly four years, sustaining the high prices of 10mg hydrocortisone tablets and resulting in significant cost to the NHS. These factors also demonstrate the need for an uplift for specific deterrence.

10.353. As parent companies of the Amdipharm Companies exercising decisive influence, the Cinven Entities and Advanz did not act to discontinue the anticompetitive behaviour during their respective ownership periods.

Adjustments at step 4

10.354. At the end of step 5 Amdipharm UK Limited's liability to pay the penalty attributable to Period D1 is reduced to £0 and therefore it is not necessary to conduct a proportionality assessment for Period D1 for Amdipharm UK Limited.

10.355. For the reasons described above, the penalty at the end of step 3 in respect of Periods D2 and D3 should be further increased.

10.356. The penalty should at least exceed the estimated financial benefits set out in Table 10.12 so that the undertaking does not derive a financial benefit from the 10mg Agreement. In addition, the CMA has considered the considerable size of the undertakings as they currently exist, their high levels of turnover outside of the relevant market, and the relevant circumstances of the case to assess whether an uplift is appropriate.

10.357. As a result, the CMA considers that the following adjustments are appropriate.

10.358. The penalty is uplifted to £35.1 million for Period D2. The uplift reflects the financial benefit of £14.16 million generated by AMCo during Period D2, the nature and impact of the infringement, and the other case specific factors discussed in paragraphs 10.352 to 10.353. The deterrence uplift also takes into account the size and financial position of the Cinven Entities, but this is not relevant to the Amdipharm Companies because they are no longer part

³⁸⁸⁴ During their ownership period 10mg hydrocortisone tablets accounted for less than [X]% of the Cinven Entities' worldwide revenues. In 2015, the last full year of the Cinven Entities' participation in the Infringement, 10mg hydrocortisone tablet revenues were £5.0 million. This is less than [X] of the Cinven Entities' 2019 worldwide turnover of £14.8 billion.

of Cinven. The CMA does not consider it necessary to apply a further uplift for Period D2 for the Amdipharm Companies to reflect their own size.³⁸⁸⁵ Therefore the Amdipharm Companies are only liable for £14.16 million.

10.359. Therefore, of the total penalty of £35.1 million:

- a. the Amdipharm Companies and the Cinven Entities are jointly and severally liable for £14,160,000; and
- b. the Cinven Entities are solely liable for the remainder.

10.360. For Period D3, the penalty has been increased to take into account the financial benefit of £6.5 million generated by AMCo in period D3, the nature and impact of the infringement, and the other case specific factors discussed in paragraphs 10.351 to 10.352, and to reflect Advanz's considerable size. The Amdipharm Companies and Advanz are jointly and severally liable for the penalty of £7.7 million.

10.361. With respect to Period D2, a penalty of £35,100,000 at the end of step 4 would represent:

- a. [REDACTED] of the Cinven Entities' relevant worldwide turnover in the financial year ending 31 December 2019;
- b. [REDACTED] of the Cinven Entities' relevant worldwide turnover over the last three financial years; and
- c. [REDACTED] of their net assets for the financial year ending 31 December 2019.

10.362. The CMA concludes that the total penalty of £35,100,000 provides an effective yet proportionate deterrent having regard to the Cinven Entities' size and financial position; the nature of the 10mg Agreement; the role of the

³⁸⁸⁵ AMCo submitted that the uplift had not been assessed by reference to AMCo's size and financial position, and that the CMA should not apply the same uplift to both Cinven and AMCo (Document 205848, AMCo's RDPS, paragraph 7.73). The CMA has assessed the proportionality of the proposed approach by reference to Advanz's financials as the Amdipharm Companies are now part of the Advanz undertaking and that is the entity which is paying the penalty. This separate assessment for Period D2 for the Amdipharm Companies and Cinven has been carried out by the CMA consistent with *Generics (UK) Limited and others v CMA* [2021] CAT 9, paragraph 196. The Amdipharm Companies are therefore not liable for an uplift which is assessed on the basis of Cinven's financial size. Cinven submitted further representations to the CMA on 7 July 2021 assuming that the Amdipharm Companies would be liable for the penalty for Period D2 up to the level of their statutory cap (Document 207029, letter from Cinven to the CMA dated 7 July 2021). For the reasons set out here the CMA has conducted a separate analysis for the Amdipharm Companies and Cinven and this has resulted in a level of the penalty for Period D2 that does not engage the Amdipharm Companies' statutory cap.

undertaking of which Cinven formed part in the 10mg Agreement and the impact of the 10mg Agreement on competition.³⁸⁸⁶

10.363. The Amdipharm Companies are wholly owned by Advanz. It is therefore appropriate to assess the proportionality of the penalty for Periods D2 and D3 against the financial position of the undertaking consisting of the Amdipharm Companies and Advanz, since it is this undertaking which is paying the penalty.

10.364. As set out at paragraph 10.346 this undertaking is of considerable size and the CMA must ensure that any penalty they are required to pay is not negligible in light of its financial capacity.³⁸⁸⁷

10.365. The total penalty of £21,860,000 for which the Amdipharm Companies and Advanz are liable for Periods D2 and D3 (which is £14,160,000 for Period D2 and £7,700,000 for Period D3) would represent approximately:

- a. 5.3% of Advanz's annual turnover in the financial year ending 31 December 2020;
- b. 5.4% of Advanz's average annual worldwide turnover over the last 3 financial years;
- c. 11.9% of Advanz's average annual Adjusted EBITDA over the last 3 financial years; and
- d. 17.1% of its average annual cash flow from operating activities over the last 3 financial years.³⁸⁸⁸

10.366. The CMA considers that the aggregated penalty for Periods D2 and D3 provides an effective yet proportionate deterrent to the undertaking consisting of the Amdipharm Companies and Advanz, having regard to the Amdipharm Companies and Advanz's size and financial position; the nature of the 10mg Agreement; the role of the undertaking of which the Amdipharm

³⁸⁸⁶ In relation to Cinven's representation about failing to properly explain uplifts for size and financial position, the Decision already explains that size and financial position is one of several factors taken into account, along with level of financial benefit and other case specific factors (Document 205805, Cinven's RDPS, paragraphs 3.67 to 3.70).

³⁸⁸⁷ See eg C-511/11 *Versalis v Commission*, paragraph 102.

³⁸⁸⁸ [§] (Document 205848, AMCo's RDPS, paragraph 7.95). The CMA does not accept these representations. The CMA has explained in paragraphs 10.363 to 10.366 that it considers the penalty to be proportionate on the basis of financial metrics, including on the basis of strong operating cashflow generation. The CMA also notes that during the financial year ending 31 December 2020, Advanz completed business acquisitions totalling £130 million out of available cash (Advanz's consolidated annual financial statements for the financial year ending 31 December 2020, Note 4). The CMA also considers that Advanz has access to financial resources. At the time the DPS was issued, AMCo was majority owned by three investment firms, including Blackstone, and was subsequently acquired by private equity investor Nordic Capital, on a cash offer basis, during the second quarter of 2021 see: [Nordic Capital acquires Advanz Pharma.](#)).

Companies and Advanz part in the 10mg Agreement and the impact of the 10mg Agreement on competition.³⁸⁸⁹

10.367. The total penalty for periods D2 and D3 is £42,800,000 of which:

- a. Cinven is liable for the penalty of £35,100,000, of which the Amdipharm Companies are jointly and severally liable for £14,160,000 for period D2.
- b. The Amdipharm Companies and Advanz are jointly and severally liable for the penalty of £7,700,000 for period D3.

10.368. The penalty for Period D1 is £243,550 for which Amdipharm UK Limited is jointly and severally liable with Waymade plc before the application of the statutory cap to Amdipharm UK Limited, which reduces its penalty to zero.

c. Waymade

i. 20mg Agreement

The penalty should be increased at step 4: financial benefit

10.369. The penalty at the end of step 3 is £1,135,682.

10.370. The CMA considers that the penalty at the end of step 3 should be increased as Waymade obtained significant financial benefits from the 20mg Agreement throughout its nearly four-year duration. The CMA has found that Auden/Actavis paid Waymade at least £1.8 million during the term of the 20mg Agreement.³⁸⁹⁰

10.371. As set out in section 10.C above, effective deterrence should ensure that an undertaking does not profit from infringing competition. The penalty of £1.1 million at the end of step 3 is significantly less than the financial benefit that Waymade accrued over the course of the 20mg Agreement and the penalty at the end of step 3 must be increased for this reason alone.

10.372. The CMA has also had regard to the fact that the financial benefit Waymade accrued during the 20mg Agreement took the form of reduced price supply of 20mg tablets and the Buyback. As a result, the relevant turnover used in the first three steps does not fully represent the value transfer from Auden/Actavis (in comparison to the value transfer in the 10mg Agreement which was solely through reduced price supply). The step 4 assessment

³⁸⁸⁹ CMA penalties guidance, paragraph 2.24.

³⁸⁹⁰ See Section 6.D.II.b.i.

therefore also represents a cross check to ensure that the value transferred to Waymade is adequately accounted for in the calculation.³⁸⁹¹

The penalty should reflect the nature and impact of the infringement

10.373. The CMA considers that the 20mg Agreement is a market exclusion agreement law which should attract severe financial penalties.

10.374. As set out in paragraphs 10.171 and 10.174.b, the CMA considers that the 20mg Agreement, in which Waymade agreed it would not enter the market for 20mg hydrocortisone tablets, had a significant impact on competition and ultimately the NHS.

The penalty should be increased at step 4: specific deterrence

10.375. Additional factors also indicate that the uplift to the penalty should be further increased, as follows.³⁸⁹²

Size and financial position

10.376. Waymade reported revenue of £26.4 million,³⁸⁹³ a loss after tax of £2.2 million and a net asset position of [X] for the financial year ending 31 December 2020.³⁸⁹⁴

10.377. The unadjusted penalty would represent:

- a. 4.6% of Waymade's worldwide turnover the financial year ending 31 December 2020;
- b. 6.7% of Waymade's average worldwide turnover in its last the last three financial years; and
- c. [X] of Waymade's net assets for the financial year ending 31 December 2020.

³⁸⁹¹ This could alternatively have been considered at step 1 by adding the payments to the relevant turnover.

³⁸⁹² CMA penalties guidance, paragraph 2.20.

³⁸⁹³ Aggregated revenue for Waymade plc and its parent company Waymade Holdings Limited which does not prepare consolidated financial statements.

³⁸⁹⁴ The reported loss after tax of £2.2million is taken from Waymade plc's consolidated financial statements, as consolidated data is not available for Waymade Holdings Limited. The reported net assets position of [X] is for Waymade Holdings Limited. The CMA also notes that Waymade plc and Waymade Holdings Limited form part of the larger Waymade Capital group of companies ([About – Waymade Capital](#)).

Turnover outside the relevant market

10.378. This undertaking generates a significant proportion of its turnover outside the relevant market.³⁸⁹⁵

Other relevant factors

10.379. As explained above, not only did Waymade benefit financially in return for not entering the market with its own product, the 20mg Agreement continued for nearly four years, sustaining the high prices of 20mg hydrocortisone tablets and resulting in significant cost to the NHS. These factors also demonstrate the need for an uplift for specific deterrence.

10.380. For each of the reasons described above, the CMA considers that the uplift to the fine penalty at the end of step 3 for the 20mg Agreement should be further increased.

Adjustment at step 4

10.381. The penalty should at least exceed the estimated financial benefit of £1.8 million set out in paragraph 10.370 so that Waymade does not derive a financial benefit from the Infringement. In addition, as set out above, the CMA has also considered the size of the undertaking as it currently exists and the relevant circumstances of the case to assess whether an uplift is appropriate. The CMA considers that an uplift is appropriate. This results in a penalty of £2.2 million.

10.382. The penalty of £2.2 million would represent approximately:

- a. 8.3% of Waymade's worldwide turnover for the financial year ending 31 December 2020;
- b. 10.2% of Waymade's average worldwide turnover in its last three financial years;³⁸⁹⁶ and
- c. [X] of Waymade's net assets for the financial year ending 31 December 2020.³⁸⁹⁷

³⁸⁹⁵ During the last full business year before the 20mg Agreement infringement ended, revenues from 20mg hydrocortisone tablets represented approximately [X] of Waymade's worldwide turnover, and currently account for less than [X] of worldwide turnover.

³⁸⁹⁶ [X]

³⁸⁹⁷ Waymade argued that its penalties equate to a higher percentage of its financial metrics than AMCo's or Allergan's (Document 205799, Waymade's RDPS, paragraph 3.74). However, the CMA considers the penalty proportionate to the specific circumstances of the case for the reasons explained set out above. The CMA also notes that removal of estimated financial benefit alone would result in a penalty which is 6.9% of Waymade's average worldwide turnover during the last financial year, and 8.4% of average turnover in its last 3 financial years.

10.383. The CMA notes that although Waymade is currently loss-making, it was profitable during the period of the infringement.³⁸⁹⁸

10.384. The CMA concludes that the penalty of £2.2 million provides an effective yet proportionate deterrent to Waymade, having regard to Waymade's size and financial position, the nature of the 20mg Agreement, Waymade's role in the 20mg Agreement and the impact of the 20mg Agreement on competition and consumers.³⁸⁹⁹ As set out above, the CMA considers that the level of the penalty should be a meaningful deterrent and to pursue both a preventative and a punitive objective, and should reflect the size of the undertaking as it currently exists.³⁹⁰⁰

10.385. The penalty at the end of Step 4 for which Waymade plc is liable is £2,200,000.

ii. 10mg Agreement

No uplift required at step 4 for financial benefit for Period D1 (Waymade)

10.386. The CMA has found that Auden/Actavis paid Waymade approximately £70,000 during Waymade's term as counterparty to the 10mg Agreement. The penalty at the end of step 3 exceeds this amount and therefore no specific uplift is required in relation to the financial benefits from the 10mg Agreement.

No uplift required at step 4 for deterrence for Period D1 (Waymade)

10.387. The CMA has not applied further specific deterrence uplift for the 10mg Agreement to reflect the size of the Waymade undertaking and the nature of the agreement on the basis that the uplift applied at step 4 of the 20mg Agreement penalty calculation sufficiently deters Waymade from this type of conduct.

10.388. Therefore no uplift at step 4 is required for the purposes of deterrence and proportionality.

³⁸⁹⁸ See also Annex F which refers to Waymade's payment of a one-off dividend in 2019 relating to the sale of a profitable part of its business.

³⁸⁹⁹ CMA penalties guidance, paragraph 2.24.

³⁹⁰⁰ Waymade has submitted that it has been '*punished*' because of the length of time that that CMA's investigation has taken and the different procedural steps that were required, noting that had a previous year's turnover been used for statutory cap purposes that this would have been lower, and stating that this '*underlies the disproportionality of the penalty*' in the circumstances (Document 205799, Waymade's RDPS, paragraphs 2.1 to 2.6). The CMA does not accept this representation. The CMA has assessed the individual penalty and taken into account that there is more than one penalty being imposed on Waymade for two separate serious infringements of competition law, and considers that in the circumstances the penalty is proportionate. In addition, the CAT has recently confirmed that the statutory cap is that which applies at the time the penalty is imposed, not by reference to an earlier year (see *FP McCann v CMA* [2020] CAT 28, paragraph 307).

10.389. The penalty of £254,620 represents only 1.0% of Waymade plc's worldwide turnover for the financial year ending 31 December 2020, 1.2% of its average turnover for the last 3 financial years, and [X] of its net assets, for the financial year ending 31 December 2020. The CMA considers this is proportionate to Waymade plc's size and financial position as at the time the financial penalty is imposed.³⁹⁰¹

10.390. The penalty of £254,620 provides an effective yet proportionate deterrent, having regard to Waymade's size and financial position as it currently exists as Waymade plc, the nature of the 10mg Agreement, Waymade's role in the 10mg Agreement and the impact of the 10mg Agreement on competition.³⁹⁰²

10.391. The penalty at the end of Step 4 is £254,620, for which Amdipharm UK Limited is jointly and severally liable up to £243,550 before the application of the statutory cap at step 5 (which reduces its liability to zero).

V. Step 5: adjustment to prevent maximum penalty from being exceeded and to avoid double jeopardy

10.392. The final amount of the penalty calculated according to the method set out above may not in any event exceed 10% of the worldwide turnover of the undertaking in its last business year.³⁹⁰³ Any adjustments necessary to comply with this statutory cap are set out below. No further adjustments are required in this case.

a. Auden/Actavis

i. The Unfair Pricing Abuses

10.393. In summary, as explained more fully below, the penalty imposed on Accord-UK for the 10mg Unfair Pricing Abuse during Periods A1-A3 is subject to the

³⁹⁰¹ Waymade argued that there is a lack of correlation between its own penalties, and that the CMA's calculations therefore lacked methodology in regard to proportionality (Document 205799, Waymade's RDPS, paragraphs 4.2 to 4.3). As described in the introduction, the CMA has calculated separate penalties for the 10mg Agreement and the 20mg Agreement to reflect the fact that they are two separate infringements, whilst taking steps to avoid double counting. This explains the difference between the two penalties that Waymade has identified. Indeed, the difference itself illustrates that the CMA's methodology is consistent with the principle that a penalty for each infringement must be specific to the offence and the offender, and with the principles of proportionality and legal certainty.

³⁹⁰² The CMA considers that the factors set out at paragraph 10.373 to 10.374 apply equally to the 10mg Agreement.

³⁹⁰³ AMCo noted that the Commission does not apply the 10% maximum each time a penalty calculation gives rise to a figure that exceeds the 10% cap citing the fines imposed by the Commission in relation to 'mono-product' companies where the penalty imposed was below that limit (Document 205848, AMCo's RDPS, paragraph 7.93). The CMA does not accept this representation as neither AMCo nor the Amdipharm Companies are such mono-product companies and in any case the Commission itself explained that such a reduction was an 'exceptional' application of its discretion under its guidelines. The CAT considered and rejected an argument in *FP McCann v CMA* that the 10% cap should only be applied for the most serious offences and reiterated that this is to operate as a cap on the amount of the penalty (*FP McCann Limited v CMA* [2020] CAT 28, paragraphs 79 to 104).

statutory cap. Allergan does not, however, benefit from the statutory cap that applies to the fine imposed on Accord-UK for Period A2 (for which Allergan and Accord-UK are jointly and severally liable). That is because Allergan is no longer the parent company of Accord-UK.³⁹⁰⁴ No adjustment to the fine imposed on Allergan is required by the statutory cap based on Allergan's worldwide turnover.

10.394. In respect of Periods A1-A3:

- a. The maximum penalty that the CMA could impose on Accord-UK with respect to Periods A1 to A3 of the 10mg Unfair Pricing Abuse (whether solely or on a joint and several basis with Allergan) is £28,378,300. Since the total penalty for Periods A1 to A3 exceeds this amount, Accord-UK's liability to pay such penalty must be adjusted.
- b. The CMA has applied the following adjustments in respect of Accord-UK's statutory cap:
 - i. first, the CMA has adjusted Accord-UK's penalty in respect of Periods A1 and A3 such that the amount for which Accord-UK is solely liable is reduced to £28,378,300 (ie the maximum fine that can be imposed on Accord-UK); and
 - ii. considering (i) the penalty for which Accord-UK is solely liable in respect of Periods A1 and A3, and (ii) the application of Accord-UK's 10% statutory cap to Periods A1-A3, the CMA must reduce the penalty imposed on Accord-UK in respect of Period A2 to zero.
- c. The adjustments to Accord-UK's penalty do not affect Allergan's liability in respect of Period A2. It is well-established that where two separate legal persons (here, Accord-UK and Allergan) no longer constitute an undertaking on the date on which a decision is adopted, each of them is entitled to have the statutory cap applied individually to itself. In these circumstances, Allergan cannot claim to benefit from the ceiling applicable to its former subsidiary.³⁹⁰⁵

10.395. For Period A4 the worldwide turnover of the undertaking of which Intas, Accord and Accord-UK together form part is relevant at step 5 and no adjustment is required in relation to this Period.

³⁹⁰⁴ C-50/12 P *Kendrion v Commission* (Judgment of the Grand Chamber), paragraph 57.

³⁹⁰⁵ C-50/12 P *Kendrion v Commission* (Judgment of the Grand Chamber), paragraph 57.

ii. The Agreements

10.396. In relation to the 10mg Agreement, the CMA has had regard to Accord-UK's statutory cap and Allergan's penalty in the same way as with the 10mg Unfair Pricing Abuse set out at paragraphs 10.393 to c above. As a result the CMA has reduced Accord-UK's penalty in respect of Period C1 to £28,378,300 (i.e. its statutory cap); and the CMA has reduced Accord-UK's liability to pay the penalty in respect of Period C2 to zero. The adjustments do not affect Allergan's liability in respect of Period C2.

iii. Allergan and Accord-UK's representations on step 5

10.397. Allergan and Accord-UK submitted that the penalty for Allergan for Period A2 of the 10mg Unfair Pricing Abuse and Period C2 the 10mg Agreement cannot exceed the penalty for Accord-UK (£28,378,300). Accordingly, any penalty imposed on Allergan should be no higher than the statutory maximum fine imposed on Accord-UK.³⁹⁰⁶ In particular, they take issue with the CMA's reliance on the Court of Justice's judgment in *Kendrion v Commission*,³⁹⁰⁷ and suggest that this judgment has been clarified in subsequent cases.³⁹⁰⁸

10.398. The CMA does not accept Accord-UK and Allergan's representations. There is clear authority from the Court of Justice on the application of the statutory cap to a parent company and its former subsidiary at the time of a decision. The statutory maximum fine applies to each of them individually. This was established by the Court in *Kendrion* and confirmed last year in *Commission v GEA Group*.³⁹⁰⁹

10.399. The CMA has considered each of the cases relied on by Accord-UK and Allergan in their representations.³⁹¹⁰ Those cases are not on point. They all concern the situation where the parent company and subsidiary are still part of the same undertaking at the time of the decision. Where a parent company's liability arises from its subsidiary's unlawful conduct, and they form a single undertaking, the fine imposed on the parent must not exceed

³⁹⁰⁶ Document 205791, Allergan's RDPS, paragraphs 98 to 108; Document 205813, Accord-UK's RDPS, paragraphs 11.1 to 11.5.

³⁹⁰⁷ Case C-50/12 P *Kendrion NV v European Commission*

³⁹⁰⁸ Allergan cites cases C-247/11 P and C-253/11 *Areva v Commission*, case C-597/13 P *Total v Commission* and Case C-516/15 P *Akzo Nobel NV v European Commission* and the opinion of AG Wahl in that case (Document 205791, Allergan's RDPS, paragraphs 98 to 108). Accord-UK also cites the opinion of AG Wahl in *Total v Commission* (Document 205813, Accord-UK's RDPS, paragraphs 11.2 to 11.3).

³⁹⁰⁹ C-823/18 P *Commission v GEA Group AG*, paragraph 75. The Court had previously also confirmed the principle in C-243/12 P *FLS Plast v Commission*, EU:C:2014:2006, paragraph 107 (which cites *Kendrion*): '...an argument that that parent company could not be ordered to pay a fine higher than the fine imposed on its subsidiary is therefore unfounded'.

³⁹¹⁰ Document 205791, Allergan's RDPS, paragraphs 98 to 108, Document 205813, Accord-UK's RDPS, paragraphs 11.1 to 11.5.

the subsidiary's fine.³⁹¹¹ Accord-UK and Allegan do not, however, form part of a single undertaking as at the date of this decision.

10.400. Furthermore, the cases relied on by Accord-UK and Allergan did not address to the application of the statutory cap. They related to the liability for the infringement, such as a reduction to the fine made by the General Court on the basis of the duration of the infringement which should have been applied to the parent company (*Total*) or the effect of the limitation defence applicable to the subsidiary on the parent's liability (*Akzo Nobel*).

b. Waymade

10.401. No adjustment is necessary with respect to Waymade's penalties in respect of each of the Agreements.

10.402. Waymade submitted that the two penalties imposed on Waymade should be considered together and that the aggregated penalties cannot exceed Waymade's statutory cap.³⁹¹² The CMA does not accept that submission in light of settled case law that the CMA is not required to aggregate the penalties imposed on an undertaking for the purpose of applying the statutory cap.³⁹¹³

c. AMCo

10.403. Absent the statutory cap, Amdipharm UK Limited would be jointly and severally liable with Waymade plc up to £243,550 (of the total penalty for Period D1 of £254,620). As Waymade and Amdipharm UK Limited are no longer part of the same undertaking, Amdipharm UK Limited has the right to have its own 10% cap applied to it. On the basis of Amdipharm UK Limited's financial statements for the year ending 31 December 2019, Amdipharm UK Limited has zero turnover and therefore its liability to pay the penalty attributable to the period from 23 October 2012 to 30 October 2012 of the 10mg Agreement must be adjusted to £0. This adjustment does not affect Waymade's liability in respect of the 10mg Agreement.

10.404. No other adjustments are required with respect to the AMCo undertaking's penalty in relation to the 10mg Agreement.

³⁹¹¹ See eg Case C-516/15 P *Akzo Nobel NV v Commission*, paragraphs 61 to 62.

³⁹¹² Document 205799, Waymade's RDPS, paragraphs 3.84 to 3.89.

³⁹¹³ T-446/05 *Amann & Söhne and Others v Commission*, paragraph 94.

VI. In the round assessment of multiple penalties imposed on some of the undertakings

- 10.405. In the present Decision, the CMA is imposing two penalties on Waymade and four penalties on the Auden/Actavis undertaking, with respect to which former parent company Allergan is jointly and severally liable with Accord-UK for part of three penalties (relating to the Unfair Pricing Abuses and the 10mg Agreement) and Intas is jointly and severally liable for part of one penalty (relating to the 10mg Unfair Pricing Abuse).
- 10.406. The imposition of multiple penalties reflects the serious nature of each individual infringement committed by these undertakings. As set out in the introduction, the CMA has taken care to ensure that the imposition of multiple penalties (i) does not lead to double counting of financial benefits generated through the Infringements; and (ii) does not lead to an uplift for specific deterrence for the same type of infringement twice.
- 10.407. In addition to this, the CMA considers, in its judgement and having regard to the financial position of the undertakings concerned, that the overall action it takes in issuing this decision is not disproportionate or excessive. Any such assessment should be based on the real-world impact of the penalties on the undertakings as they exist today. It should therefore be carried out after any adjustments to take into account the statutory cap have been applied, as this forms a more accurate reflection of the amounts that will actually be payable in aggregate.
- 10.408. For the reasons set out below, the CMA concludes that in each instance where multiple penalties are imposed, the overall outcome after the steps noted in paragraph 10.405 above have been taken is not excessive or disproportionate by reference to the size and financial position of the undertaking at the time the penalties are being imposed.³⁹¹⁴

a. Waymade

Table 10.13: total penalty for Waymade plc

Legal entity	Infringement	Total penalty	Percentage of worldwide turnover
Waymade plc	10mg Agreement	£254,620	1.0%
	20mg Agreement	£2,200,000	8.3%
	Total	£2,454,620	9.3%

³⁹¹⁴ CMA penalties guidance, paragraph 2.20.

10.409. Waymade's aggregate penalty liability is £2,454,620. The CMA has assessed whether these penalties in aggregate would be disproportionate and excessive if imposed on Waymade.

10.410. Waymade's aggregate penalty for two separate serious infringements of competition law of £2,454,620 represents 9.3% of most recent worldwide turnover.³⁹¹⁵ The CMA does not consider this aggregated penalty to be disproportionate or excessive in the context of the serious and harmful Infringements committed which had a severe impact.

b. Auden/Actavis

10.411. The Auden/Actavis undertaking was involved in all four Infringements. At this stage of the penalty calculation, the CMA has assessed whether the sum of the penalties imposed would be disproportionate or excessive for the undertakings as they currently exist, recognising that Accord-UK is no longer part of Allergan, but has become part of Intas. The question whether or not the total of the four penalties would be disproportionate and excessive must be carried out with respect to these two currently distinct undertakings: Allergan and Intas, the latter of which now includes Accord-UK.

Table 10.14: total penalty for Allergan

Legal entity	Infringement	Total penalty	Percentage of worldwide turnover
Allergan	10mg Unfair Pricing	£74,300,000	0.2%
	20mg Unfair Pricing	£34,800,000	0.1%
	10mg Agreement	£2,000,000	0.01%
	Total	£111,100,000	0.3%

10.412. The total aggregate penalty for which Allergan is liable either solely or jointly and severally with Accord-UK is £111,100,000.

10.413. This total aggregate penalty for three separate serious infringements of competition law represents 0.3% of Allergan's most recent worldwide turnover.³⁹¹⁶ The CMA does not consider this total penalty to be

³⁹¹⁵ Waymade's aggregated penalty for the two infringements also represents 11.4% of average annual worldwide turnover for the last 3 years and 6.5% of net assets in the last financial year.

³⁹¹⁶ Allergan's aggregated penalty for the four infringements also represents 0.4% of average annual worldwide turnover for the last 3 years, 0.8% of profit after tax for the last 3 financial years, and 0.4% of net assets in the last financial year.

disproportionate or excessive in the context of the serious and harmful Infringements committed which had a severe impact.

Table 10.15: total penalty for the Accord-UK/Intas undertaking

Undertaking	Infringement	Legal entities	Total penalty	Percentage of worldwide turnover
Accord	10mg Unfair Pricing	Intas/Accord/ Accord-UK	£44,400,000	2.7%
		Accord-UK	£28,378,300	1.7%
	20mg Unfair Pricing	Accord-UK	£8,082,119	0.5%
	10mg Agreement	Accord-UK	£28,378,300	1.7%
	20mg Agreement	Accord-UK	£2,798,525	0.2%
	Total		£112,037,244	6.8%

10.414. Intas, Accord and Accord-UK are jointly and severally liable for £44,400,000 for Period A4 of the 10mg Unfair Pricing Abuse. Accord UK is liable for a further £67,637,244 representing penalties for Periods A1 and A3 of the 10mg Unfair Pricing Abuse (capped at £28.4 million), all periods of the 20mg Unfair Pricing Abuse, the 10mg Agreement (also capped at £28.4 million) and the 20mg Agreement.

10.415. The CMA has assessed the total penalty against the size of Intas including Accord-UK. This aggregated penalty for four separate serious infringements of competition law represents 6.3% of Intas's worldwide turnover.³⁹¹⁷ The CMA does not consider this amount to be disproportionate or excessive in the context of the serious and harmful Infringements committed which had a severe impact.

³⁹¹⁷ Intas's aggregated penalty for the four infringements also represents 8% of average annual worldwide turnover for the last 3 years, 72% of profit after tax for the last 3 financial years, and 11% of net assets in the last financial year.

VII. Step 6: application of reductions for leniency, settlement or voluntary redress

10.416. Step 6 provides an adjustment for leniency, settlement and/or voluntary redress in appropriate cases. No such adjustment is appropriate in this case.^{3918, 3919}

VIII. Payment of penalty

10.417. The CMA requires the legal entities to which this Decision is addressed to pay the penalty applicable to it:

- a. Auden/Actavis:
 - i. For the 10mg Unfair Pricing Abuse:
 - Accord-UK is liable for £28,378,300;
 - Allergan is liable for £74,300,000; and
 - Accord-UK, Accord and Intas are jointly and severally liable for a further £44,400,000.
 - ii. For the 20mg Unfair Pricing Abuse:
 - Accord-UK is liable for £6,082,119; and
 - Allergan and Accord-UK are jointly and severally liable for a further £2,000,000.
 - iii. For the 10mg Agreement:
 - Accord-UK is liable for £28,378,300; and
 - Allergan is liable for £34,800,000.
 - iv. For the 20mg Agreement:
 - Accord-UK is liable for £2,798,525

³⁹¹⁸ [X] (Document 205848, AMCo's RDPS, paragraph 7.95). In its step 4 assessment above the CMA has considered the proportionality of the penalty on AMCo and [X]. The CMA therefore rejects this representation.

³⁹¹⁹ Waymade has submitted that at step 6 the CMA should take into account other factors which will deter Waymade from breaching competition law in the future, citing the burden of the CMA's investigation on Waymade as '*disproportionately resource intensive*' and that it has moved to a position of being an '*antitrust compliant company*' (Document 205799, Waymade's RDPS, paragraphs 3.91 to 3.95). The CMA rejects these submissions as these are not relevant factors at step 6 which does not seek to address the deterrent effect of penalties for infringements of competition law.

b. AMCo:

i. For the 10mg Agreement:

- the Cinven Entities are liable for £20,940,000;
- the Amdipharm Companies and the Cinven Entities are jointly and severally liable for a further £14,160,000; and
- Advanz and the Amdipharm Companies are jointly and severally liable for a further £7,700,000.

c. Waymade:

i. For the 20mg Agreement:

- Waymade is liable for £2,200,000.

ii. For the 10mg Agreement:

- Waymade is liable for £254,620.

10.418. The penalties will become due to the CMA in their entirety on 16 September 2021 and must be paid to the CMA by close of banking business on that date.³⁹²⁰

³⁹²⁰ Details on how to pay the penalty are set out in the letter accompanying this Decision.

SIGNED:

[✂]

**Andrea Coscelli, Chief Executive Officer, for and on behalf of the
Competition and Markets Authority**

[✂]

**Paul Hughes, CMA Panel Member, for and on behalf of the Competition and
Markets Authority**

[✂]

**Stephen Blake, Senior Legal Director, Cartels and Consumer Protection, for
and on behalf of the Competition and Markets Authority**

All of whom are the members of, and who together constitute, the Case Decision
Group