Decision of the Competition and Markets Authority

Excessive and unfair pricing with respect to the supply of liothyronine tablets in the UK

Case 50395

29 July 2021

Confidential information in the original version of this Decision has been redacted from the published version on the public register. Redacted confidential information in the text of the published version of the Decision is denoted by [✂].

The names of individuals mentioned in the description of the infringement in the original version of this Decision have been removed from the published version on the public register. Names have been replaced by a general descriptor of the individual's role.

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1. Executive Summary

A. Addresses of this decision

1.1 This decision of the Competition and Markets Authority (the '**CMA**'), of which Annexes 1 to 8 form part (this '**Decision**'), is addressed to:

(a) The '**Mercury Pharma Companies**':

(i) [Mercury Pharmaceuticals Limited;

(ii) Advanz Pharma Services (UK) Limited; and

(iii) Mercury Pharma Group Limited;

(b) HgCapital LLP ('**HgCapital**');

(c) The '**Cinven Entities**':

(i) Cinven Capital Management (V) General Partner Limited;

(ii) Cinven (Luxco 1) S.A.;

(iii) Cinven Partners LLP ('**Cinven Partners**'); and

(d) Advanz Pharma Corp. Limited ('**Advanz Pharma Corp**'),

collectively the '**Parties**'.

1.2 During the period 1 November 2007 to 31 July 2017, there was a single undertaking which consisted of the Mercury Pharma Companies and, at various points, HgCapital, the Cinven Entities and Advanz Pharma Corp. HgCapital and the Cinven Entities are former parents of the Mercury Pharma Companies.[1] Advanz Pharma Corp is the current parent of the Mercury Pharma Companies. The undertaking has undergone a series of corporate restructurings and name changes since 2007, and for convenience it is referred to as '**Advanz**' throughout this Decision.

1.3 Advanz was at all relevant times the sole supplier of UK-licensed 20mcg liothyronine sodium tablets ('**Liothyronine Tablets**').

1.4 By this Decision, the CMA gives notice to the Parties that it has decided that Advanz abused its dominant position in breach of the prohibition imposed by

[1] HgCapital owned the Mercury Pharma Companies between 30 December 2009 and 30 August 2012; the Cinven Entities owned the Mercury Pharma Companies between 31 August 2012 and 20 October 2015.

section 18 (the '**Chapter II prohibition**') of the Competition Act 1998 (the '**Act**'), by charging excessive and unfair prices for Liothyronine Tablets (the '**Infringement**') from at least 1 January 2009 to 31 July 2017 (the '**Infringement Period**').[2]

B. Summary of Advanz's conduct

I. Liothyronine Tablets and the conditions they treat

1.5 Liothyronine Tablets are used in the treatment of patients who have a thyroid hormone deficiency. Thyroid hormones play a crucial role in many aspects of the body's normal functioning, including heart and digestive function, metabolism, brain development, bone health and muscle control. Individuals who suffer from an underactive thyroid (hypothyroidism) produce too few of these hormones with a resulting slowing of metabolism. This can cause weight gain, tiredness, sluggishness and depression. In extreme cases it can cause coma or even death.

1.6 Although the majority of patients who suffer from hypothyroidism are treated using an alternative medicine (UK-licensed levothyroxine tablets '**Levothyroxine Tablets**'), which cost a fraction of the price of Liothyronine Tablets, there remains a sub-set of patients who do not respond adequately to Levothyroxine Tablets.

II. Advanz's pricing strategy and conduct

1.7 Liothyronine Tablets were originally developed in the UK in the mid-1950s and sold under the brand name 'Tertroxin'. Advanz acquired Tertroxin in 1992, when it was already long off-patent and continued to sell the product under the Tertroxin brand name until 2007.

1.8 In 2007, Advanz devised what it called a '*price optimisatio*n' strategy. Advanz's internal documents show that this strategy was a key driver of Advanz's pricing policy throughout the Infringement Period. The strategy involved Advanz identifying long off-patent drugs, where it faced limited or no competition and benefited from high barriers to entry. By 'de-branding' these drugs, it removed them from price regulation which only applied to branded drugs, enabling it to set whatever prices it chose. By identifying markets in

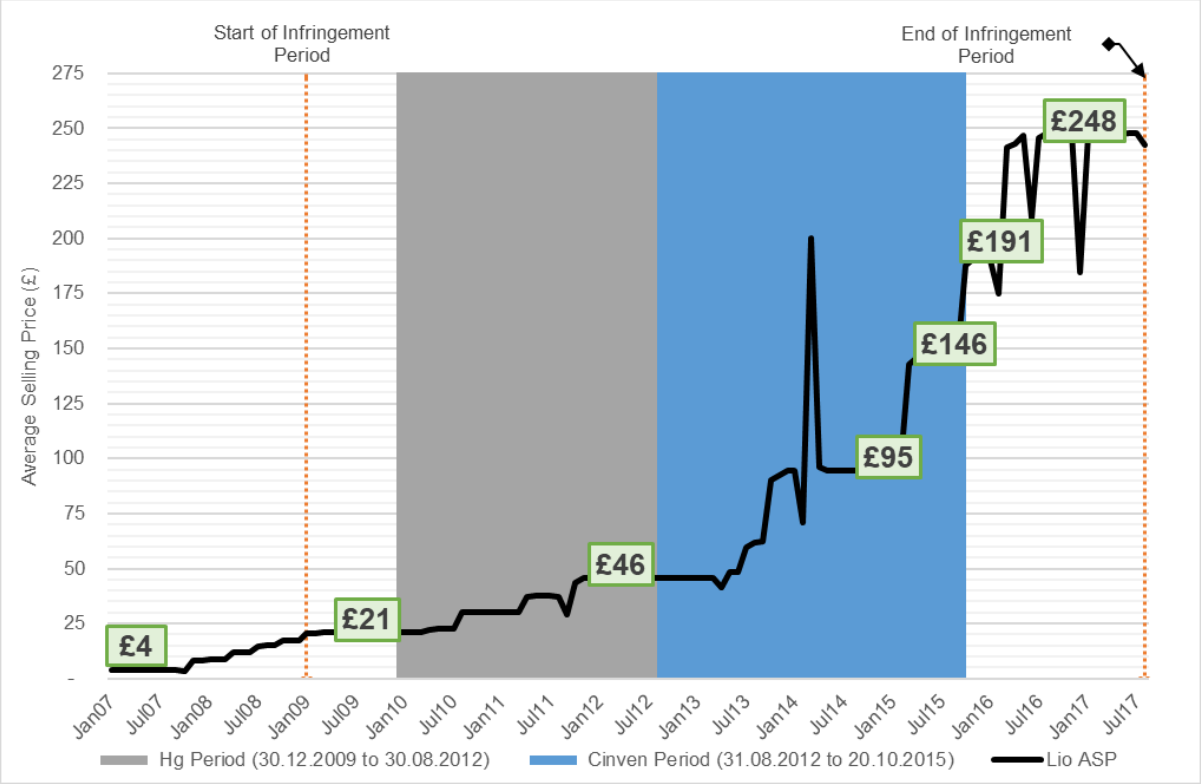
[2] The CMA has decided for reasons of administrative priority not to pursue its investigation in respect of Advanz's conduct during the period from 1 November 2007 to 31 December 2008 or following 31 July 2017. See *Prioritisation principles for the CMA* (CMA16), dated April 2014.

which it was insulated from competition, the strategy was designed to enable Advanz to increase prices substantially and to sustain these high prices.

1.9 In October 2007, Advanz began applying this strategy to Liothyronine Tablets. At that time, the price of Liothyronine Tablets was **£4.05** per 28 tablets and Liothyronine Tablets were already one of Advanz's top ten most profitable products.

1.10 Advanz removed the 'Tertroxin' brand, re-launched Liothyronine Tablets as a generic product, and immediately implemented a price increase. As a result, Advanz nearly doubled the price of the drug overnight. Within a year of de-branding, Advanz had more than doubled its price again and by January 2009, its average sales price ('**ASP**') for Liothyronine Tablets had reached **£20.48**. Under HgCapital's ownership (December 2009 to August 2012), the ASP of Liothyronine Tablets increased from nearly £21 per pack to nearly £46 per pack; under the Cinven Entities' ownership (August 2012 to October 2015), this increased again to nearly £190 per pack. By July 2017, nearly 10 years after de-branding, Advanz had increased the ASP of Liothyronine Tablets from £4.05 to **£247.87**, representing a price increase of **6,021%** since September 2007. These increases are shown in Figure 1.1.

Figure 1.1: Advanz's monthly ASP for Liothyronine Tablets (January 2007 – July 2017)



Source: CMA analysis of data submitted by Advanz and Prescription Cost Analysis ('PCA') data for England

1.11 As a result of these price increases, NHS spending on Liothyronine Tablets increased from around **£600,000** per year before Advanz started its price optimisation strategy to more than **£30 million** in the last full year of the Infringement, despite volumes remaining largely stable.

1.12 Advanz's price increases were not driven by any meaningful innovation or investment, and its costs did not change materially at the time of de-branding or afterwards. Advanz's decision to gradually ratchet up the price of Liothyronine Tablets over a number of years avoided attracting scrutiny, with price increases managed carefully to avoid the risk that they would catch the attention of the Department of Health and Social Care ('**DHSC**'). Cinven Partners noted in its internal recommendation to purchase the business from HgCapital that '*Mercury therefore operates below the radar*',[3] and internal emails show that Advanz took great care not to '*catch eyes of DH, due to price increase*'.[4]

III. Competition in the supply of generic drugs

1.13 Advanz's conduct exploited a loophole in the regulation of drug prices. During the Infringement Period, the prices of unbranded generic drugs were unregulated in the UK. Whereas the profits made from branded drugs were generally constrained by regulation, the assumption underlying the pricing of generic drugs in the UK was that, once patents have expired and competitors become free to enter with generic versions of a drug, competition would prevent suppliers from setting high prices for those drugs. This period is often referred to as the 'third phase of the product lifecycle' (following initial development of a drug (the first phase), and its commercialisation under patent (the second)). By this point, the cost of the drug's development should long since have been recouped and any innovation rewarded. At this stage, the public interest in lowering the price of medicines eclipses the public interest in incentivising innovation, which will have been rewarded through the patent regime. During the third phase, competition between suppliers is expected to keep prices low and secure value for money for the NHS.

1.14 However, the assumption that market forces will regulate generic drug prices only holds good where competition works. For some generic drugs competition is impeded or delayed, or may not be sustainable. This may be because of market features such as barriers to entry or expansion, or where the market is too small to attract entry.

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[3] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 6.
[4] Document LIO0279, Email from [Advanz employee] to [Advanz Commercial Servies Director] dated 29 May 2013.

1.15 Liothyronine Tablets were identified by Advanz as one such generic drug, with competition not working properly as a result of high barriers to entry and the small size of the market. In 2012, the Financial Times reported [✂], a Cinven partner [✂], as describing such off-patent medicines as '*little jewellery boxes'* which *'can still attract strong sales*', and as noting that they faced only a '*limited risk of price competition*'.

IV. The consequences of Advanz's conduct

1.16 In accordance with its price optimisation strategy, Advanz used its market power to extract ever-increasing rents from the NHS, diverting constrained NHS resources to the detriment of the NHS and patients. Advanz's high prices necessarily resulted in funds being less available for other NHS services or for investments in new technologies, new drugs, and improvements in patient care.

1.17 In addition, Advanz's pricing eventually led to adverse consequences for hypothyroid patients. In July 2015, by which point Advanz had driven the price of Liothyronine Tablets to £146, Liothyronine Tablets were identified by an NHS body as an item that represented '*poor value for money*' and were added to an NHS '*drop list*' to encourage switching away. Despite this, Advanz implemented further substantial price increases, bringing its ASP above £247 in early 2016. Following inclusion of Liothyronine Tablets on the drop list, some NHS clinical commissioning groups started to amend their prescribing guidance to GPs with the aim of limiting prescriptions of Liothyronine Tablets.

1.18 As a result of the changes in guidance, GPs started to withdraw Liothyronine Tablet prescriptions from some patients. Those patients were faced with a choice of having their treatment with Liothyronine Tablets brought to an end or purchasing unlicensed liothyronine at their own expense and with the risks associated with losing their GP's oversight of their treatment.

1.19 The impact of Advanz's price optimisation strategy is still being felt to this day. Advanz's exploitative prices eventually inflated the value of the market to such an extent that, in spite of the high barriers to entry around this small market, it attracted interest from potential entrants. ASPs had by the point of new entry in 2017 reached £247.87. Since 2017, the price of Liothyronine Tablets has fallen considerably. However, competition takes time to eliminate the impact of a decade-long strategy of sustained, significant price increases and, while the price of Liothyronine Tablets continues to decline, current prices remain well above the level that would be expected for a generic drug first sold over sixty years ago.

C. Advanz's prices were excessive and unfair

1.20 To determine whether Advanz's prices for Liothyronine Tablets infringed competition law, it is necessary for the CMA to consider whether Advanz was dominant in a relevant market, and to establish whether its prices were 'excessive' and 'unfair'.

1.21 Advanz's ability to increase its prices by 6,021% was made possible by its dominant position in the market for the supply of Liothyronine Tablets in the UK.

1.22 Throughout the Infringement Period, Advanz charged prices for Liothyronine Tablets that were clearly excessive and unfair:

(a) **Advanz's prices were excessive**: When its prices are compared with the costs of supplying Liothyronine Tablets plus a reasonable rate of return ('**Cost Plus**'), the amounts by which Advanz's prices exceeded Cost Plus (the '**Differential**') ranged from 900% to around 2,500% during the Infringement Period. The Differential in each year is set out in Table 1.1 below.

Table 1.1: Comparison of the ASPs of Liothyronine Tablets with the Differential

	2009	2010	2011	2012	2013	2014	2015	2016	2017*
Liothyronine Tablets ASP (£)	20.80	25.66	37.73	45.52	61.84	94.63	146.42	229.23	247.77
Cost Plus (£)	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78
Differential (£)	18.72	23.56	34.61	42.77	57.85	89.52	140.79	219.36	237.99
Differential (%)	900%	1119%	1110%	1554%	1449%	1751%	2501%	2222%	2434%
Revenue differential (£m)	2.66	3.33	5.25	6.13	8.79	13.24	21.08	33.89	17.82
Note: ASPs are annual averages; the 2017 figure is the average to July 2017.									

Source: CMA analysis.

(b) Further, even when a number of sensitivities (i.e. alternative approaches with regard to the allocation of common costs, the valuation and amortisation of product rights and a higher rate of return) are applied, the Differential was at all times material, ranging from above 300% in 2009 to almost 2,000% by 2017.

(c) **These prices were not only excessive by reference to Advanz's costs but were also unfair** given:

(i) The substantial disparity between Advanz's prices and the economic value of its Liothyronine Tablets (taking account of the age of Liothyronine Tablets, their therapeutic value and the lack of any evidence that the NHS was readily willing to pay a premium for Liothyronine Tablets);

(ii) The absence of alternative Liothyronine Tablet suppliers, lack of regulatory constraint, high demand inelasticity and high barriers to entry, which enabled Advanz to sustain prices that bore no relationship to the economic value of Liothyronine Tablets;

(iii) The commercial purpose of Advanz's pricing strategy, which was to exploit the lack of pressure on its pricing resulting from these competitive conditions;

(iv) The significant increases in price, namely a 6,021% increase in Advanz's prices between 2007 and 2017, and a 1,110% increase over the Infringement Period with no material increase in costs or innovation;

(v) The significant adverse impact that Advanz's price increases had on the NHS and patients; and

(vi) The lack of any independent or objective justification for the conduct.

(d) **In addition, there is no reason to consider that Advanz's prices were fair when compared to competing products**. The CMA has considered various comparators proposed by the Parties. However, it has found that none of the comparators put forward are valid and meaningful. The Parties argue in particular that the prices of Liothyronine Tablets following entry in 2017 by Morningside and Teva[5] ('**Post-Entry Prices**') are a relevant comparator. However, in the circumstances of this case, the prevailing Post-Entry Prices continue to be significantly inflated by Advanz's abusive exercise of market power during the Infringement Period, and so do not indicate that Advanz's pricing during the Infringement Period was fair.

D. The Parties' representations on the case

1.23 The Parties' representations in response to the CMA's provisional findings in this case are addressed in the relevant sections of this Decision, including its Annexes. The CMA has summarised its responses to the principal themes raised by the Parties here.

[5] Morningside Healthcare Ltd ('**Morningside**') and Teva Pharmaceuticals Europe BV ('**Teva**').

I. Acquiescence

1.24 Advanz maintains that there can have been no abuse of a dominant position as it did not act unilaterally, but rather that the prices of Liothyronine Tablets were the outcome of agreement between Advanz and the DHSC/NHS. It claims that there was explicit approval of its price notifications, and further that the DHSC/NHS had an opportunity to object to its prices, but nevertheless paid them. It argues that this amounted to acquiescence by the DHSC/NHS and that this provides a defence to enforcement of the Chapter II prohibition.

1.25 The evidence does not support this argument. Its own internal documents show that in the case of Liothyronine Tablets, Advanz was deliberately raising prices for a niche drug that was '*below the radar*' of DHSC/NHS attention.

1.26 In any case, the CMA considers that the argument that there can be no breach of the Chapter II prohibition where there is acquiescence is wrong in law.

II. Portfolio pricing

1.27 The Parties argue that the CMA is wrong to rely on its Cost Plus calculation in determining whether Advanz's prices were excessive. They argue in particular that it is inappropriate to use a Cost Plus approach in the pharmaceuticals sector, where prices are set across a portfolio of products.

1.28 The CMA rejects this argument. Undertakings in a dominant position, as Advanz was for Liothyronine Tablets, have a special responsibility not to abuse their market power in relation to those products. This is confirmed by case law, which makes clear that it is not appropriate to assess the excessiveness of Advanz's prices on a portfolio basis.

III. Other arguments and comparators

1.29 The Parties have also argued that the CMA should use other comparators to assess whether Advanz's Liothyronine Tablet prices are unfair. These have been assessed and dismissed by the CMA. The CMA dismisses the Parties' arguments based on **Post-Entry Prices** for the reasons set out in paragraph 1.22(d) above.

(a) **Competitors' entry-incentivising price levels** ('**Entry Plan Prices**'): The Parties argue that the CMA's approach would require dominant companies to price at a level that would foreclose entry. However, it is not a necessary element of the test for excessive pricing that market entry is viable. Competition is not an end in itself. On the contrary, in the absence of

enforcement, where an incumbent is insulated from competition by very high barriers to entry, it could extract high economic profits indefinitely from consumers by pricing just below the entry-incentivising level. While entry may generate non-price benefits, no significant benefits were likely to materialise in relation to Liothyronine Tablets given that there was limited scope to increase output or to improve this old and established drug.

(b) **Competitors' expectations of market prices** ('**Forecast Prices**'): The Parties argue that prices forecast by new and potential entrants in the market should be used as a measure of competitive pricing. However, third parties' forecasts are likely to have been inflated by Advanz's pricing conduct, as they necessarily used the abusively high prices as inputs into their models.

(c) **Cournot modelling**: The Parties have also submitted Cournot modelling in order to calculate an equilibrium price. However, in this case, their modelling does not reflect real world competition in the supply of generic medicines and the results of their modelling are inconsistent with the prices of generic medicines that are typically observed.

(d) **Multi-firm assessment**: The Parties have also argued that if, in a competitive market, there were multiple suppliers of Liothyronine Tablets, the unit costs per supplier would be higher because firms would need to recover fixed costs over lower volumes. According to the Parties, an adjustment to reflect multiple suppliers (the '**multi-firm adjustment**') should therefore be included in the CMA's calculation of Cost Plus or elsewhere in the assessment. However, such an approach would be inappropriate as a matter of law and economic principle:

(i) The courts have confirmed that a Cost Plus assessment based on a dominant undertaking's actual costs is an appropriate approach where it can be done.

(ii) A multi-firm adjustment would enable an incumbent monopolist to recoup as pure economic profit the modelled costs of operating in a hypothetical multi-player market, which bears no relation to the incumbent's actual costs. This would result in significant harm to consumer welfare and would greatly reduce the effectiveness of the Chapter II prohibition on excessive pricing.

E. The CMA's decision and penalties

1.30 The CMA has found that Advanz infringed the Chapter II prohibition intentionally, or at the very least negligently, and has decided to impose a total financial penalty of **£101,442,899** in relation to the Infringement on Advanz Pharma Corp and its subsidiaries, the Mercury Pharma Companies

as well as HgCapital and the Cinven Entities, with each being liable for the following amount:

(a) HgCapital is liable for a penalty of **£8.6 million**;

(b) The Cinven Entities are liable for a penalty of **£51.9 million**; and

(c) Advanz Pharma Corp and its subsidiaries, the Mercury Pharma Companies, are liable for a penalty of **£40,942,899** (the statutory maximum).[6]

1.31 In setting the fines at these levels, the CMA has in particular taken into account that Advanz made a total profit of over **£92.3 million** from the Infringement, of which:

(a) **£5.7 million** dates from the period the Mercury Pharma Companies were controlled by HgCapital;

(b) **£34.1 million** dates from the period the Mercury Pharma Companies were controlled by the Cinven Entities; and

(c) **£52.5 million** dates from the period the Mercury Pharma Companies were controlled by Advanz Pharma Corp.

1.32 The CMA considers that in order effectively to penalise and deter, the fines imposed for the Infringement should exceed these profits by a material amount. It is not enough simply to eliminate the Parties' gains from the Infringement. The CMA has also borne in mind that the Infringement was particularly serious in nature and resulted in significant harm to the NHS and patients.

[6] The CMA would have imposed a penalty of **£65.2 million**, but it reduced this figure to £40,942,899 to ensure that the penalty did not exceed 10% of Advanz Pharma Corp's worldwide turnover, which is the statutory maximum that the CMA can impose for an infringement of competition law.

2. The Investigation

2.1 On 25 October 2016, the CMA launched a formal investigation under the Act, having determined that it had reasonable grounds for suspecting that Advanz had infringed the Chapter II prohibition and Article 102 of the Treaty on the Functioning of the European Union ('**TFEU**').

2.2 Under the European Union (Withdrawal Agreement) Act 2020, section 2(1) of the European Communities Act 1972 (under which EU law had effect in the UK's national law) remained in force until the end of the Transition Period.[7] Following the end of the Transition Period, EU law no longer applies in the UK. This Decision does not therefore consider whether Article 102 TFEU has been infringed.

2.3 This section sets out details of the CMA's evidence gathering and engagement with relevant parties in its investigation.

A. Advanz

2.4 On 25 October 2016, the CMA conducted unannounced inspections at the UK premises of Advanz Pharma Services (UK) Limited ('**Advanz Pharma Services**') under section 27 of the Act requiring the preservation and production of documents.[8] Advanz produced a number of documents at the inspection.

2.5 Following the inspection, the CMA conducted a review of the evidence preserved. The review was carried out at the CMA's premises, with consent from Advanz and with its legal representatives present. As a result, the CMA extracted documents relevant to the investigation which were subsequently placed onto the CMA's file.

2.6 In addition, the CMA made a number of requests for information and documents from Advanz under section 26 of the Act[9] and transferred evidence onto its case file which it gathered under section 26 of the Act in case 50277.[10] The CMA also held a number of meetings with Advanz.[11]

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[7] Section 1A, Withdrawal Act (as introduced by section 1, Withdrawal Agreement Act).
[8] The CMA's s.27 notice dated 25 October 2016. Advanz Pharma Services was called Concordia International Rx (UK) Limited at the time.
[9] The CMA issued 30 section 26 notices to Advanz between 25 October 2016 and 8 April 2021.
[10] Cases 50277-1, 50277-2 and 50277-3 relate to anti-competitive and abusive conduct in relation to hydrocortisone tablets. The CMA issued a single decision in these cases on 15 July 2021.
[11] State of Play meetings were held on 8 February 2017, 2 May 2017, 2 October 2017, 28 November 2018 and 20 May 2020. Meetings were also held on 19 January 2017, 9 February 2017, 1 October 2018 and 29 June 2021.

B. HgCapital

2.7 The CMA requested information and documents from HgCapital under section 26 of the Act[12] and also held meetings with HgCapital.[13]

C. The Cinven Entities

2.8 The CMA requested information and documents from the Cinven Entities under section 26 of the Act[14] and transferred evidence onto its case file which it had gathered under section 26 of the Act in case 50277.[15] The CMA also held meetings with the Cinven Entities.[16]

D. Other sources of information

2.9 In the course of its investigation, the CMA requested information under section 26 of the Act from a number of third parties, including those listed in Table 2.1 below:

Table 2.1: Information obtained from third parties

Category	Entity
Suppliers	[✂]
Wholesalers	[✂]
Other companies active in the pharmaceutical industry	[✂]
Government departments and public bodies	Department of Health and Social Care (DHSC), formerly Department of Health (DH or DoH) Medicines & Healthcare products Regulatory Agency (MHRA) NHS Business Services Authority (NHS BSA) NHS Clinical Commissioners (NHSCC) National Institute for Health and Care Excellence (NICE)
Pharmacies	[✂]
Specialists	[✂]
GP Software providers	[✂]
European Competition Network	Austria Belgium Bulgaria Croatia

[12] The CMA issued six section 26 notices to HgCapital between 30 June 2017 and 14 April 2021.
[13] State of Play meetings were held on 2 August 2017, 4 October 2017, 28 November 2018 and 2 June 2020. Meetings were also held on 25 September 2018 and 29 June 2021.
[14] The CMA issued 10 section 26 notices to the Cinven Entities between 11 July 2017 and 14 April 2021.
[15] The CMA's s.26 notices dated 20 October 2016 and 11 November 2016.
[16] State of Play meetings were held on 26 July 2017, 2 October 2017, 28 November 2018 and 19 May 2020. Meetings were also held on 26 September 2018 and 29 June 2021.

Category	Entity
(ECN) – EU/EEA Member States	Cyprus The Czech Republic Denmark Estonia Finland France Germany Greece Hungary Ireland Italy Latvia Lithuania Luxembourg Malta The Netherlands Poland Portugal Romania Slovakia Slovenia Spain Sweden Iceland Norway

2.10 The CMA additionally met with the DHSC to discuss the pricing framework for Liothyronine Tablets. It obtained witness statements from Julie Lizbeth Wood, the then Chief Executive of NHS Clinical Commissioners and Linda Mary Mynott, the Chief Executive and Chair of the Board of Trustees of Thyroid UK. It also held clarificatory follow-up meetings with third parties who had provided the CMA with information.

E. Issue of the 2017 SO and the appointment of a Case Decision Group

2.11 On 21 November 2017, the CMA issued a Statement of Objections (the '**2017 SO**') to the Parties setting out its provisional findings. In the 2017 SO, the CMA set out the facts and the evidence on which it relied, the objections it raised in terms of the alleged infringements of the Chapter II prohibition and Article 102 of the TFEU, the action it proposed to take and its reasons for the proposed actions.

2.12 Following the issue of the 2017 SO, the CMA appointed a Case Decision Group to decide whether or not, based on the facts and evidence before it,

and taking account of the Parties' representations, the legal test for establishing an infringement had been met.[17]

2.13 The Parties submitted written representations on the 2017 SO to the CMA between 16 and 20 April 2018 and made oral representations between 21 and 31 May 2018.[18]

F. The *Phenytoin CAT* judgment and issue of the 2019 SSO

2.14 On 7 June 2018, the Competition Appeal Tribunal (the '**CAT**') handed down its judgment in the *Phenytoin* case.[19] This judgment set aside part of the CMA's decision in *Phenytoin* insofar as it dealt with abuse.

2.15 Following the *Phenytoin CAT* judgment and the representations made by the Parties in response to the 2017 SO, the Case Decision Group decided that, although it provisionally remained of the view that Advanz had committed a competition law infringement, material changes to its case were required by the judgment. Accordingly, on 30 January 2019 the CMA issued a supplementary statement of objections (the '**2019 SSO**'). In the 2019 SSO, the CMA set out the material changes to its case as well as new evidence which supported its objections.

2.16 The Parties submitted written representations on the 2019 SSO to the CMA on 11 June 2019[20] and made oral representations between 31 July 2019 and 3 September 2019.

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[17] The role of the Case Decision Group is described in *Guidance on the CMA's investigation procedures in Competition Act 1998 (CA98) cases (CMA8)*, dated 4 November 2020.
[18] Advanz submitted document LIO6288, Advanz's reply to the 2017 SO ('**Advanz RSO'**), document LIO6361.1, Annex 1 – '*Economic analysis in relation to alleged excessive pricing*' ('**First Compass Lexecon Report**'), document LIO6361.3, Annex 2 – '*Report of* [✂]' ('**First FTI Report**') and supporting documents; Cinven submitted document LIO6330, Cinven's response to the 2017 SO ('**Cinven RSO**'), document LIO6331, '*Economic assessment of the CMA's excessive pricing case*' ('**First Cinven CRA Report**') and supporting documents; HgCapital submitted document LIO6258, HgCapital's response to the 2017 SO ('**HgCapital RSO**'), document LIO6259, '*Excessive pricing allegations in relation to Liothyronine in the UK – an economic assessment of the period of HgCapital's ownership*' ('**First HgCapital CRA Report**') and supporting documents.
[19] *Pfizer and Flynn v CMA* ('***Phenytoin CAT***') [2018] CAT 11.
[20] Advanz submitted document LIO7781, Advanz's reply to the 2019 SSO ('**Advanz RSSO-2019'**), document LIO7784, '*Economic observations on the SSO*' ('**Second Compass Lexecon Report**'), document LIO7786, '*Report of* [✂]' ('**Second FTI Report**'); document LIO7791, Cinven's response to the 2019 SSO ('**Cinven RSSO-2019**'), document LIO7794, *Economic assessment of the CMA's excessive pricing case*' ('**Second Cinven CRA Report**') and supporting documents; HgCapital submitted document LIO7798, HgCapital's response to the 2019 SSO ('**HgCapital RSSO-2019**'), document LIO7801, '*Excessive pricing allegations in Liothyronine – an economic response to the SSO*' ('**Second HgCapital CRA Report**') and supporting documents.

G. Further evidence gathered by the CMA following representations on the SSO and issue of the Letters of Facts

2.17 Following receipt of the written and oral representations on the SSO, the CMA requested further information and documents from the Parties. The CMA also requested further information and documents from a number of third parties.

2.18 On 7 October 2019, the CMA sent a Letter of Facts (the '**First Letter of Facts**') to the Parties which identified additional evidence supporting the CMA's provisional findings as set out in the 2019 SSO on which it proposed to rely.[21]

2.19 The Parties submitted written representations to the CMA on the matters referred to in the First Letter of Facts between 21 and 28 October 2019.

2.20 On 5 February 2020, the CMA sent a second Letter of Facts (the '**Second Letter of Facts**') to the Parties which identified additional evidence supporting the CMA's provisional findings as set out in the 2019 SSO on which it proposed to rely.

2.21 The Parties submitted written representations to the CMA on the matters referred to in the Second Letter of Facts between 19 and 25 February 2020.

H. Issue of the Draft Penalty Statement

2.22 On 21 November 2019, the CMA issued a Draft Penalty Statement ('**DPS**') to each of Advanz, HgCapital and the Cinven Entities. The DPS set out the CMA's provisional findings regarding the directions and financial penalties that it proposed to impose on Advanz, HgCapital and the Cinven Entities respectively if the CMA were to reach an infringement decision against that Party.

2.23 The Parties submitted written representations on the DPS to the CMA on 12 December 2019[22] and made oral representations between 16 December 2019 and 13 January 2020. Advanz responded to additional questions on 29 January 2020.[23]

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[21] For further detail on the procedure relating to a letter of facts, see *Guidance on the CMA's investigation procedures in Competition Act 1998 (CA98) cases (CMA8)*, dated 4 November 2020, paragraph 12.27.
[22] Document LIO7973, Advanz's response to the DPS ('**Advanz RDPS**'); document LIO7978, Cinven's response to the DPS ('**Cinven RDPS**'); document LIO7981, HgCapital's response to the DPS ('**HgCapital RDPS**').
[23] Document LIO8016, Advanz's response to CMA's questions dated 21 January 2021.

I. The *Phenytoin CoA* judgment and issue of the 2020 SSO

2.24 On 10 March 2020, the Court of Appeal handed down its judgment in the *Phenytoin* case.[24]

2.25 The Case Decision Group decided to revise the 'Abuse' chapter of the 2019 SSO following the *Phenytoin CoA* judgment and new cost data submitted by Advanz. Accordingly, on 10 July 2020 the CMA issued a further supplementary statement of objections (the '**2020 SSO**').

2.26 The Parties submitted written representations on the 2020 SSO to the CMA on 26 August 2020[25] and made oral representations between 18 September 2020 and 12 October 2020.

J. Further evidence gathered by the CMA following representations on the 2020 SSO and issue of the Letters of Facts

2.27 Following the receipt of the Parties' written and oral representations on the 2020 SSO, the CMA requested further information from Advanz. The CMA also requested further information and/or documents from a number of third parties.

2.28 On 29 December 2020, the CMA sent a Letter of Facts (the '**Third Letter of Facts**') to the Parties which identified additional evidence supporting the CMA's provisional findings as set out in the 2020 SSO on which it proposed to rely.

2.29 The Parties submitted written representations to the CMA on the matters referred to in the Third Letter of Facts between 20 and 27 January 2021.

2.30 On 23 April 2021, the CMA sent a Letter of Facts (the '**Fourth Letter of Facts**') to the Parties which identified additional evidence supporting the

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[24] *Competition and Markets Authority v Flynn Pharma Limited and Flynn Pharma (Holdings) Limited and Pfizer Inc. and Pfizer Limited* ('***Phenytoin CoA***') [2020] EWCA Civ 339.

[25] Advanz submitted document LIO12043, Advanz's response to the 2020 SSO ('**Advanz RSSO-2020**'), document LIO12044, '*Economic observations on the further Abuse Chapter to the Supplementary Statement of Objections* ('**Third Compass Lexecon Report**'), document LIO12045, '*Report of* [✂]' ('**Third FTI Report**') and supporting documents; Cinven submitted document LIO12052, Cinven's response to the 2020 SSO ('**Cinven RSSO-2020**'), document LIO12055, '*An economic review of the Liothyronine second SSO*' ('**Third Cinven CRA Report**'), document LIO12054, '*Oxera's comments on the supplementary SO*' ('**Cinven Oxera Report**') and supporting documents; HgCapital submitted document LIO12062, HgCapital's response to the 2020 SSO ('**HgCapital RSSO-2020**'), document LIO12063, '*Liothyronine in the Hg period: comments on the CMA's updated Cost Plus analysis*' ('**Third HgCapital CRA Report**') and supporting documents.

CMA's provisional findings as set out in the 2020 SSO on which it proposed to rely.

2.31 The Parties submitted written representations to the CMA on the matters referred to in the Fourth Letter of Facts on 12 May 2021.

3. Factual background

3.1 This chapter provides factual background to the CMA's investigation, in particular setting out: the key entities relevant to the investigation; a description of liothyronine, including its pharmacological characteristics and usage in treating conditions including hypothyroidism; the regulatory framework governing the supply of Liothyronine Tablets; an overview of Advanz's manufacturing and distribution of Liothyronine Tablets; Advanz's prices and volumes of Liothyronine Tablets; and information relating to the supply of Levothyroxine Tablets, which are the primary treatment for hypothyroidism.

A. Key entities

I. Overview of Advanz

3.2 The undertaking referred to as Advanz[26] for the purposes of this Decision has undergone a number of corporate changes and restructurings since 2007. These can be divided into four stages:

(a) From at least 1 November 2007 until 29 December 2009: Prior to 29 December 2009, the Goldshield group and the Amdipharm group existed as two independent pharmaceutical groups. Goldshield Group plc, the ultimate parent entity of the Goldshield group (including the Mercury Pharma Companies) during this period, was listed on the London Stock Exchange until 2009. The Amdipharm group had been established as part of the pharmaceutical group Waymade in 2003.

(b) From 30 December 2009 until 30 August 2012: In December 2009, Goldshield was subject to a management buyout backed by the HgCapital private equity house, and shortly thereafter Goldshield Group plc became Goldshield Group Limited. On 22 March 2012, Goldshield Group Limited was renamed Mercury Pharma Group Limited, and the Goldshield group was re-branded as the Mercury Pharma group. The Amdipharm group was still part of Waymade at this stage.

(c) From August/October 2012 until 20 October 2015: On 31 August 2012, the Mercury Pharma group was acquired by the Cinven private equity house's

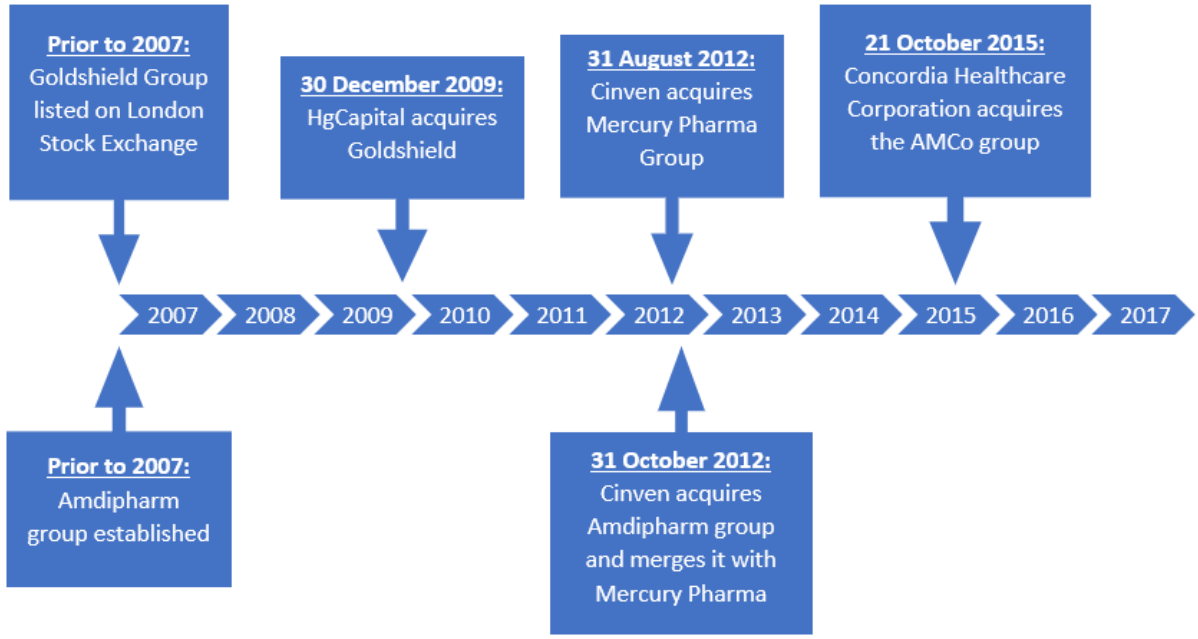
[26] References in this Decision to 'Advanz', insofar as they relate to the time period from 1 November 2007 to 31 July 2017, are to the undertaking in the form in which it existed at the relevant point in time, as set out below. References to the conduct or legal and factual representations of 'Advanz' after the end of the Infringement Period are to the undertaking in the form in which it exists at the time of this Decision (Advanz Pharma Corp and the Mercury Pharma Companies, as described in paragraphs 3.15 ff below).

Fifth Fund (the '**Fifth Cinven Fund**'). On 31 October 2012, the Amdipharm group was also acquired by the Fifth Cinven Fund. Cinven then merged the Amdipharm and Mercury Pharma groups to create the '**Amdipharm Mercury**', or '**AMCo**' group.

(d) From 21 October 2015 until at least 31 July 2017: On 21 October 2015, the pharmaceutical group headed by Advanz Pharma Corp (then known as Concordia Healthcare Corporation)[27] purchased 100% of the shares in the ultimate holding company of the AMCo group.[28]

3.3 These changes of ownership are plotted along the timeline at Figure 3.1 below.

Figure 3.1: Timeline of Ownership



Source: CMA analysis

[27] Concordia Healthcare Corporation changed its name to Concordia International Corporation on 28 June 2016 (document PAD001, Cision PR Newswire: '*Concordia Healthcare Corp announces name change to Concordia International Corp*'), and on 29 November 2018 Concordia International Corporation changed its name to Advanz Pharma Corporation (document PAD205, Advanz: *'Consolidated Financial Statements of ADVANZ PHARMA Corp. December 31, 2018 and 2017*'), page 11. On 1 January 2020, Advanz Pharma Corporation was renamed Advanz Pharma Corp. Limited (document PAD210, Advanz: *'ADVANZ PHARMA Announces Changes to its Board of Directors and Completion of its Continuance to Western Europe*', 8 January 2020).
[28] The holding company was Amdipharm Mercury Limited, formerly called CCM Pharma Ltd. It was subsequently renamed Concordia International (Jersey) Limited and was dissolved on 29 June 2017 (document LIO3955, Advanz's response to question 1 of the CMA's s.26 notice dated 21 August 2017).

II. Entities forming part of Advanz

3.4 The following section provides an overview of the key entities referred to in this Decision, which form or formed part of the undertaking referred to as Advanz during the Infringement Period. A list of key individuals associated with Advanz during different stages of the Infringement Period is set out at Annex 2.

a. Mercury Pharma group

3.5 The Goldshield group (subsequently re-branded the Mercury Pharma group as explained below) was founded in the early 1990s as a speciality pharmaceuticals group, providing prescription pharmaceuticals and non-prescription medicines to patients and healthcare authorities.[29]

3.6 The HgCapital private equity house acquired the Goldshield group in a deal valuing the group at £179 million in 2009 (see further below). In mid-2010 HgCapital removed Goldshield's senior management and appointed new management and directors in their place, including a new CEO, [✂].

3.7 In 2012, HgCapital re-branded the Goldshield group as the Mercury Pharma group. The Mercury Pharma group includes the Mercury Pharma Companies – Mercury Pharma Group Limited,[30] Advanz Pharma Services (UK) Limited[31] and Mercury Pharmaceuticals Limited.[32] During the Infringement Period:

(a) Mercury Pharma Group Limited was the entity responsible for the implementation of the strategic direction of the principal operating subsidiaries of the group.[33]

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[29] See document PAD003, Bloomberg: '*Mercury Pharma Overview*'.
[30] Mercury Pharma Group Limited is a private limited company (it was formerly called Goldshield Group Plc from 8 May 1998 to 4 January 2010, and then Goldshield Group Limited from 15 January 2010 to 20 March 2012). Prior to the management buyout in 2009, Mercury Pharma Group Limited was the ultimate parent company of the Mercury Pharma group: document LIO2940.24, HgCapital's '*Mercury Pharma group shareholding summary*'.
[31] Advanz Pharma Services (UK) Limited is a wholly-owned subsidiary of Mercury Pharma Group Limited (it was formerly called Concordia International Rx (UK) Limited from 17 June 2016 until 30 October 2018; Amdipharm Mercury Company Limited from 22 March 2013 until 17 June 2016; Mercury Pharma Management Services Limited from 20 March 2012 until 22 March 2013; and Goldshield Management Services Limited from 26 February 2003 until 20 March 2012): document LIO3954, '*Annex 2: Updated structure chart*'.
[32] Mercury Pharmaceuticals Limited is a wholly-owned subsidiary of Mercury Pharma Group Limited (it was formerly called Goldshield Pharmaceuticals Ltd from 2 October 1992 to 20 March 2012 and Mercury Pharma Limited from 20 March 2012 to 26 March 2012).
[33] See document PAD004, '*Amdipharm Mercury Annual Review 2013*', page 16.

(b) Advanz Pharma Services (UK) Limited[34] provided management services to the AMCo group and employed its UK senior management.[35]

(c) Mercury Pharmaceuticals Limited was the entity within the Advanz group which sold Liothyronine Tablets in the UK.[36]

3.8 In 2012, the Fifth Cinven Fund acquired the Mercury Pharma group. It subsequently acquired the Amdipharm group and merged it with the Mercury Pharma group to form the AMCo group (Amdipharm Mercury Company).[37]

b. HgCapital

3.9 The HgCapital private equity house is based in the UK and Germany.[38]

3.10 On 30 December 2009, the HgCapital private equity house, acting via limited partnerships comprising its previous mid-market buyout fund, HgCapital 6 (the '**HgCapital 6 Fund**'), acquired a majority stake in the Mercury Pharma group (then known as the Goldshield group) as part of a management buyout valuing the group at £179 million. The HgCapital 6 Fund was managed by HgCapital, a UK limited liability partnership.[39]

3.11 The HgCapital 6 Fund held a majority stake in the Mercury Pharma group until 31 August 2012, when it fully disposed of its stake via direct sale to the Fifth Cinven Fund, for an enterprise value of £465 million.[40] Public sources noted at the time of the sale that the HgCapital private equity house received '*more than double what it paid just three years ago*' for the group.[41] Its listed investment trust, HgCapital Trust plc, noted in relation to its own share in the investment that '*[t]he initial proceeds and residual value from the sale represent an investment multiple of 4.2x (which could increase to 4.3x once all further potential proceeds have been received) and a gross IRR* [Internal Rate of Return] *of 67% p.a. over the investment period*'.[42]

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[34] Formerly known as Amdipharm Mercury Company Limited, often abbreviated to 'AMCo', which was also the group name during the period of Cinven's ownership and many third parties refer to the group as AMCo. Where this Decision discusses 'AMCo', this refers to the undertaking during the period of Cinven's ownership. Where this Decision specifically discusses the entity formerly named Amdipharm Mercury Company Limited, it will use its current name Advanz Pharma Services (UK) Limited.
[35] Document LIO4427, Advanz's response to question 2 of the CMA's s.26 notice dated 25 September 2017.
[36] Document LIO2589, Advanz's response to question 12 of the CMA's s.26 notice dated 27 February 2017.
[37] PAD097, Cinven: '*Our Investments*'; document PAD121, '*Amdipharm Mercury Annual Review 2012*', page 14.
[38] See document PAD201, HgCapital: '*About us - © Hg 2019*'.
[39] Document LIO2940, HgCapital's response to questions 1 and 2 of the CMA's s.26 notice dated 26 May 2017; document LIO2940.24, HgCapital's '*Mercury Pharma group shareholding summary*'. See also document PAD092, '*HgCapital finalises £80 million stake in Goldshield MBO*'.
[40] Document LIO2940, HgCapital's response to questions 1 and 2 of the CMA's s.26 notice dated 26 May 2017; document LIO2940.24, HgCapital's '*Mercury Pharma group shareholding summary*'. See also document PAD093, HgCapital: '*Announces sale of Mercury Pharma*'.
[41] Document PAD094, '*Hg Capital doubles money with Mercury Pharma sale*'.
[42] See document PAD095, '*HgCapital Trust plc 2012 annual report and accounts*', page 19.

c. Cinven

3.12 The Cinven Entities form part of an international private equity house referred to in the remainder of this Decision as '**Cinven**'. Healthcare is one of six sectors on which Cinven focuses its investment activity.[43]

3.13 The Fifth Cinven Fund acquired the Mercury Pharma group on 31 August 2012, for '*an enterprise value of £465 million*', and the Amdipharm group on 31 October 2012, for '*a total consideration of £367 million*'.[44] Cinven integrated the Amdipharm and Mercury Pharma groups to form the AMCo group. Prior to the sale to Concordia Healthcare Corporation in October 2015, the Fifth Cinven Fund held a majority stake in Amdipharm Mercury Limited, the 100% owner of the AMCo group (including the Mercury Pharma Companies – Mercury Pharma Group Limited, Advanz Pharma Services (UK) Limited and Mercury Pharmaceuticals Limited).[45]

3.14 On 21 October 2015, Cinven sold its stake in the AMCo group to Concordia Healthcare Corporation for an enterprise value of £2.3 billion in what Cinven described as '*one of the most successful deals we've ever done*'. Concordia Healthcare Corporation paid $1.2 billion in cash, $700 million in shares and $220 million in additional payments relating to the AMCo group's future performance, as well as assuming its debt.[46] Cinven noted that its investment '*returned cash proceeds of 3.5x cost*'.[47]

d. Advanz Pharma Corp

3.15 Concordia Healthcare Corporation re-branded as Concordia International Corporation in 2016, and in 2018 it re-branded again, as Advanz Pharma Corporation.[48] Following a group restructuring, Advanz Pharma Corporation

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[43] See document PAD006, Cinven: '*About Us*'.
[44] The acquisition was effected through Jersey holding company CCM Pharma Limited, which was subsequently renamed Amdipharm Mercury Limited (later Concordia International (Jersey) Limited, and since dissolved). See documents PAD097, Cinven: '*Our Investments*'; document PAD121, '*Amdipharm Mercury Annual Review 2012*', page 14; document LIO3872, Cinven's response to questions 1 and 3 of the CMA's s.26 notice dated 20 October 2017.
[45] Document LIO3881, Cinven's '*Annex 5 _ Structure chart of the Amdipharm group following the A_1110205_0*'; see document PAD007, AMCo: '*Annual Review 2014*', page 24.
[46] See document PAD087, FT: '*Cinven to sell AMCo to Concordia in £2.3bn deal*'.
[47] See document PAD096, Cinven: '*Annual Review 2015*', page 4.
[48] Document PAD001, Cision PR Newswire: '*Concordia Healthcare Corp announces name change to Concordia International Corp*'), and on 29 November 2018, Concordia International Corporation changed its name to Advanz Pharma Corporation (document PAD205, Advanz: *'Consolidated Financial Statements of ADVANZ PHARMA Corp. December 31, 2018 and 2017*'), page 11.

was renamed Advanz Pharma Corp Limited and became a Jersey-registered corporation in 2020.[49]

3.16 The Mercury Pharma Companies – Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited and Mercury Pharma Group Limited – are currently all indirectly wholly-owned by Advanz Pharma Corp.[50]

3.17 On 1 June 2021 Advanz Pharma Corp was acquired by the private equity firm Nordic Capital for $846 million.[51]

B. Liothyronine

3.18 This section describes: liothyronine; its presentation; the conditions it can treat, including hypothyroidism; the method of treatment; and alternative medicines that can be used in treating hypothyroidism.

I. Description of product and presentation

3.19 Liothyronine is a synthetic hormonal preparation of the naturally occurring thyroid hormone, triiodothyronine (or T3).[52] The body predominantly produces a different thyroid hormone called thyroxine (or T4) which is the precursor (or pro-hormone) of T3. Each of the body's tissues converts T4 into T3 when required for normal functioning of almost all of the body's metabolic processes.[53] The thyroid hormones play a crucial role in the body's heart and digestive function, metabolism, brain development, bone health and muscle control.

3.20 When the thyroid is underactive and too few of these hormones are produced (this is called hypothyroidism), metabolism slows down potentially causing weight gain, tiredness, sluggishness and depression, as well as other symptoms.[54] If an underactive thyroid remains untreated, complications such as heart disease and a life-threatening condition called myxoedema coma can

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[49] '*Consolidated Financial Statements of ADVANZ PHARMA Corp. Limited*', 31 December 2020, page 3, available at: https://www.advanzpharma.com/media/uploads/ADVZ-Financials-Annual-with-Audit-opinion-2020-FINAL-17032021.pdf
[50] Document LIO3975, '*Annex 5.2 – Current corporate structure chart of the AMCo Group*'. See also document LIO3954, '*Annex 2: Updated structure chart*'.
[51] Nordic Capital acquires speciality pharmaceutical company ADVANZ PHARMA in deal worth ~ $846 million', 1 June 2021, available at: https://www.advanzpharma.com/news/2021/nordic-capital-acquires-specialty-pharmaceutical-company-advanz-pharma-in-deal-worth-846-million.
[52] Document LIO1862, MHRA's response to question 6(a) of the follow-up questions to the CMA's s.26 notice dated 28 November 2016.
[53] Document LIO1504, Society for Endocrinology's response to question 1 of the CMA's s.26 notice dated 20 December 2016.
[54] Document LIO2114.9, '*RCP statement 2011*', page 2; document LIO1504, Society for Endocrinology's response to question 2 of the CMA's s.26 notice dated 20 December 2016; document LIO0460, '*Final Endocrinology Market Overview – BD&L – 16.10.14.ppt*', page 14.

occur.[55] Synthetic versions of T3 and T4 can be taken as a supplement or replacement for the natural thyroid hormones where individuals do not produce enough of these hormones themselves.[56] This usually requires life-long treatment.[57]

3.21 During the Infringement Period, liothyronine sodium was licensed in the UK for supply as a tablet of 20mcg strength, in packs of 28 tablets. Liothyronine Tablets consist of an active pharmaceutical ingredient ('**API**') and excipients (inactive substances). They were originally developed in the UK by Glaxo Operations UK Ltd ('**Glaxo**') in the mid-1950s and were sold under the brand name 'Tertroxin'.[58] Liothyronine sodium may also be supplied in capsule form, as a liquid or as a powder to be used in a solution for injection.[59]

3.22 On 9 October 1992, Goldshield acquired a portfolio of products including Tertroxin from Medeva plc ('**Medeva**') for a total purchase price of £1 million.[60] The MA for Tertroxin was transferred to Goldshield by Medeva as part of this transaction.[61] The product was de-branded in October 2007[62] and at the same time the pack size was reduced from 100 tablets per pack to 28 tablets per pack.[63]

3.23 The duration of treatment and the dosage of Liothyronine Tablets are determined by the licensed indication with reference to individual patients' needs (see paragraphs 3.26 to 3.30 below).[64] Advanz's Liothyronine Tablets have a shelf life of 12 months.[65]

II. Conditions treated by Liothyronine

3.24 Liothyronine Tablets are used to treat some of the more severe conditions in which the thyroid does not produce enough thyroxine and to balance the

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[55] See document PAD070, NHS: '*Thyroid Under-active*'.
[56] Document LIO1862, MHRA's response to question 6(a) of the follow-up questions to the CMA's s.26 notice dated 28 November 2016.
[57] Document LIO1504, Society for Endocrinology's response to question 4(k) of the CMA's s.26 notice dated 20 December 2016.
[58] Document LIO3087, '*Annex 18 - Amdipharm Mercury Management Presentation dated August 2015.PDF*', page 16, and document LIO3489.43, '*Liothyronine tablets – Position update*', pages 3 and 4.
[59] Document LIO2268, TPA's response to question 11(b) of the CMA's s.26 notice dated 13 February 2017.
[60] Document LIO1096, Advanz's response to questions 4 and 6 of the CMA's s.26 notice dated 25 October 2016.
[61] Document LIO0373, *'Medeva re ex Glaxo portfolio of MAREVAN, NEO NACLEX, EUDEMINE, MAREVAN, CYTACON, ELTROXIN, TERTROXIN, TRI- IODOTHYRONINE, FERSADAY 9 Oct 1992.pdf*'; document LIO0608, '*PL 10972-0033-MHRA Scientific Advice Meeting - 2016-mercury-pharmaceuticals-ltd - draft Mor and Mike 18122015.docx*', page 1.
[62] Document LIO3061, Advanz's response to question 7(b) of the CMA's s.26 notice dated 25 January 2017; document LIO2310, DHSC's response to question 2 of the CMA's s.26 notice dated 9 February 2017.
[63] Document LIO1521, Advanz's response to question 1 of the follow-up questions to the CMA's s.26 notice dated 25 October 2016
[64] Document LIO3061, Advanz's response to question 1(b) of the CMA's s.26 notice dated 25 January 2017.
[65] Document LIO3061, Advanz's response to question 7(b) of the CMA's s.26 notice dated 25 January 2017. Advanz has informed the CMA that Morningside and Teva's Liothyronine Tablets both have a shelf life of 24 months (document LIO6288, Advanz RSO, paragraph 6.162.4).

effect of medicines used to treat an overactive thyroid.[66] Most commonly it is used to treat hypothyroidism.

3.25 The Summary of Product Characteristics ('**SMPC**') sets out the other licensed indications for Liothyronine Tablets, which are referred to in more detail below.[67]

a. Primary use for Liothyronine Tablets: hypothyroidism

3.26 The Society for Endocrinology estimates that more than 95% of Liothyronine Tablet prescriptions in the UK are issued for the treatment of hypothyroidism.[68]

3.27 According to the British Thyroid Association ('**BTA**'), '*[h]ypothyroidism affects 2 to 5% of the UK population equivalent to about 1.3 to 3.2 million individuals*'.[69] The Society for Endocrinology narrows this range to around 3% of the population (about 2 to 2.5 million people).[70] It informed the CMA that there has been '*a steady increase in the number of people diagnosed with hypothyroidism across both the UK and other developed nations*', citing a study which found that the number of patients treated for hypothyroidism increased by 70% between 2001 and 2009 and adding that:

> 'This is a durable trend, with the number of thyroid hormone prescriptions (including both levothyroxine, liothyronine and other preparations) in England increasing from 7 million to 19 million between 1998 and 2007. The comparable figure, derived from the 2015 DH Prescription Cost Analysis was 29.8 million, showing a continued upward trend'.[71] (endnotes omitted)

3.28 Hypothyroid patients have described their symptoms to the CMA, and in evidence to Parliament, in the following ways:

(a) '*Before I was given [Liothyronine Tablets] I was a dead person, hugely overweight, slept all day, unable to function, had joint pains and muscles pains, extremely tired and lethargic, had no appetite at all. I lost all my*

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[66] See document PAD071, eMC: '*Liothyronine Sodium BP 20micrograms Tablets*'.
[67] Document PAD012, MHRA: '*Summary of product characteristics*'.
[68] Document LIO1504, Society for Endocrinology's response to question 3 of the CMA's s.26 notice dated 20 December 2016. The Society of Endocrinology estimated that 3,500 patients were diagnosed with Thyroid Cancer in 2014 (see document LIO1504, Society for Endocrinology's response to question 1(a) of the CMA's s.26 notice dated 20 December 2016).
[69] Document LIO2152, BTA's response to question 1 of the CMA's s.26 notice dated 13 February 2017.
[70] Document LIO1504, Society for Endocrinology's response to question 1(a) of the CMA's s.26 notice dated 20 December 2016.
[71] Document LIO1504, Society for Endocrinology's response to question 1(b) of the CMA's s.26 notice dated 20 December 2016.

hair/body hair head hair and eyebrows and had enormous bags under my eyes, unable to go to the toilet, my heart was suffering, I was so unwell, I didn't know how to exist – I was suffering'.[72]

(b) '*I developed the symptoms again but in a much more rapid and dramatic form (extreme tiredness, lethargy, mental confusion, weight gain and sensitivity to cold). […] A consultant endocrinologist put me on a combination of [Levothyroxine Tablets and Liothyronine Tablets] and I rapidly returned to full health again*'.[73]

(c) '*I was always tired, cold, found it hard to concentrate, very forgetful, had dry skin, my hair was falling out, weight gain, constipation and neck and shoulder pain […] I was very disappointed when the Dr told me that NHS Tayside had put a blanket ban on [Liothyronine Tablets] and it was no longer being prescribed due to the soaring cost*'.[74]

(d) '*As the years passed I felt half the woman I was, brain fog, fatigue, low blood pressure, joint pain. […] Still ill, I continued to visit my GP, along came raised liver enzymes, b12 deficiency, folate deficiency, fatty liver disease, high blood pressure, hair loss, severe hot/cold intolerance, head sweats, palpitations, fibromyalgia, the list was endless. […] I was given a trial of [Liothyronine Tablets] and my life changed! […] I will be forever grateful for my [Liothyronine Tablets] but live in fear that I will have it removed at anytime due to the cost and funding issues*'.[75]

3.29 The Chief Executive of Thyroid UK has explained that:

> *One of the main symptoms of hypothyroidism is tiredness, which can severely affect what a person can do day to day. For example, a person with hypothyroidism may be too tired to do anything after work, even to spend time with their family. Their personal and social life can also be disrupted due to tiredness. Another of the main symptoms of hypothyroidism is muscle pain. A lot of people have no choice but to walk to get around and their muscles hurt simply from walking. Other symptoms of hypothyroidism include weight gain, hair loss, dry skin, memory*

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[72] Document LIO5921, Email to the CMA from [name withheld] dated 21 January 2018.
[73] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*', page 16.
[74] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*', page 44.
[75] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*', page 59.

problems, depression and puffiness of the eyes. In some cases, hypothyroidism has been linked to infertility and miscarriage. One of the patients who contributed to the House of Lords dossier said that she was pregnant 6 weeks after starting her treatment with liothyronine, having miscarried twice previously while she was treated with levothyroxine.'[76]

b. Other conditions

3.30 In addition to use as a treatment for hypothyroidism, Liothyronine Tablets may be prescribed to treat the following conditions:

(a) *Thyroid Cancer*: Liothyronine Tablets are used for patients undergoing thyroid withdrawal as part of radioactive iodine treatment for thyroid cancer,[77] a rare type of cancer that affects the thyroid gland.[78] The shorter half-life[79] of Liothyronine Tablets compared to Levothyroxine Tablets means that patients being treated for thyroid cancer remain in a hypothyroid state for a shorter period of time.[80]

(b) *Refractory depression*: Liothyronine Tablets may be used to treat depressive symptoms in combination with more conventional antidepressant therapy. The number of patients taking Liothyronine Tablets for this reason is estimated to be less than 1,000 annually.[81]

(c) *Goitre*: Liothyronine Tablets can also be used to treat or prevent goitre.[82] However, the Society for Endocrinology indicated that hormone treatment for goitre was rarely performed in the UK, due to limited efficacy. Where it is performed, Levothyroxine is the primary treatment.[83]

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[76] Document LIO11979, Linda Mary Mynott's witness statement, paragraph 9.
[77] Document LIO0588, *'Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 40; document LIO1504, Society for Endocrinology's response to question 1 of the CMA's s.26 notice dated 20 December 2017.
[78] See document PAD011, NHS: '*Thyroid Cancer overview*'.
[79] The half-life of a drug is the time it takes for the amount of it in the body to be reduced by half.
[80] Document LIO1504, Society for Endocrinology's response to question 1 of the CMA's s.26 notice dated 20 December 2017.
[81] Document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 40; document LIO1504, Society for Endocrinology's response to question 1(a) of the CMA's s.26 notice dated 20 December 2017.
[82] Document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 40; document LIO2535, RCGP's response to question 1 of the CMA's s.26 notice dated 03 February 2017.
[83] Document LIO2034, Note of call between the CMA and the Society for Endocrinology dated 2 February 2017, page 9.

(d) *Myxoedema coma*: Myxoedema coma may be treated with Liothyronine Tablets given by stomach tube, although it is more usual for an injection to be used.[84]

(e) *Thyrotoxicosis*: Liothyronine Tablets can be used in the treatment of thyrotoxicosis as an adjunct to carbimazole to prevent sub-clinical hypothyroidism developing during treatment.[85]

III. Method of treatment (duration, dosage, and how the product works)

3.31 Liothyronine Tablets are the second line treatment for hypothyroidism. Where they are taken, they are taken orally and the dosage will vary depending on whether they are taken alone or in combination with Levothyroxine Tablets (which are the primary treatment - see paragraph 3.38 below).

a. Liothyronine Tablet strengths

3.32 Only 20mcg Liothyronine Tablets were available during the Infringement Period, although 5mcg and 10mcg strengths have subsequently been licensed. The information set out in this section relates to Liothyronine Tablets as they were prescribed during the Infringement Period, when no other strengths were available.

b. Use of Liothyronine Tablets alone

3.33 According to the Society for Endocrinology, a full thyroid hormone replacement using Liothyronine Tablets alone would generally require a daily dose of between 30mcg and 50mcg.[86] The SMPC for Liothyronine Tablets provides a slightly wider range, stating that for adults the starting dose is 10mcg or 20mcg every eight hours, increasing after one week, if necessary, to the usual recommended daily dose of 60mcg in two or three divided doses. A patient requiring a dose of less than 20mcg would need to cut or dissolve the Liothyronine Tablet to achieve the required dose.[87]

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[84] Document LIO3061, Advanz's response to question 6(b) of the CMA's s.26 notice dated 25 January 2017; see document PAD012, eMC: '*Liothyronine Sodium BP 20micrograms Tablets*'; see also document PAD013, '*Prescribing Information Liothyronine Sodium 20 micrograms Tablets*'.
[85] See document PAD012, MHRA: '*Summary of product characteristics*'.
[86] Document LIO1504, Society for Endocrinology's response to question 4(k) of the CMA's s.26 notice dated 20 December 2017.
[87] See document PAD012, MHRA: '*Summary of product characteristics*'; document LIO1504, Society for Endocrinology's response to question 4(k) of the CMA's s.26 notice dated 20 December 2016.

c. Combined use of Liothyronine Tablets and Levothyroxine Tablets

3.34 Where Liothyronine Tablets and Levothyroxine Tablets are taken in combination, the recommended combined dose is Levothyroxine Tablets 125mcg once daily and Liothyronine Tablets 5mcg twice daily. In practice, given that the only licensed dosage of Liothyronine Tablets in the UK during the Infringement Period was 20mcg, many patients took supra-physiological doses of Liothyronine Tablets such as 10mcg twice daily, recalibrating the combination by taking reduced dosages of Levothyroxine Tablets of 75mcg or 100mcg daily.[88]

IV. Manufacturing process

3.35 Liothyronine Tablets are difficult to manufacture '*due to the low amount of active substance in the product and potential sensitivity of liothyronine to apparently minor changes in processing technology*',[89] and are considered as '*non-standard*', requiring careful process design to assure uniformity of content of active substance.[90]

3.36 According to the MHRA:

> 'The manufacture of liothyronine products is to be considered complex despite using conventional blending, granulation and compression technology'.[91]
>
> 'Once formulated, liothyronine also shows a sensitivity to light and environmental conditions, showing adverse trends with temperature and humidity'.[92]

3.37 The MHRA confirmed that it is not aware of a manufacturing process for liothyronine that does not face challenges.[93] The manufacture of the Liothyronine Tablets supplied by Advanz is considered further below.

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[88] Patients receiving a 20mcg tablet may have to cut the tablets which is likely to provide a less consistent dosage than using products which are specifically manufactured at that strength: see document LIO1504, Society for Endocrinology's response to question 4(k) of the CMA's s.26 notice dated 20 December 2016.
[89] Document LIO1862, MHRA's response to question 5 of the follow-up questions to the CMA's s.26 notice dated 28 November 2016.
[90] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[91] Document LIO1862, MHRA's response to question 5 of the follow-up questions to the CMA's s.26 notice dated 28 November 2016.
[92] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[93] Document LIO1862, MHRA's response to question 5 of the follow-up questions to the CMA's s.26 notice dated 28 November 2016.

V. Other thyroid treatments

a. Levothyroxine Tablets

i. Description of product and presentation

3.38 Levothyroxine, which is a synthetic version of the hormone thyroxine (or T4), is the first line treatment for hypothyroidism and the vast majority of patients with hypothyroidism are effectively treated with Levothyroxine alone.[94] Thyroxine must be converted to triiodothyronine (T3, for which liothyronine is the synthetic version) to perform its function.[95] According to the Society for Endocrinology, most NHS endocrinologists:

> '[A]re reluctant to prescribe liothyronine for hypothyroidism, as there is little evidence of advantage over levothyroxine, however some will give a therapeutic trial of liothyronine used in combination with levothyroxine to find out if there is any benefit to the individual patient'.[96]

3.39 Liothyronine Tablets may however be preferred for treating severe and acute hypothyroid states because their effect is faster and more potent than that of Levothyroxine Tablets.[97]

3.40 While some hypothyroid patients are prescribed Liothyronine Tablets because they do not respond adequately to Levothyroxine Tablets, the patient groups are otherwise very similar.[98]

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[94] Levothyroxine has been the first line treatment for hypothyroidism throughout the Infringement Period. Document LIO2114.9, '*RCP statement 2011*', page 3; see also document LIO2152, BTA's response to questions 1 and 7(b) of the CMA's s.26 notice dated 13 February 2017; document LIO1504, Society for Endocrinology's response to questions 1 and 4(b) of the CMA's s.26 notice dated 20 December 2016; document LIO2268, TPA's response to question 6(b) of the CMA's s.26 notice dated 13 February 2017; document LIO2154, Wiersinga, W M, Duntas, L, Fadeyev, V, et al.: '*2012 ETA Guidelines: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism*', European Thyroid Journal, 2012, page 55.

[95] Document LIO2268, TPA's response to question 11 (a) of the CMA's s.26 notice dated 13 February 2017.

[96] Document LIO1504, Society for Endocrinology's response to question 4(a) of the CMA's s.26 notice dated 20 December 2016. See also document LIO2154, Wiersinga, W M, Duntas, L, Fadeyev, V, et al.: '*2012 ETA Guidelines: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism*', European Thyroid Journal, 2012, page 55; and document PAD169, Taylor, P N, Razvi, S, Muller, I, et al.: '*Liothyronine cost and prescriptions in England*', Lancet Diabetes Endocrinol 2019, which refers to document LIO2154, Wiersinga, W M, Duntas, L, Fadeyev, V, et al.: '*2012 ETA Guidelines: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism*', European Thyroid Journal, 2012, and states '*acknowledging the limitations (small size, short duration, inconsistent dosage) of previous studies, specialist society guidance recognises that a trial of liothyronine might be appropriate in selected patients*'.

[97] See document PAD012, MHRA: '*Summary of product characteristics*'; document LIO1504, Society for Endocrinology's response to question 4(k) of the CMA's s.26 notice dated 20 December 2016.

[98] Document LIO12119, '*Note of call with Simon Pearce (Newcastle University)',* 13 October 2020, paragraph 12.

3.41 Like Liothyronine Tablets, Levothyroxine Tablets can also be used to treat conditions other than hypothyroidism, such as goitre, and are prescribed for patients who have undergone treatment for thyroid cancer.[99]

3.42 Levothyroxine Tablets are a well-established medication, having been in use in the UK for more than 90 years. They were first synthesized in 1927 and launched under patent by Glaxo.[100] Advanz (then Goldshield) acquired the product in 1992 when it was marketed under the brand name Eltroxin, as part of the same transaction in which it acquired Liothyronine Tablets (see paragraph 3.22 above).[101]

3.43 Levothyroxine Tablets are now available as an unbranded generic product from different suppliers (see paragraph 3.195 below) in 12.5mcg, 25mcg, 50mcg, 75mcg and 100mcg strengths. Advanz's branded Eltroxin product is available in 25mcg, 50mcg and 100mcg strengths.[102]

3.44 Levothyroxine Tablets are typically sold in packs of 28. Packs of 500 and 1,000 tablets are also available from some suppliers, but they represent a small proportion of overall sales.[103]

3.45 The 12.5mcg and 75mcg strengths were introduced by Teva in 2016, and are also sold in packs of 28 tablets.[104]

3.46 According to the MHRA, 1,200 million Levothyroxine Tablets were prescribed in 2017 in the UK,[105] which is equivalent to up to 43 million packs of 28 tablets.[106]

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[99] Document PAD142, NHS: '*Treatment - Goitre*'; document PAD150, British Thyroid Foundation: '*Thyroid Cancer*'.
[100] See document LIO2155, '*Trends in thyroid hormone prescribing and consumption in the UK*', page 2; and document LIO0740, '*Mercury Pharma Confidential Information Memorandum*', page 59.
[101] See document LIO0740, '*Mercury Pharma Confidential Information Memorandum*', page 59; and document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 36.
[102] Document LIO2197, Teva's '*45116589_1_Annex 5.xls *License Product*'.
[103] From 2010 to 2016, packs of 500 and 1000 tablets (combined) accounted for between 0.16 and 0.42% of Advanz's total Levothyroxine Tablet sales. In 2017, packs of 500 and 1000 tablets (combined) accounted for 0.46% of sales (calculated from information provided in document LIO7460, Advanz 's '*Annex 1 - Data template with pack size*'). According to Accord-UK Ltd ('**AUK**'), which supplies Levothyroxine Tablets in packs of 28 and 1000, over the Infringement Period, the 1000 tablet packs have represented [✂] of sales volumes: see document LIO7453, AUK's response to question 2 of the CMA's s.26 notice dated 21 August 2018. Teva supplies Levothyroxine Tablets in packs of 28: see document PAD173, Teva: '*Teva addresses unmet patient need with UK levothyroxine launch*', 17 October 2016. Wockhardt states that it only supplies Levothyroxine Tablets in packs of 28: see document LIO7473, Wockhardt's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[104] Document LIO7456, Teva's response to question 1 of the CMA's s.26 notice dated 21 August 2018; and document PAD173, Teva: '*Teva addresses unmet patient need with UK levothyroxine launch*', 17 October 2016.
[105] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[106] This number may be slightly lower, taking into account packs of 500 and 1,000 tablets. However, as these are not a high proportion of packs sold, this is unlikely to be material.

ii. Manufacturing process

3.47 The manufacturing process for Levothyroxine Tablets has many similarities to the manufacturing process for Liothyronine Tablets.[107] Like Liothyronine Tablets, Levothyroxine Tablets are also difficult to manufacture and are considered '*non-standard*'.[108] The low content of active pharmaceutical ingredient per tablet presents challenges to assuring content uniformity.[109] Levothyroxine Tablets may be sensitive to parameters such as light, moisture and temperature, and '*conditions to maintain physical stability should be carefully defined prior to process design*'.[110] However, Liothyronine Tablets are less prone to instability and less sensitive to process conditions than Levothyroxine Tablets.[111]

iii. Differences between Liothyronine Tablets and Levothyroxine Tablets

3.48 Levothyroxine Tablets have a number of different properties compared to Liothyronine Tablets, including a longer half-life, which provides stable and physiological quantities of thyroid hormones for patients requiring replacement and makes them suitable for once-daily dosing. By contrast, Liothyronine Tablets have a much shorter half-life and steady-state levels cannot be maintained with once daily dosing.[112]

3.49 Guidance from the Royal College of Physicians states that Liothyronine Tablets have not been unequivocally proven to be of benefit in the treatment of hypothyroidism and their use should be reserved to accredited endocrinologists.[113] There has been guidance to this effect throughout the Infringement Period.[114] The Thyroid Patient Association considers that information provided by the Royal College of Physicians is not relied on greatly by its members '*partly because of problems in the methodology used in arriving at their conclusions (e.g. dismissal of research demonstrating*

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[107] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[108] Document LIO0246, MHRA's '*Levothyroxine Tablet Products: A Review of Clinical & Quality Considerations*', page 20.
[109] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[110] Document LIO0246, MHRA's '*Levothyroxine Tablet Products: A Review of Clinical & Quality Considerations*', pages 16 and 17.
[111] Document LIO6884, MHRA's response to question 2 of the CMA's s.26 notice dated 5 July 2018.
[112] See document PAD083, PrescQIPP Bulletin 121, February 2016.
[113] Document LIO2114.9, '*RCP statement 2011*', pages 3 and 4; see also document LIO2152, BTA's response to question 5 of the CMA's s.26 notice dated 13 February 2017.
[114] In 2007 the BTA released a statement that combined Liothyronine Tablets and Levothyroxine Tablets cannot be recommended: see document PAD010, BTA: '*A Statement from the British Thyroid Association Executive Committee February 2007*'. See also document PAD098, BTA: '*Management of primary hypothyroidism*'; document PAD191, NICE: '*Hypothyroidisim topic summary (2018)*'.

patient preference for T4 + T3 combinations), and partly because the importance of T3 for many patients, is not emphasised there'.[115]

3.50 According to the Society of Endocrinology:

> 'Most "conventional" NHS practitioners are reluctant to prescribe [Liothyronine Tablets] due to lack of evidence for benefit and increased risk of adverse effects. This not only encompasses lack of efficacy in RCTs [Randomised Controlled Trials], but physiological reasons including short half-life, widely fluctuating blood levels and difficulties in monitoring. This view is endorsed by British and American Thyroid Association guidelines'.[116]

3.51 Notwithstanding equivocal guidance, Liothyronine Tablets continue to be prescribed for hypothyroidism and the number of packs of Liothyronine Tablets dispensed in the UK increased from 122,354 in 2008 to 147,194 in 2016.[117] While Levothyroxine Tablets have been recognised as the first-line treatment for hypothyroidism throughout the Infringement Period, some NHS endocrinologists will give patients a therapeutic trial of Liothyronine Tablets used in combination with Levothyroxine Tablets to find out if there is any benefit to the individual patients; some GPs and private practitioners will also prescribe such treatment.[118] There is evidence that some patients who take Levothyroxine Tablets experience persistent symptoms despite adequate biochemical correction[119] and that some patients can either not convert or only slowly convert T4 into T3.[120] Lastly, Advanz's internal documents indicate that Liothyronine Tablets are preferred in cases of severe hypothyroid conditions as the drug metabolises faster than Levothyroxine.[121]

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[115] Document LIO2268, TPA's response to question 2 of the CMA's s.26 notice dated 13 February 2017.
[116] Document LIO1504, Society for Endocrinology's response to question 4(g) of the CMA's s.26 notice dated 20 December 2016.
[117] CMA analysis based on PCA data for England, Wales, Scotland and Northern Ireland which reports volumes in terms of number of tablets dispensed. As explained at paragraph 3.22 above, in October 2007 Advanz de-branded and reduced the pack size of its Liothyronine Tablets from 100 to 28 tablets. This resulted in a significant increase in the number of packs of Liothyronine Tablets dispensed in 2008. To take this change into account, the CMA has estimated the number of 28-tablet pack-size equivalents of Liothyronine Tablets dispensed.
[118] Document LIO1504, Society for Endocrinology's response to question 4(a) of the CMA's s.26 notice dated 20 December 2016.
[119] Document LIO2114.2, '*Management of Primary Hypothyroidism - Statement by BTA Exec Committee*', page 4; document LIO2157, '*BTA Executive Committee Information for members on prescribing Liothyronine (L-T3)*', December 2016, page 1; document PAD098, '*Management of primary hypothyroidism:statement by the BTA Executive Committee*', page 3.
[120] For example, the Di02 gene can cause problems with conversion of T4 to T3: document LIO2268, TPA's response to question 6(c) of the CMA's s.26 notice dated 13 February 2017. See also document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*', 19 October 2018, page 3.
[121] Document LIO1724, Advanz's '*Mercury PPA report.pdf*', page 21.

b. NDT

3.52 Natural Desiccated Thyroid ('**NDT**') is not a synthetic product but consists of raw animal thyroid hormone. It contains both T3 and T4, but in different amounts from that found in the human body.[122] It is available under various brand names including 'Armour Thyroid' but is not licensed in the UK.[123] The BTA states that '*[m]ost international guidelines recommend against the use of armour thyroid due to concerns with potential adverse effects*'.[124] Despite this, patient groups have stated that some patients have a preference for NDT.[125]

c. Other formulations of liothyronine sodium tablets and capsules

3.53 Several different formulations of liothyronine sodium are available in other countries and have been supplied in the UK as unlicensed products from time to time. The supply of these products is subject to separate regulatory guidance (see paragraph 3.112 below).[126] The MHRA informed the CMA that it had been notified of over 4,000 applications to import unlicensed liothyronine tablets and capsules into the UK from 1 January 2007 to April 2017.[127]

3.54 The significant majority of imports of unlicensed liothyronine were of tablets with strengths other than 20mcg, including 5mcg, 10mcg and 25mcg tablets.[128]

3.55 Liothyronine is also produced in capsule forms, which are not licensed in the UK. However, they may be used by patients who are allergic to the excipients used in Liothyronine Tablets.[129]

3.56 Liothyronine sodium is also available in the UK as a powder which is used to produce a solution administered to a patient as an injection. This is a licensed product for which the MA is held by Advanz. Liothyronine injection is used to treat severe under-activity of the thyroid gland (myxoedema) when it is not possible to administer a thyroid treatment orally. It may be used in

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[122] Document LIO2152, BTA's response to question 16(a) of the CMA's s.26 notice dated 13 February 2017.
[123] Document LIO2268, TPA's response to question 6(d) of the CMA's s.26 notice dated 13 February 2017.
[124] Document LIO2152, BTA's response to question 16(a) of the CMA's s.26 notice dated 13 February 2017. See also document PAD184, SPS NHS: '*What clinical evidence is there to support the use of desiccated thyroid extract products?*'.
[125] Document LIO2268, TPA's response to question 6(d) of the CMA's s.26 notice dated 13 February 2017, and document LIO2114.1, Thyroid UK's response to question 6(e) of the CMA's s.26 notice dated 08 February 2017.
[126] Unless certain exemptions apply, a medicinal product must be the subject of an MA or product licence before being placed on the market in the UK. The term 'unlicensed' is used to describe medicines which have no MA or product licence in the UK.
[127] Document LIO2772, MHRA's '*Response to Q3c CMA Project Forest.xls*'.
[128] Document LIO2772, MHRA's '*Response to Q3c CMA Project Forest.xls*'.
[129] Document LIO2268, TPA's response to question 11 of the CMA's s.26 notice dated 13 February 2017.

combination with other medicines such as steroids and is not used to treat hypothyroidism.[130]

3.57 Liothyronine can also be produced in liquid form. However, liquid formulations are only used for babies or small children and may give rise to dosing issues which lead to inadvertent over- or under-dosing.[131]

C. Regulatory framework for the supply of Liothyronine Tablets

3.58 This section describes the prescription of Liothyronine Tablets; how prescribing works; how dispensing takes place; the trends in volumes prescribed between September 2007 and July 2017; the authorisations needed to supply pharmaceutical products in the UK; and the pricing framework that applies.

I. Liothyronine Tablets are a prescription only medicine

3.59 Treatment of hypothyroid patients with Liothyronine Tablets is generally initiated in hospitals (secondary care) by a specialist, with subsequent prescriptions issued by GPs (primary care).[132] Less commonly, hypothyroid patients may also be diagnosed by their GP and referred to an endocrinologist.[133]

3.60 Liothyronine Tablets are not available for purchase over-the-counter, but must be prescribed by a GP or an endocrinologist.[134]

3.61 Healthcare professionals select the relevant medicine to prescribe for the patient based on what is therapeutically most appropriate and effective.[135] While the NHS typically pays for the medicine, healthcare professionals'

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[130] See document PAD078, MHRA: '*Liothyronine Sodium 20 micrograms Powder for Solution for Injection*'.
[131] Document LIO1504, Society for Endocrinology's response to question 10 of the CMA's s.26 notice dated 20 December 2016.
[132] Document LIO2675, Advanz's response to question 14 of the CMA's s.26 notice dated 29 March 2017.
[133] Document LIO2114.1, Thyroid UK's response to questions 6(a)-(c) of the CMA's s.26 notice dated 08 February 2017; and document LIO2268, TPA's response to question 6(j) of the CMA's s.26 notice dated 13 February 2017, where the TPA states that '*[s]hould Levothyroxine fail to resolve the patient's hypothyroidism, and if symptoms cannot be attributed to any other problems, then the only remaining option (nowadays usually on the advice of an endocrinologist), is to try a combination of Liothyronine and Levothyroxine, Liothyronine alone, or NDT.*'
[134] See document PAD071, Mercury Pharma: '*Liothyronine Sodium BP 20micrograms Tablets*'.
[135] While doctors may not choose which medicine to prescribe based on prices (or indeed have limited awareness of the prices of different pharmaceutical products), their prescribing behaviour may nevertheless be indirectly informed by price insofar as they are increasingly encouraged to prescribe generic (rather than branded) products, to follow prescribing guidelines (for example, through use of pre-approved formularies) and to meet certain budgetary objectives at local level.

prescribing decisions are not typically driven primarily by price considerations.[136]

3.62 Once a patient is established on a particular medicine, there are often significant medical reasons why it is disadvantageous to alter their medication. For example, patients who are established on Liothyronine Tablets who then transfer to another drug, such as Levothyroxine Tablets, may be exposed to clinical risks and may experience a deterioration in their quality of life and well-being.[137] There may be additional costs associated with altering a patient's medication, including further GP time in effecting a switch.[138]

3.63 The ability of the dispenser (typically the pharmacy) to decide which medicine to dispense is limited by the prescriber's decision. Within the parameters of the prescription, the dispenser will typically choose the cheapest version of the medicine, since it pays for the drug and is reimbursed by the NHS at a fixed level (see paragraphs 3.87 to 3.88 below).

II. Prescribing

3.64 As Liothyronine Tablets are no longer sold as a branded product, prescriptions are generally 'open' (that is, they specify the generic name, dosage and tablet strength) as distinct from 'closed' (which specify the particular brand, manufacturer or supplier). Most of the pharmacies contacted by the CMA confirmed that prescriptions for Liothyronine Tablets are generally 'open'.[139]

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[136] A market study by the OFT in 2007 found that doctors' ability to rank branded drugs in order of price was generally no better than chance: document PAD151, OFT: '*The Pharmaceutical Price Regulation Scheme - An OFT market study*', February 2007, box 2.3, page 23 and Annex C. These findings were based on a survey of 1,000 English GPs conducted as part of research by the National Audit Office into value for money in primary care. Although the data used to inform the study were collected in 2006, the findings are still relevant to GPs' behaviour during the Infringement Period given the proximity of the timing of this report to the start of the Infringement Period. While these findings related to doctors' ability to rank certain branded products (and hypothyroid treatments were not one of the medicine classes considered), these products were included because they are commonly prescribed and familiar to most clinicians. As Liothyronine Tablets are unbranded and likely to be less frequently prescribed, the CMA considers that the finding of doctors' price insensitivity would also hold for Liothyronine Tablets. See also a Department of Health study published in 2002, which found that '*Most prescribers did not assimilate information on drug costs and price changes and were often unaware of prices or price changes*': document PAD123, Association of the British Pharmaceutical Industry ('ABPI') and DHSC: '*PPRS: The study into the extent of competition in the supply of branded medicines to the NHS*', December 2002, pages 16 and 162.

[137] Document LIO2152, BTA's response to questions 12, 14(d) and 15 of the CMA's s.26 notice dated 13 February 2017; see also document PAD014, BTA: '*Info for endocrinologists*'.

[138] Document LIO2114.1, Thyroid UK's response to question 9(e) of the CMA's s.26 notice dated 08 February 2017.

[139] Document LIO2592, Lloyds Pharmacy Ltd's response to question 10 of the CMA's s.26 notice dated 10 February 2017; document LIO2226, Boots UK Ltd's response to question 10 of the CMA's s.26 notice dated 10 February 2017; document LIO2611, Superdrug Stores PLC's response to question 10 of the CMA's s.26 notice dated 10 February 2017; document LIO2214, Wm Morrison Supermarkets PLC's response to question 10 of the

3.65 Prescribers have a number of sources of information available when making a prescribing decision, including professional recommendations. Prescribers may also prescribe unlicensed medicinal products (see paragraph 3.53 above).

a. Recommendations from specialist bodies

3.66 GPs and specialist prescribers receive professional recommendations and guidance which they may take into account in their prescribing decisions. Professional recommendations and guidance issued by entities such as the National Institute for Health and Care Excellence ('**NICE**'), various clinical commissioning groups ('**CCGs**'), PrescQIPP and the NHS Clinical Commissioners ('**NHSCC**') have specifically dealt with the prescription of Liothyronine Tablets.

i. NICE

3.67 NICE is a non-governmental public body which provides national guidance and advice to improve health and social care.[140] This guidance includes technology appraisals aimed at ensuring that the NHS provides access to clinically and cost-effective treatments.[141]

3.68 NICE provides Clinical Knowledge Summaries ('**CKS**'), which are summaries of current evidence in relation to common and significant presentations in primary care, for use by primary care professionals to assist in their decision-making.[142] The hypothyroidism CKS provides guidance on the condition, including in relation to diagnosis, management and prescribing. It recommends prescribing Levothyroxine Tablets in primary care, as opposed to combination therapy (i.e. Liothyronine Tablets and Levothyroxine Tablets), although it notes that combination therapy may be considered by endocrinology specialists and that Liothyronine Tablets are sometimes prescribed when Levothyroxine Tablets fail.[143] NICE has recommended Levothyroxine Tablets as a first-line treatment throughout the Infringement Period.[144]

CMA's s.26 notice dated 10 February 2017; document LIO2509, L Rowland & Co's response to question 10 of the CMA's s.26 notice dated 10 February 2017; document LIO2220, Tesco Stores Ltd's response to question 10 of the CMA's s.26 notice dated 10 February 2017; and document LIO2258, Well Pharmacy's response to question 10 of the CMA's s.26 notice dated 10 February 2017.

[140] Document PAD015, NICE: '*Who we are*'. NICE's role is officially limited to England, but its guidance may also be used by the devolved administrations in Wales, Scotland and Northern Ireland.

[141] Document PAD192, NICE: '*What we do*'.

[142] Document PAD016, NICE: '*About*'.

[143] Document PAD191, NICE '*Hypothyroidisim topic summary (2018)*'. See also document PAD207, NICE guideline: '*Thyroid disease: assessment and management*', 20 November 2019, pages 11 and 34.

[144] Document PAD017, NICE '*Hypothyroidism CKS*'.

ii. CCGs

3.69 CCGs are statutory bodies responsible for planning and commissioning health care services for their local areas. There were 207 CCGs in England around the end of the Infringement Period, reducing to 106 by the date of this Decision.[145] CCGs may seek to reduce costs to meet their prescribing budgets, for example by identifying cheaper alternative drugs that can be prescribed to patients, provided this can be done while preserving the same (or better) levels of patient care. For example, some CCGs have recently issued guidance to GPs recommending the routine prescribing of Levothyroxine Tablets as opposed to Liothyronine Tablets for the treatment of hypothyroidism.[146]

3.70 CCGs took varying approaches to their recommendations regarding prescribing Liothyronine Tablets during the Infringement Period. Advanz submitted an analysis, which the CMA accepts, summarising the recommendations contained within CCG Guidance[147] as follows:

(a) The majority of CCGs recommend prescribing Levothyroxine Tablets as a first line treatment, with the use of Liothyronine Tablets being restricted in some way, for example only to be prescribed by a specialist, or only to be used by existing patients but not for new patients.

(b) A minority of CCGs (less than 20%) recommend only prescribing Levothyroxine Tablets.

(c) A very small number of CCGs do not indicate a preference for either Liothyronine Tablets or Levothyroxine Tablets in treating hypothyroidism.

3.71 Evidence submitted to Parliament by a coalition of thyroid groups in October 2018 found that there is a variation in the prescribing rates of CCGs of almost 5,000%.[148] In a response to a written question in January 2018, Lord O'Shaughnessy, the then Under Secretary of State for Health in the House of Lords, confirmed that '*[a] number of CCGs had already created local policies on the prescribing of liothyronine before the national consultation started in*

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[145] Document PAD018, NHSCC: '*CCGS*', dated 2017; NHSCC: *'CCGs*', updated in 2021, available at: https://www.nhscc.org/ccgs/.
[146] Document LIO3061, Advanz's response to question 1(e) of the CMA's s.26 notice dated 25 January 2017; See also document LIO7789.12, NHS Brighton and Sussex University Hospitals: '*Information for patients currently treated with T3 (liothyronine)*'.
[147] Document LIO2944, Advanz's response to question 4 of the CMA's s.26 notice dated 26 May 2017, and document LIO2945.9, Advanz's '*Annex 10 - CCG guidance analysis*'. The CMA has reviewed the analysis and while it does not agree with Advanz's classifications of the guidance in all cases, these differences do not undermine the overall findings to any great extent.
[148] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*', 19 October 2018, page 4.

July 2017'.[149] The minister subsequently confirmed in July 2018 that the NHSCC '*will reiterate to clinical commissioning groups (CCGs) by the end of July 2018 that the intention of the guidance was to end the routine prescription of liothyronine only where it was clinically appropriate to do so*'.[150] However, in the meantime, the practices of CCGs have varied. A motion to regret moved in the House of Lords in June 2018 in relation to the Branded Health Service Medicines (Costs) Regulations 2018 regretted that those Regulations '*do not propose any action to be taken in respect of the high cost charged by [Advanz] and other companies for the drug Liothyronine for the treatment of hypothyroidism, thereby depriving patients of the use of that essential drug, and further do not put an end to the practice of a growing number of Clinical Commissioning Groups refusing to follow the latest guidance from NHS England on making that drug available to NHS patients via referral to thyroid specialists'*.[151]

3.72 CCGs rely on GP prescribing software to disseminate recommendations and prescribing information. This software provides GPs with national and locally authored patient safety information messages, recommendations, and other prescribing information.[152, 153]

iii. PrescQIPP

3.73 PrescQIPP is an organisation that works to help identify areas for potential changes in prescribing practice. It is an NHS-funded not-for-profit organisation that supports quality, optimised prescribing for patients. It produces evidence-based resources and tools for primary care commissioners, including prescribing guidance on the best treatment options, taking into account the primary considerations of clinical efficacy and patient welfare, as well as cost.[154] The vast majority of CCGs are members of PrescQIPP.[155] PrescQIPP's forward annual work plan is set each year in consultation with its

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[149] Document PAD175, UK Parliament: '*Liothyronine:Written question - HL5228*'. The national consultation refers to the consultation carried out by the NHSCC (see paragraph 3.76 below).
[150] Document PAD176, UK Parliament: '*Liothyronine:Written question - HL9699*'. See also document PAD177, UK Parliament: '*Liothyronine:Written question - 169810*'.
[151] Document PAD178, UK Parliament: '*Motion to Regret moved by Lord Hunt of Kings Heath on 20 June 2018*', Volume 791, Column 2066 (text only).
[152] Document PAD122, '*Prescribing in General Practice*', page 3.
[153] Software providers have told the CMA that their software does not provide alternative drug recommendations at the point of prescribing: document LIO3834, INPS Ltd's response to question 6 of the CMA's s.26 notice dated 19 July 2017; document LIO3837, The Phoenix Partnership (TPP) Ltd's response to question 6 of the CMA's s.26 notice dated 19 July 2017; document LIO3977, EMIS Group PLC's response to the CMA's s.26 notice dated 19 July 2017, page 5; document LIO3966, CSC Computer Science Limited's response to question 6 of the CMA's s.26 notice dated 19 July 2017. One software provider, ScriptSwitch, told the CMA that software users (e.g. CCGs) could configure ScriptSwitch's software to provide prescribers with targeted information, for example relating to price savings: document LIO3862, ScriptSwitch Ltd's response to questions 5 and 6 of the CMA's s.26 notice dated 19 July 2017.
[154] See document PAD019, PrescQIPP: '*Info*'.
[155] See document PAD020, PrescQIPP: '*Subscribers*'.

members. In 2012, PrescQIPP released its first list of Drugs to Review for Optimised Prescribing ('**DROP-List**'), which includes drugs that commissioners consider to be low priority, poor value for money or for which there were safer alternatives.[156]

3.74 In July 2015, PrescQIPP added Liothyronine Tablets to the DROP-List. It noted that '*as with all switches, patients will need to be considered individually to determine whether a particular switch is suitable for them*'.[157] In February 2016, PrescQIPP issued a bulletin reinforcing the recommendation to review all patients taking Liothyronine Tablets (alone or in combination with Levothyroxine Tablets) for suitability for switching to Levothyroxine Tablets and to switch all suitable patients to Levothyroxine Tablets.[158]

3.75 The Society for Endocrinology told the CMA that the inclusion of Liothyronine Tablets on the DROP-List may have had a regional impact on GP decisions to prescribe Liothyronine Tablets, dependent on local CCG implementation of the advice.[159] The BTA's view is consistent with this, confirming that the weight placed on price over clinical need was likely to be '*highly variable amongst prescribers*'.[160]

iv. NHSCC guidance

3.76 On 21 July 2017, the NHSCC, the membership organisation of CCGs, published draft guidance for CCGs, setting out advice on medicines of low priority for NHS funding.[161] The guidance was finalised on 30 November 2017 following consultation.[162]

3.77 The consultation which preceded the final NHSCC guidance included Liothyronine Tablets in the category of '*[i]tems which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation*', on the basis that the price of Liothyronine Tablets '*has risen significantly and there is limited evidence for efficacy above Levothyroxine*'. It proposed that treatment with Liothyronine

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[156] Document PAD021, PrescQIPP Bulletin 117, July 2015.
[157] Document PAD021, PrescQIPP Bulletin 117, July 2015.
[158] Document PAD083, PrescQIPP Bulletin 121, February 2016.
[159] Document LIO1504, Society for Endocrinology's response to question 7 of the CMA's s.26 notice dated 20 December 2016.
[160] Document LIO2152, BTA's response to question 8 of the CMA's s.26 notice dated 13 February 2017.
[161] Document PAD022, NHSCC: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*'.
[162] Document PAD127, NHSCC: '*Items which should not routinely be prescribed in primary care: Guidance for CCGs*' (the '**NHSCC guidance**'). See also document LIO12042, Julie Lizbeth Wood's witness statement.

Tablets should not be initiated in new patients, and that prescribers should be supported in de-prescribing Liothyronine Tablets.[163]

3.78 However, although Liothyronine Tablets remained in this category, the final NHSCC guidance departed from the proposals in the consultation, stating that it had received a significant number of responses arguing that '*liothyronine is an effective treatment which is invaluable to patient wellbeing, quality of life and condition management*'. On that basis, the issued NHSCC guidance states that '*prescribing of liothyronine in appropriate patients should be initiated by a consultant endocrinologist in the NHS, and that deprescribing in "all" patients is not appropriate as there are recognised exceptions*'.[164]

3.79 The NHSCC summarised responses to its consultation in support of its final position. The majority of respondents stated that Liothyronine Tablets should be prescribed in primary care '*if, in exceptional circumstances, there is a clinical need*'. This view was shared by clinicians as well as patients, members of the public and other organisations. Against this, there was little support for allowing prescribing of Liothyronine Tablets among CCGs, linked to the cost of Liothyronine Tablets: '*Our CCGs have been actively pursuing a reduction in Liothyronine prescribing in recent months. […] At a lower cost, there would be less need to pursue deprescribing of a medication that some patients feel very strongly have had a positive effect on their quality of life*'.[165]

v. Other considerations

3.80 In terms of factors influencing prescribing decisions, The Society for Endocrinology indicated that pressure from patients is likely to play a significant role in the prescribing of Liothyronine Tablets as a growing number of patients demand treatment based on information they have obtained from patient forums and from the internet.[166] Prescribing doctors are required to conduct a thorough examination for alternative causes of ill-health before prescribing Liothyronine Tablets. Only in exceptional circumstances where no alternative causes are identified, may patients be considered for a trial of Liothyronine Tablets.[167]

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[163] Document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*'.
[164] Document PAD127, NHSCC guidance, page 8 and section 4.9.
[165] Document LIO7789.15, NHSCC: '*Items which should not be routinely prescribed in primary care: Consultation Report of Findings*', section 4.9.
[166] Document LIO1504, Society for Endocrinology's response to question 4(g)-(i) of the CMA's s.26 notice dated 20 December 2016; document LIO2152, BTA's response to question 9 of the CMA's s.26 notice dated 13 February 2017.
[167] Document LIO2152, BTA's response to question 7 of the CMA's s.26 notice dated 13 February 2017 and document LIO1504, Society for Endocrinology's response to question 4b of the CMA's s.26 notice dated 20 December 2016.

b. Prescribing unlicensed medicinal products

3.81 According to the General Medical Council's guidance on '*[g]ood practice in prescribing and managing medicines and devices*', doctors should usually prescribe licensed medicines in accordance with the terms of their licence. However, doctors may prescribe unlicensed medicines where, on the basis of an assessment of the individual patient, they conclude, for medical reasons, that it is necessary to do so to meet the specific needs of the patient. The guidance goes on to say that prescribing unlicensed medicines may be necessary where:

(a) There is no suitably licensed medicine that will meet the patient's need;

(b) A suitable licensed medicine that would meet the patient's need is not available, for example where there is a shortage in supply; or

(c) The prescribing forms part of a properly approved research project.[168]

3.82 The MHRA indicates that it is for the prescriber to decide whether an individual patient has '*special needs*' which a licensed product cannot meet.[169] Accordingly, the clinical risk of prescribing the correct medication sits with the prescribing clinician.

3.83 In May 2013, there was a shortage of Liothyronine Tablets in the UK.[170] The MHRA recognised the potential need to prescribe unlicensed liothyronine instead, but pointed to the risks of such unlicensed products by stating that unlicensed liothyronine and Liothyronine Tablets may not be interchangeable.[171] MHRA guidance states that if an unlicensed product is supplied in response to a supply shortage of the applicable licensed product, this should be seen as a temporary expedient and should not be taken as a justification for long-term supply.[172]

III. Dispensing

3.84 Pharmacy dispensing is a specialised and heavily regulated profession.[173]

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[168] Document PAD023, General Medical Council: '*Good practice in prescribing and managing medicines and devices*', paragraphs 67-69.
[169] Document PAD168, MHRA: '*The supply of unlicensed medicinal products ("specials")*' ('**MHRA 14**').
[170] Document PAD079, GOV.UK: '*Liothyronine 20 microgram tablets: continuity of supply and potential need for patient monitoring*'.
[171] Document PAD099, MHRA: '*Liothyronine (Tertroxin) 20 microgram tablets - continuity of supply – update*'.
[172] Document PAD168, MHRA 14, paragraph 2.5.
[173] In England and Wales, the activities of pharmacies are governed by various regulations, particularly the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013 SI 2013/349. Similar regulations apply in Scotland and Northern Ireland.

3.85 The majority of pharmacies told the CMA that they did not routinely stock or dispense unlicensed liothyronine during the Infringement Period.[174] Boots said that, if a patient presented a prescription indicating an unlicensed version, it would liaise with the prescriber to discuss whether a licensed version was appropriate and, if not, either try to order the unlicensed drug or [✂].[175]

3.86 Boots and Superdrug purchased both licensed and unlicensed liothyronine.[176] The proportion of Boots' total purchases of liothyronine accounted for by unlicensed liothyronine rose from [✂] in 2011 to [✂] in 2016.[177] Both Boots and Superdrug explained that unlicensed products in general were ordered in response to specific patient demand.[178]

3.87 When choosing which supplier to use, most pharmacies said they took price into account.[179] However, most pharmacies also said that they paid their wholesaler's list price for Liothyronine Tablets and did not have any influence over this price, although they may negotiate percentage discounts on the wholesaler's prices.[180] Well Pharmacy added that it had made a number of complaints to Advanz, including in relation to '*continual price increases*'.[181]

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[174] Document LIO2592, Lloyds Pharmacy Ltd's response to question 3 of the CMA's s.26 notice dated 10 February 2017; document LIO2226, Boots UK Ltd's response to question 4 of the CMA's s.26 notice dated 10 February 2017; document LIO2518, Asda Stores Ltd's response to question 3 of the CMA's s.26 notice dated 10 February 2017; document LIO2509, L Rowland & Co's response to question 3 of the CMA's s.26 notice dated 10 February 2017; document LIO2511, Phoenix Healthcare Distribution Ltd ('**Phoenix Healthcare**')'s response to question 3 of the CMA's s.26 notice dated 10 February 2017; document LIO2611, Superdrug Stores PLC's response to question 4 of the CMA's s.26 notice dated 10 February 2017; document LIO2258, Well Pharmacy's response to questions 3 and 4 of the CMA's s.26 notice dated 10 February 2017; document LIO2220, Tesco Stores Ltd's response to questions 3 and 4 of the CMA's s.26 notice dated 10 February 2017; and document LIO2214, Wm Morrison Supermarkets PLC's response to questions 3 and 4 of the CMA's s.26 notice dated 10 February 2017.

[175] Document LIO2226, Boots UK Ltd's response to question 4 of the CMA's s.26 notice dated 10 February 2017.

[176] Document LIO2226, Boots UK Ltd's response to questions 1 and 3 of the CMA's s.26 notice dated 10 February 2017; document LIO2611, Superdrug Stores PLC's response to questions 1 and 3 of the CMA's s.26 notice dated 10 February 2017.

[177] Document LIO2226, Boots UK Ltd's response to question 3 of the CMA's s.26 notice dated 10 February 2017.

[178] Document LIO2611, Superdrug Stores PLC's response to question 4 of the CMA's s.26 notice dated 10 February 2017. [✂]. Document LIO2226, Boots UK Ltd's response to questions 4 and 11 of the CMA's s.26 notice dated 10 February 2017.

[179] Document LIO2226, Boots UK Ltd's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2518, Asda Stores Ltd's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2509, L Rowland & Co's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2592, Lloyds Pharmacy Ltd's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2214, Wm Morrison Supermarkets PLC's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2611, Superdrug Stores PLC's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2220, Tesco Stores Ltd's response to question 6 of the CMA's s.26 notice dated 10 February 2017; document LIO2258, Well Pharmacy's response to question 6 of the CMA's s.26 notice dated 10 February 2017. Other factors cited by some pharmacies included: availability; security of supply; credibility of supplier; licensing; and patient suitability and safety.

[180] Document LIO2518, Asda Stores Ltd's response to question 8 of the CMA's s.26 notice dated 10 February 2017; document LIO2258, Well Pharmacy's response to questions 8 and 9 of the CMA's s.26 notice dated 10 February 2017; document LIO2509, L Rowland & Co's response to question 8 of the CMA's s.26 notice dated 10 February 2017; and document LIO2220, Tesco Stores Ltd's response to question 8 of the CMA's s.26 notice dated 10 February 2017.

[181] '*The prices were dictated to us*': document LIO2258, Well Pharmacy's response to questions 8 and 9 of the CMA's s.26 notice dated 10 February 2017.

3.88 Pharmacies receive payment for the prescriptions they fulfil from the NHS patient's CCG.[182] The amount they receive in respect of licensed products is set by the price of the product listed in the Drug Tariff (less any discount) – see paragraph 3.141 below. Pharmacies dispensing unlicensed medicinal products are reimbursed the price they pay for that product (i.e. invoice price less any discount or rebate given), unless the product is listed under Part VIIIB of the Drug Tariff. Unlicensed products, including unlicensed liothyronine, are not listed under Part VIIIB of the Drug Tariff.

IV. Distribution of Liothyronine Tablets

3.89 Advanz relies on the use of intermediaries to distribute Liothyronine Tablets in the UK.

3.90 During the Infringement Period, Advanz used a pre-wholesaler (Alloga) which stored the Liothyronine Tablets prior to distributing them in response to orders received from Advanz's wholesalers. The pre-wholesaler invoiced the wholesaler on behalf of Advanz, managed Advanz's product inventory, and provided additional customer services. Advanz paid the pre-wholesaler a service fee for its provision of services.[183]

3.91 Advanz's wholesalers store, distribute and sell Liothyronine Tablets in response to orders from pharmacies and hospitals.[184] During the Infringement Period, wholesaler prices to pharmacies were set by reference to the Drug Tariff Price for each product.[185]

3.92 At the outset of the Infringement Period, Advanz supplied Liothyronine Tablets through one of two wholesalers: Alliance Healthcare (Distribution) Ltd ('**Alliance**') or AAH Pharmaceuticals Ltd ('**AAH**'). From 20 December 2014 until at least the end of the Infringement Period, Liothyronine Tablets were only available from Alliance.[186]

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[182] The CCGs are the relevant purchasers in England. The purchasing entities differ in Scotland, Wales and Northern Ireland, but the CMA considers that this does not materially impact the findings in this Decision.
[183] [✂].
[184] Document LIO1521, Advanz's response to question 3(e) of the follow-up questions to the CMA's s.26 notice dated 25 October 2016.
[185] Document LIO1521, Advanz's response to question 3(c) of the follow-up questions to the CMA's s.26 notice dated 25 October 2016. See also paragraph 3.141 below.
[186] Document LIO1096, Advanz's response to question 12 of the CMA's s.26 notice dated 25 October 2016.

3.93 Most pharmacy groups have a single primary wholesaler at any given time and would only use other wholesalers when they could not source a particular product from their primary wholesaler.[187]

V. Marketing Authorisations and licences to import unlicensed medicinal product

3.94 Pharmaceutical manufacturers and distributors operating in the UK are subject to a system of licensing and inspection. Unless exempt, a medicinal product must be covered by a marketing authorisation ('**MA**') before being placed on the market in the UK.[188]

a. Marketing Authorisations

3.95 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. Where an application for an MA relates to a generic product, the manufacturer must demonstrate by means of a bioequivalence study that the generic product is therapeutically equivalent to the reference product and that standards of efficacy and safety are the same.[189]

3.96 A company which holds an MA may manufacture the pharmaceutical product itself or contract with a third-party to manufacture the pharmaceutical product on its behalf. The company which holds the MA (and not the third-party manufacturer) is primarily responsible for ensuring that the product complies with its licence and other applicable legislation.

3.97 In the UK, MAs are granted by the MHRA. MAs identify specifications relating to the manufacturing of the licensed product. If a particular batch of the licensed product does not comply with these specifications for any reason, the MA holder would need to seek approval from the MHRA if it wished to place the product on the market. If no alternative product is available, the MHRA may allow the product to be released following a review of the benefits and

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[187] Document LIO2592, Lloyds Pharmacy Ltd's response to question 1 of the CMA's s.26 notice dated 10 February 2017; document LIO2226, Boots UK Ltd's response to question 1 of the CMA's s.26 notice dated 10 February 2017 (Boots stated in addition that it '*purchased medicines from the wholesaler Sangers (NI) Limited … until September 2016*' in Northern Ireland); document LIO2518, Asda Stores Ltd's response to question 1 of the CMA's s.26 notice dated 10 February 2017; document LIO2611, Superdrug Stores PLC's response to question 1 of the CMA's s.26 notice dated 10 February 2017; document LIO2258, Well Pharmacy's response to question 1 of the CMA's s.26 notice dated 10 February 2017; document LIO2220, Tesco Stores Ltd's response to question 1 of the CMA's s.26 notice dated 10 February 2017; and document LIO2214, Wm Morrison Supermarkets PLC's response to question 1 of the CMA's s.26 notice dated 10 February 2017.
[188] The Human Medicines Regulations 2012, Part 4.
[189] See the Human Medicines Regulations 2012, and in particular Part 5.

risks of placing such product on the market. In such circumstances, the approval is referred to as a batch specific variation ('**BSV**').[190]

b. Increased complexity

3.98 Although the pharmaceutical regulatory framework in the UK was stable during the Infringement Period, some of the requirements associated with the MA application process have increased in complexity.[191] According to the MHRA, some products which were granted a licence before around 2000 might not necessarily be awarded a licence under the MA application process which applied towards the end of the Infringement Period.[192]

c. Marketing Authorisation applications for Liothyronine Tablets

3.99 Until June 2017, Advanz was the only holder of an MA for Liothyronine Tablets, although several other MAs had been applied for. Since then, two MAs for Liothyronine Tablets have been granted and additional applications have been made (see paragraph 3.110 below).

3.100 On 15 June 2017, the MHRA granted Morningside an MA in respect of Liothyronine Tablets. Morningside had commenced development in 2012 and submitted its application for the MA on 13 July 2015, following which it received a number of deficiency letters from the MHRA.[193] Morningside stated that '*the process for obtaining [an MA] was also challenging*', despite receiving '*tremendous support from the MHRA*'.[194] Morningside subsequently submitted further data which the MHRA reviewed in January 2017 and considered satisfactory.[195]

3.101 In 2017, [✂].[196] Further, at the time of the NHS review of its guidance for Liothyronine Tablets (see paragraphs 3.76 to 3.79 above), Morningside said that it [✂].[197] Morningside has subsequently stated that '*based on current demand, Morningside is able to meet all requirements without increasing manufacturing capacity*'.[198]

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[190] Document LIO1460, Note of call between the CMA and the MHRA dated 2 December 2016.
[191] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 32.
[192] Document LIO1460, Note of call between the CMA and the MHRA dated 2 December 2016.
[193] Document LIO2017, Morningside's response to question 1 of the CMA's s.26 notice dated 25 January 2017.
[194] Document LIO3232, Morningside's response to questions 2(a) and 3(a) of the CMA's s.26 notice dated 7 July 2017.
[195] Document LIO3022, MHRA's '*Public Assessment Report*'.
[196] Document LIO3962, Morningside's response to question 3 of the follow-up questions to the CMA's s.26 notice dated 7 July 2017.
[197] Document LIO3962, Morningside's response to question 3 of the follow-up questions to the CMA's s.26 notice dated 7 July 2017.
[198] Document LIO6435.1, Morningside's response to question 2 of the CMA's s.26 notice dated 11 May 2018.

3.102 Morningside commenced supplying Liothyronine Tablets on 21 August 2017, with a weighted average sales price of [✂].[199]

3.103 Morningside's [✂].[200]

3.104 Morningside [✂].[201]

3.105 On 22 August 2019, Morningside was additionally granted an MA in respect of 5mcg and 10mcg strengths of liothyronine.[202]

3.106 On 14 August 2017, the MHRA granted Teva an MA in respect of Liothyronine Tablets. Teva first contacted the MHRA regarding an MA application for the manufacture of Liothyronine Tablets in [✂] 2014 and submitted an application on [✂].[203]

3.107 Teva began supplying Liothyronine Tablets on 29 September 2017, with a weighted average sales price of £230 per pack.[204] Teva's weighted average sales price had [✂] per pack by February 2021.[205]

3.108 Teva informed the CMA that it had first identified an opportunity in the Liothyronine Tablets market in July 2014:

> 'Teva had recently completed development of Levothyroxine (another compound used to replace thyroid hormone) and had therefore become aware of compounds in this therapeutic area and developed some relevant technical expertise'.[206]

3.109 It identified that '*[t]he price is increased every quarter, maybe due to lack of competition, volume is slightly decreasing (-4%)*',[207] and set out its aspirations, referring to a '*highly profitable product with a significant market share for Teva UK* [✂]'.[208] Teva informed the CMA that:

> '[W]hen deciding whether or not to develop Liothyronine, Teva's analysis indicated that the then sales of Liothyronine in the UK were estimated to be in the region of US$17 million. As such, at

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[199] Document LIO6435.2, Morningside's response to question 1 of the CMA's s.26 notice dated 11 May 2018.
[200] Document LIO12177, Morningside's response to the CMA's s.26 notice dated 8 March 2021.
[201] Document LIO7809, DHSC's response to the CMA's s.26 notice dated 14 March 2019.
[202] Document LIO12070, MHRA's response to the CMA's s.26 notice dated 7 September 2020.
[203] Document LIO2195, Teva's response to question 6 of the CMA's s.26 notice dated 25 January 2017.
[204] Document LIO6442, Teva's response to questions 1 and 2 of the CMA's s.26 notice dated 11 May 2018, and document LIO6443, Teva's '*66698419_1_Annex 1 (2).XLSB*'.
[205] Document LIO12182, Teva's response to the CMA's s.26 notice dated 8 March 2021.
[206] Document LIO2195, Teva's response to question 2 of the CMA's s.26 notice dated 25 January 2017.
[207] Document LIO2196, Teva's '*45117645_1_Annex 1.pdf *Liothyronine Presentation*', page 7.
[208] Document LIO2196, Teva's '*45117645_1_Annex 1.pdf *Liothyronine Presentation*', page 10.

the time Teva anticipated that, on a best case scenario, it could therefore capture sales of approximately [✂] million'.[209]

3.110 Other companies that have applied for an MA are either continuing to work with the MHRA to satisfy its requirements, or have withdrawn their MA applications rather than engage in further investment to obtain an MA:

(a) On [✂], [PE16] submitted an application for an MA in respect of Liothyronine Tablets.[210] [✂]. It's application was pending as at 10 March 2021 and the MHRA has not announced the grant of an MA at the date of this Decision.[211]

(b) [PE1] initiated a development project for Liothyronine Tablets in [✂].[212] Its application was pending as at 5 March 2021 and [PE1] has told the CMA that it anticipates approval of its application [✂].[213]

(c) In 2011, [PE3] sought to enter the UK [✂] markets with [✂] as its supplier for the API.[214] [PE3] operates in [✂], commercialising both liothyronine and levothyroxine. [✂], however, ceased its supply of the API for the UK market in 2013.[215] In September 2013 [PE3] withdrew its MA application.[216] [PE3] informed the CMA that it had discovered during the application process [✂].[217]

(d) [PE2] submitted an application for an MA for the supply of Liothyronine Tablets on [✂] 2016, with the intention of launching the product in Q4 2017 or Q1 2018.[218] [✂].[219] In 2020 [PE2] informed the CMA that it had decided to terminate its development of Liothyronine Tablets [✂].[220]

3.111 A number of other companies have explored the possibility of developing Liothyronine Tablets, but they have not (or have not yet) taken significant steps towards obtaining an MA.[221] Still more companies have contacted the

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[209] Document LIO2195, Teva's response to question 2 of the CMA's s.26 notice dated 25 January 2017.
[210] Document LIO7846, [PE16]'s response to question 1 of the CMA's s.26 notice dated 21 August 2019.
[211] Document LIO12178, [PE16]'s response to question 1 of the CMA's s.26 notice dated 24 February 2021.
[212] Document LIO3321, [PE1]'s response to question 1 of the CMA's s.26 notice dated 30 June 2017; document LIO6584, [PE1]'s response to question 1 of the CMA's s.26 notice dated 7 June 2018; document LIO12077, [PE1]'s response to question 1 of the CMA's s.26 notice dated 25 September 2020.
[213] Document LIO12170, [PE1]'s response to question 1 of the CMA's s.26 notice dated 24 February 2021.
[214] Document LIO2206, [PE3]'s response to questions 1 and 8 of the CMA's s.26 notice dated 25 January 2017.
[215] Document LIO0283, Advanz's '*AMCo Management pack Apr 2013 – Investors.pdf*', page 23.
[216] Document LIO2206, [PE3]'s response to question 6 of the CMA's s.26 notice dated 25 January 2017.
[217] Document LIO2206, [PE3]'s response to question 1 of the CMA's s.26 notice dated 25 January 2017.
[218] Document LIO1906, [PE2]'s response to question 6 of the CMA's s.26 notice dated 27 January 2017.
[219] Document LIO6598, [PE2]'s response to question 1 of the CMA's s.26 notice dated 7 June 2018.
[220] Document LIO12079, [PE2]'s response to question 1 of the CMA's s.26 notice dated 25 September 2020.
[221] Document LIO3842, [PE12]'s response to the CMA's s.26 notice dated 13 July 2017; document LIO3980, Advanz's response to question 1 of the CMA's s.26 notice dated 25 July 2017; document LIO6578, [PE10]'s response to the CMA's s.26 notice dated 7 June 2018; document LIO12084A, [PE10]'s response to the CMA's s.26 notice dated 25 September 2020; document LIO12092, [PE20]'s response to the CMA's s.26 notice dated 30 September 2020.

MHRA with queries about MAs in respect of Liothyronine Tablets, but have not taken any steps towards developing Liothyronine Tablets.[222]

d. Supply of unlicensed medicinal products

vi. General framework

3.112 Regulation 167 of the Human Medicines Regulations 2012 sets out an exemption from the requirement for a medicinal product placed on the market in the UK to be the subject of an MA, in the case of products supplied to meet special patient needs. Unlicensed products may benefit from this exemption.

3.113 An importer of unlicensed medicines into the UK must obtain a licence from the MHRA and complete a comprehensive notification of intention to import.[223] During the Infringement Period, two types of licence could be obtained depending on whether the product was imported from within or outside the European Economic Area ('**EEA**'):

(a) An MHRA manufacturer 'specials' licence was needed to import unlicensed medicines from outside the EEA.[224]

(b) An MHRA wholesaler licence (also known as a wholesale dealer's licence or a wholesaler distribution authorisation) was needed to import unlicensed medicines from inside the EEA.[225] The wholesaler had to comply with EU Guidelines and pass regular inspections of its site to qualify for the licence.[226] The MHRA could refuse to grant a licence or '*grant a licence otherwise than as applied for*', providing an explanation for its decision and a 28 day period for the applicant to respond.[227]

3.114 In either case, the unlicensed medicine could only be supplied in order to meet the special needs of an individual patient (see paragraphs 3.81 to 3.82 above).

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[222] Document LIO12167, MHRA's response to the CMA's s.26 notice dated 18 February 2021; Document LIO6958, [PE19]'s response to the CMA's s.26 notice dated 25 July 2018; Document LIO6536, [PE15]'s response to the CMA's s.26 notice dated 7 June 2018.
[223] Under the standard provisions of licences, the MHRA has 28 days to query the notification after which date the importer may import the product (Regulation 24 and Schedule 4 to the Human Medicines Regulations 2012).
[224] Document PAD174, DHSC and MHRA Guidance: '*Import a human medicine*', 9 August 2005 ('**DHSC and MHRA Guidance**'); see also document PAD168, MHRA 14.
[225] Document PAD174, DHSC and MHRA Guidance; see also document PAD168, MHRA 14.
[226] Document PAD028, MHRA: '*Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration*', Guidance Note 6, pages 6-7.
[227] Document PAD028, MHRA: '*Notes for applicants and holders of a Wholesale Dealer's Licence (WDA(H)) or Broker Registration*', Guidance Note 6, page 7.

vii. Prices of Overseas Liothyronine

3.115 Where liothyronine is licensed in EEA States ('**Overseas Liothyronine**'), tablets may be in different strengths and formulations to Liothyronine Tablets in the UK (see paragraph 3.53 above). In Advanz's view, this means that UK Liothyronine Tablets are '*unique and not interchangeable with other formulations that maybe available in other markets*'.[228] For example strengths vary between different countries (see Table 3.1 below) and formulations vary: Aventis Pharma Ltd's ('**Sanofi**') product is lactose-free, whereas Advanz's Liothyronine Tablets are not.[229] Advanz also submits that Overseas Liothyronine may be lower quality than UK Liothyronine Tablets, although it does not provide evidence in support of this.[230]

3.116 Prices of Overseas Liothyronine vary significantly between different EEA States.

3.117 Table 3.1 below sets out the strengths and prices of Overseas Liothyronine in 2017 in those EEA States in which the CMA has been informed that it is licensed.[231]

Table 3.1: Prices of Overseas Liothyronine where licensed (2017)

Country[232]	Tablet strength[233] (mcg)	Number of tablets per pack	Sales volumes	Price[234] per pack (local currency)	Price for 28 tablets equivalent (£)[235]
UK	20	28	74,859	£247.77	£247.77
The Czech Republic	25	30	3,915	50.91 CZK	£1.58
France	25	30	110,199	2.46 EUR	£2.01

[228] Document LIO0669, Email from [Advanz Global Marketing Director] to [Advanz Vice President Global Medical] dated 09 May 2016. See further, paragraph 4.52 below.
[229] Document PAD128, Thyroid UK: '*Thyroid Hormone Replacements Medication*'.
[230] Document LIO7784, Second Compass Lexecon Report, paragraph 7.26.
[231] See the following responses to its voluntary requests for information dated 10 July 2018 from the following EEA Member States: Czech Republic (LIO7054 and LIO7057); France (LIO7321, LIO7322, LIO7661, LIO7659, LIO7346 and LIO7771) Germany (LIO7736 and LIO7738); Malta (LIO7358 and LIO7536); Netherlands (LIO6998, LIO6999, LIO7444, LIO7447, and LIO7839); Norway (LIO6798 and LIO6799); Sweden (LIO6783, LIO6850, LIO6851, PAD129 and PAD130). In response to its voluntary information requests dated 10 July 2018 the CMA received information that liothyronine was not available and/or licensed during the Infringement Period in the following EEA Member States: Austria (LIO6921), Belgium (LIO7076, and appendix LIO7077), Croatia (LIO6960), Cyprus (LIO6898, and appendix LIO6899), Denmark (LIO6924), Finland (LIO6943), Hungary (LIO7284), Iceland (LIO7417 and appendix LIO7418, and document LIO7385), Ireland (LIO6930), Italy (LIO7436 and appendix LIO7437), Latvia (LIO6938), Lithuania (LIO7384), Luxembourg (LIO6800), Poland (LIO7773), Romania (LIO6940), Slovakia (LIO6965) and Slovenia (LIO6876 and LIO7191). The CMA did not receive a response to its voluntary information requests from the following EEA Member States: Bulgaria, Estonia, Greece, Portugal and Spain; the CMA is aware from document LIO2206, Uni-Pharma's response to question 1 of the CMA's s.26 notice dated 25 January 2017 that Overseas Liothyronine is supplied in Greece.
[232] Figures for UK are based on the CMA analysis of data submitted by Advanz for the period from January to July 2017. Data from EEA Member states are in the documents referred to in footnote 231.
[233] The only available strength or the closest one to the strength of Liothyronine Tablets in the UK (25mcg).
[234] Pharmacy retail price, or, if not provided, pharmacy purchase price.
[235] Based on the European Central Bank's average annual exchange rates.

Country[232]	Tablet strength[233] (mcg)	Number of tablets per pack	Sales volumes	Price[234] per pack (local currency)	Price for 28 tablets equivalent (£)[235]
Germany	20[236]	50, 100	2,454,002[237]	10.55 EUR, 19.75 EUR	£5.18, £4.85
	20[238]	50, 100	660,784	9.27 EUR, 16.34 EUR	£4.55, £4.01
Malta	25	30	24,750	3.55 EUR	£2.95
The Netherlands	25	30	406,630[239]	23.50 EUR	£19.23
Norway	20	100	735,180	276.6 NOK	£7.28
Sweden	20	100	32,636	229.04 SEK	£5.84

Source: CMA analysis of responses to information requests

3.118 The price of Overseas Liothyronine is also constrained by regulation in the majority of EEA States in which it is licensed. Specific forms of regulation may differ, as set out in Table 3.2 below.

Table 3.2: Regulatory regimes for Overseas Liothyronine

Country	Information regarding regulatory regime
The Czech Republic	The price is not regulated.[240]
France	Liothyronine sold by dispensing pharmacies is subject to a price cap.[241] The French regulator sets prices taking into account the improvements the drug brings to medical services, the results of an economic evaluation where necessary, the prices of products with the same therapeutic aim, expected or actual sales volumes and the conditions of use of the drug.[242]
Germany	Liothyronine has been subject to a price freeze since 2010.[243] German regulation seeks to reconcile the objectives of encouraging innovation and ensuring efficient use of resources.[244]
Malta	The price is subject to public procurement regulations.[245] Maltese medicines policy seeks to promote equity and sustainability of the pharmaceutical sector.[246]
The Netherlands	Liothyronine is in principle subject to price regulation under the Wet Geneesmiddelenprijzen (the 'Drug Prices Act'), which sets the maximum prices of drugs according to the average of the prices of comparable medicines in reference countries (the UK, France, Belgium

[236] Merck Serono GmbH, Novothyral 20 mcg.
[237] Sales volumes for both 15mcg and 20mcg tablet strengths.
[238] Sanofi, Thybon Henning 20 mcg.
[239] Sales volumes before multiplying by the Defined Daily Dose (DDD) of 60 mcg and for all three strengths (5mcg, 12.5mcg and 25mcg) combined, last available for 2016.
[240] Document LIO7057, Czech response to the follow-up question to the CMA's voluntary request for information dated 10 July 2018.
[241] Document LIO7661, French response (1) to the follow-up question to the CMA's voluntary request for information dated 10 August 2018.
[242] Document PAD131, Legifrance (France): '*Code de la sécurité sociale - Article L162-16-4*'.
[243] Document LIO7736, German response to the CMA's voluntary request for information dated 10 July 2018.
[244] Document PAD132, OECD: '*Pharmaceutical Reimbursement and pricing in Germany*', June 2018.
[245] Document LIO7536, Maltese response to a follow-up question to the CMA's voluntary request for information dated 10 July 2018.
[246] Document PAD133, Ministry for Health (Malta): '*Pharmaceutical Strategy and Policy*'.

Country	Information regarding regulatory regime
	and Germany). To be able to calculate an average price there must be a price in the pricelist of at least two of the reference countries. In the case of liothyronine there are not enough comparable products to use as references in practice.[247]
Sweden	The price of liothyronine in Sweden is subject to reimbursement (without limitation) and regulated.[248] Swedish regulation aims to use medicines in the most cost-effective way in order to achieve the greatest possible health gains for the resources allocated to medicines.[249]
Norway	The price of liothyronine in Norway is regulated.[250] Maximum pharmacy purchase prices are set using the average of the three lowest prices from a basket of countries.[251] It seeks to ensure both access to medicine regardless of ability to pay and the use of cost-effective medicines.[252]

Source: CMA analysis of responses to information requests

VI. Funding and pricing framework

3.119 This section first sets out in general terms the arrangements by which the NHS funds prescription drugs such as Liothyronine Tablets, and the assumptions that underlie the DHSC's approach to the pricing of branded and generic drugs.[253]

3.120 The section then sets out the framework within which Advanz sets its prices for Liothyronine Tablets, and in particular:

(a) The mechanism for setting the reimbursement prices of generic drugs;

(b) The schemes in place during the Infringement Period to secure value for money for the NHS in relation to branded and generic drugs; and

(c) The Secretary of State's reserve power to intervene in drug pricing.

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[247] Document LIO7447, Dutch response to the follow-up question (2) to the CMA's request for information dated 10 July 2018; and document LIO7839, Dutch response to the CMA's follow-up question dated 1 August 2019.
[248] Document LIO6850, Swedish response to the follow-up question to the CMA's voluntary request for information dated 10 July 2018.
[249] Document PAD134, The Dental and Pharmaceutical Benefits Agency (Sweden): '*PPRI Pharma Profile - Sweden 2017*', page 17.
[250] Document LIO6798, Norwegian response to the CMA's voluntary request for information dated 10 July 2018.
[251] Document PAD135, The Norwegian Medicines Agency: '*Maximum price*'.
[252] Document PAD136, The Norwegian Medicines Agency: '*Our goals and tasks*'.
[253] This case involves Liothyronine Tablets, which are a long off-patent and de-branded drug. Advanz's contemporaneous documents frequently refer to Liothyronine Tablets as a 'generic' drug. The term 'generic' is not a term of art and it sometimes carries different meanings depending on context. In its internal documents, Advanz generally uses the term to indicate that Liothyronine Tablets are off-patent and have been de-branded (i.e. they are no longer sold under the original brand name, Tertroxin). However, in the pharmaceutical industry the term 'generic' is often simply used to emphasise that a drug is off-patent. For example, 'genericisation', 'generic competition' and 'generic entry' can refer to the off-patent competition that follows an originator's product loss of exclusivity. In other contexts, the term 'generic' may be used to emphasise the fact that the drug is unbranded (whether it has been de-branded or otherwise) and 'genericisation' can refer specifically to a product being de-branded. In this Decision the meaning of the term 'generic' is context-specific. Where ambiguity might otherwise arise, the CMA specifies what meaning the term is used to convey.

3.121 In summary, the NHS is required to fund the cost of prescriptions for drugs such as Liothyronine Tablets (which, as an unbranded generic drug long off-patent, would in the ordinary course be expected to be sold at a low price). It does so via the reimbursement price: the price at which CCGs reimburse pharmacies for prescriptions. The reimbursement price for Liothyronine Tablets is set out in a list published monthly by the DHSC (the '**Drug Tariff**'), and during the Infringement Period was based on Advanz's list price directly (when it was in Category C of the Drug Tariff – see paragraph 3.142 below) or indirectly (when it was in Category A). Advanz's selling prices for Liothyronine Tablets were not affected either by the scheme for generic drugs (Scheme M) or by statutory price control throughout the Infringement Period:

(a) It is unclear whether a relevant Advanz entity was a member of Scheme M during the Infringement Period but, in any event, Advanz did not during the Infringement Period provide the DHSC with information relating to Liothyronine Tablets under Scheme M, which were not in Category M during the Infringement Period; and

(b) Statutory price control was precluded since Advanz was a member of the voluntary PPRS throughout the Infringement Period and as a member of the PPRS its pricing of Liothyronine Tablets was exempt from statutory price control (this exemption was removed after the Infringement Period, in August 2017).

a. NHS funding

3.122 As set out above, the clinical decision to prescribe a pharmaceutical product to a patient is taken by a patient's GP or by a specialist endocrinologist. When the treatment is initiated by a specialist, the GP's role is in some cases limited to issuing repeat prescriptions. In both situations, the funding is provided by the patient's local CCG. In practice, once the decision to prescribe a product has been taken, the NHS (in the form of the patient's local CCG) has no option but to fund the product.

3.123 The NHS is principally funded by UK taxpayers.[254] Within the NHS's overall budget, there are funds allocated to certain activities, such as prescribing pharmaceutical products, from which the cost of dispensing Liothyronine Tablets is met. Each year, NHS England sets each CCG a prescribing budget and GP practices are expected to prescribe within this budget.[255] Increases in

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[254] See document PAD038, NHS: '*Overview*': the NHS also derives some revenue from user charges, for example prescription payments.
[255] See document PAD039, NHS: '*Prescription Services*'. See also document PAD040, BMA: '*GP practice prescribing budget*'.

the price of any drug result in a consequent decrease in the financial resources available to fund other healthcare services. Notwithstanding the significant scale of the NHS budget, legitimate demands for healthcare exceed its levels and resources have to be prioritised.

3.124 In recent years, the NHS has also been required to find significant efficiency savings. For example, in 2010, the NHS Efficiency Policy (also known as the Quality, Innovation, Productivity and Prevention Plan) was introduced, which tasked the NHS with making up to £20 billion of efficiency savings by 2015 in order to make more funds available to treat patients.[256] To achieve savings, various tools are used by and available to the NHS to encourage the prescription of cheaper alternative drugs where this can be done while preserving the same (or better) levels of patient care. As referred to above at paragraph 3.73, PrescQIPP has published the DROP-List, which identifies drugs which NHS commissioners consider as low priority, poor value for money or for which there were safer alternatives.

b. Branded and generic drug pricing

3.125 There are three phases to the lifecycle of a drug.

(a) The first phase involves its development to launch and is characterised by substantial investments in research and development.

(b) The second phase involves the initial launch and sale of the drug. In this stage, a drug typically benefits from patent protection, which provides legal exclusivity and potentially enables high prices and profits.

(c) The third phase is genericisation, where patents have expired, exclusivity has been lost and generic entry is expected to occur, resulting in a decrease in prices.[257]

3.126 The first phase of the drug lifecycle is characterised by investment with no sales and therefore no reward. The reward for this investment is expected to come during the second phase, when innovative medicinal products can secure market exclusivity via the patent regime for up to 20 years (with limited extensions). Patentholders are granted a legal monopoly that allows them to recoup the cost of the research and development required to produce a patented product. The expectation is that this will allow them to make sufficient profits during the lifetime of the patent to incentivise ongoing

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[256] See document PAD074, NHS: '*Efficiency*'.
[257] These phases are discussed by the European Commission in its Pharmaceutical Sector Inquiry, document PAD143, EC: '*Pharmaceutical Sector Inquiry Final Report*', July 2009.

innovation in the industry. The patentholder enjoys a period of exclusivity in recognition of its innovation – a benefit both to the patentholder and (indirectly) to the consumer more generally because of the incentives it creates.

3.127 The market power that a patent may afford its holder (depending on the circumstances) has led authorities in many jurisdictions to implement some form of regulation to cap prices charged or profits made. In the UK, this purpose was served during the Infringement Period by the PPRS (see paragraphs 3.138 to 3.140 below).

3.128 The case of Liothyronine Tablets, however, involves the supply of an unbranded generic drug in the third phase of the drug lifecycle. In the UK, the suppliers of unbranded generic drugs are in principle free to set their prices as they choose. This is based on the assumption that competition will bring down prices, once generic competitors are free to enter the market and compete on price. Once a drug becomes generic (i.e. relevant patent protections have expired), the expectation is that the cost of the innovation that led to its creation has been recouped and the price should fall. The DHSC's policy during the Infringement Period was therefore to rely on competition to control generic drug selling prices, as summarised in documents produced by and for Advanz:

(a) [✂] (Advanz CEO) explained to investors that '*[d]rugs not captured under the PPRS are not subject to formal price controls (with competition encouraged to ensure prices remain competitive)*'.[258]

(b) Other investor presentations noted that: '*Un-branded product enjoys free pricing with an assumption that competitive dynamics will keep the prices down'*;[259] for non-PPRS drugs *'there is <u>no regulatory price ceiling</u> … so that pricing is largely governed by competition'* (emphasis in original)*;* and that *'[t]he UK has a stable pricing mechanism for branded products (PPRS) and a free pricing approach for generics*'.[260]

3.129 In the majority of cases, this is believed to be an effective means of securing value for money for the NHS. As the British Generics Manufacturers Association ('**BGMA**') states:

> 'Generic medicines make the drugs bill affordable and promote innovation. When an original branded drug loses its patent

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[258] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', page 17.
[259] Document LIO0232, Mercury Pharma materials presentation, September 2012, slide 10.
[260] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', pages 7 and 52.

protection, generic equivalents are launched, typically by many manufacturers. The competition between these manufacturers drives down prices'.[261]

3.130 This model – of relying on competition to keep prices for generic (i.e. off-patent) drugs down – can only work, though, where competitors can promptly enter the market and compete on price.

3.131 However, some generic markets do not deliver these benefits. This may be because of market features (such as barriers to entry or expansion or because the market is too small to attract entry) or because of conduct such as collusion. This means that effective entry may be delayed or does not occur at all, shielding the drug from competition. There was no effective price control for such 'niche' generic drugs during the Infringement Period (as explained below).

3.132 The suppliers of such unbranded generic drugs could therefore find themselves in a position of holding substantial market power in relation to very old medicines which, although very important to patients, have not been subject to any recent innovation or investment.

3.133 Some suppliers have used this market power to impose very high prices. This issue is of significant concern to the DHSC. For example, in October 2016 the then Secretary of State for Health stated in Parliament:

> '… 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 ….'[262]

3.134 Liothyronine Tablets were one such niche unbranded generic drug during the Infringement Period.

3.135 Liothyronine Tablets were first sold in the UK in the 1950s. Therefore any patents relevant to the sale of Liothyronine Tablets would likely have expired by the end of the 1970s at the latest. Until Advanz de-branded the drug, the price under the PPRS remained low (although still profitable: see paragraph 5.264 below): in September 2007 the ASP was the equivalent of £4.05.[263]

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[261] Document PAD214, BGMA: '*About generics*'.
[262] Document PAD035, Debate - Health Service Medical Supplies (Costs) Bill, page 10.
[263] As noted at paragraph 3.22 above, Advanz reduced the number of tablets per pack from 100 to 28.

3.136 Advanz acquired the branded product (sold as Tertroxin) in 1992 and 'de-branded' Liothyronine Tablets in October 2007, discontinuing the brand and introducing an unbranded generic version.

3.137 Once it was de-branded, the drug was no longer regulated under the PPRS or the statutory scheme for branded drugs. From this point onwards, Liothyronine Tablets sold by Advanz became a generic drug outside effective price regulation. As explained below, Advanz's decision to discontinue the brand allowed it to price without effective constraints and to increase dramatically prices for Liothyronine Tablets throughout the Infringement Period (see Section 5.D below).

c. Branded drugs: the PPRS

3.138 The PPRS was a voluntary agreement between the DHSC and the Association of the British Pharmaceutical Industry which applied to manufacturers and suppliers of branded medicines to the NHS throughout the Infringement Period.[264] The PPRS was designed to ensure '*that safe and effective medicines are available on reasonable terms to the National Health Service*' and '*a strong, efficient and profitable pharmaceutical industry*'.[265] 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*'.[266]

3.139 Throughout the Infringement Period, Advanz was a member of the PPRS.[267] In particular, Mercury Pharmaceuticals Limited – the selling entity and MA holder for Liothyronine Tablets – was a member of the PPRS for all of the Infringement Period.[268] However, given that the PPRS only applied to branded products, it did not apply to Liothyronine Tablets after they had been de-branded in October 2007.

3.140 The 2014 PPRS expired on 31 December 2018 and was replaced by the 2019 Voluntary Scheme for Branded Medicines Pricing and Access.[269] Given that

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[264] Section 261(2) of the National Health Service Act 2006 (the '**NHS Act**'); see also document PAD033, DHSC: '*The Pharmaceutical Price Regulation Scheme 2014*' (the '**2014 PPRS**'), '*Products Covered*': '*Scheme Products are branded, licensed health service medicines*', paragraph 3.14.
[265] Document PAD033, 2014 PPRS, page 9, paragraph 1.2.
[266] Document PAD124, ABPI: '*Understanding the 2014 Pharmaceutical Price Regulation Scheme*', page 1; see also document PAD073, ABPI: '*Understanding the Pharmaceutical Price Regulation Scheme (PPRS)*'.
[267] The Amdipharm Mercury group was a member of the 2014 PPRS, which was effective between 1 January 2014 and 31 Dcember 2018: document PAD073, ABPI: '*Understanding the Pharmaceutical Price Regulation Scheme (PPRS)*'. Both the Amdipharm and Mercury Pharma groups were members of the 2009 PPRS, which was effective from 1 January 2009 until its replacement by the 2014 PPRS. Following Cinven's acquisition of both groups, they were treated as a single entity for PPRS purposes: document LIO2393, Note of meeting between the DHSC and AMCo dated 25 July 2013, paragraph 8. Goldshield Group Plc was a member of the PPRS schemes from 2005 to 2008: document PAD034, DHSC: '*2005 Scheme Members published*'.
[268] Document LIO2944, Advanz's response to question 13 of the CMA's s.26 notice dated 26 May 2017.
[269] Document PAD194, DHSC: '*The 2019 Voluntary Scheme for Branded Medicines Pricing and Access - Chapters and Glossary*'.

this latter scheme did not apply during the Infringement Period, the CMA does not consider this new scheme further here.

d. The Drug Tariff

3.141 The Drug Tariff is the primary mechanism for determining how dispensers are reimbursed for generic drugs. It is produced on a monthly basis by NHS Prescription Services[270] and governs the price that is reimbursed to the dispenser for fulfilling NHS prescriptions, subject to any price concessions agreed between the DHSC and the Pharmaceutical Services Negotiating Committee (the '**NHS Reimbursement Price**' or '**Drug Tariff Price**').[271] The NHS Reimbursement Price for Liothyronine Tablets was set out in Part VIII of the Drug Tariff during the Infringement Period from November 2010.[272] The Drug Tariff provides that a dispenser is reimbursed for medicines dispensed at a 'basic price' (less any clawback discount).[273]

3.142 Medicines listed in Part VIII of the Drug Tariff fall into three different pricing categories:[274]

(a) *Category A*: There is a minimum requirement that products in Category A are listed either: (i) by two wholesalers; or (ii) by one wholesaler and by two manufacturers. Prices are 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 is set using a weighted average of prices from a basket of two wholesalers and two generic manufacturers.

(b) *Category C*: This category typically applies when a product is only available as a branded product or as a generic product from one or two sources. The

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[270] Document PAD029, NHS BSA: '*Services*'. Health services are a devolved matter (Schedule 5 to the Scotland Act 1998, Schedules 2 and 3 to the Northern Ireland Act 1998 and Schedule 7 to the Government of Wales Act 2006). However, the National Assembly for Wales operates a common policy with the DHSC and therefore the Drug Tariff currently covers both England and Wales. Scotland and Northern Ireland maintain and publish separate Drug Tariffs.
[271] For the purposes of the CMA's assessment, the NHS Reimbursement Price also includes the PPRS list price of Tertroxin, prior to generic Liothyronine Tablets falling under the Drug Tariff.
[272] Document LIO2310, DHSC's response to questions 3 and 4 of the CMA's s.26 notice dated 9 February 2017.
[273] See the NHS Act 2006, sections 164 and 165, and the National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013/349, Regulation 89. 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. However, there are some drugs that are not subject to a discount and these drugs are listed on the Discount Not Given list, which is published in Part 2 of the Drug Tariff. Liothyronine Tablets remained listed on the Discount Not Given list at the end of the Infringement Period.
[274] See the DHSC, Guidance notes in Part VIIIA of the Drug Tariff.

price of a drug within Category C is based on a list price for a particular proprietary product, manufacturer or supplier.

(c) *Category M*: This category typically applies to commonly used generics that are available from several sources. The price of a drug within Category M is set using a weighted average from retrospective sales and volume data supplied to the DHSC by manufacturers (during the Infringement Period, under Scheme M (see further below)).

3.143 The DHSC may make adjustments to the Drug Tariff Price which are independent of prices and sales data. For example, in April 2019 the DHSC applied a £10 million monthly adjustment across Category M Drug Tariff Prices, to ensure that sufficient margin was available to community pharmacies. This adjustment resulted in the final Category M Drug Tariff Price for Liothyronine Tablets rising by 1% between January 2019 and April 2019 despite manufacturers' prices falling during that period.[275]

3.144 Between December 2007 and November 2010, Liothyronine Tablets were not listed in the Drug Tariff, and were therefore reimbursed according to Part II, Clause 8C in the Drug Tariff:

> 'The basic price for a drug which is not listed in Part VIII of the Tariff shall be the list price, for supplying to contractors, of the pack size to be used for a prescription for that quantity, published by the manufacturer, wholesaler or supplier. In default of any such list price, the price shall be determined by the Secretary of State for Health and the Welsh Ministers'.[276]

3.145 From November 2010 to April 2015, Liothyronine Tablets were listed in Category A of the Drug Tariff. In May 2015, Liothyronine Tablets were moved to Category C,[277] where they remained until March 2018 when they were moved to Category A.[278] In January 2019, Liothyronine Tablets were moved to Category M, following determination that they fulfilled the relevant criteria and after consultation with the Pharmaceutical Services Negotiating Committee. They remain in Category M at the date of this Decision.[279]

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[275] Document LIO7822, DHSC's response to question 5 of the CMA's s.26 notice dated 18 July 2019.
[276] See the DHSC, Guidance notes in the Drug Tariff.
[277] Document LIO2310, DHSC's response to questions 3 and 4 of the CMA's s.26 notice dated 9 February 2017, and public NHS BSA data.
[278] Document LIO6878, DHSC's response to question 9 of the CMA's s.26 notice dated 2 July 2018.
[279] Document LIO7822, DHSC's response to question 1(a) of the CMA's s.26 notice dated 18 July 2019, Drug Tariff Part VIII, Category M Prices – Quarter 2 July 2021, available at: https://www.nhsbsa.nhs.uk/sites/default/files/2021-06/part%20viiia%20july%2021.xlsx

3.146 When Liothyronine Tablets were in Category C, their reimbursement price was based on Advanz's list price – this applied from 2015 until after the end of the Infringement Period. After Liothyronine Tablets were moved to Category A in 2018, their reimbursement price was based on a weighted average of [✂] list prices.[280] After Liothyronine Tablets were moved to Category M, their reimbursement price was determined according to a formula which adjusts the reimbursement price by reference to increases or decreases in the ASP.[281]

e. Scheme M

3.147 During the Infringement Period, 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 manufacturers and suppliers of generic medicines for use in the NHS who chose to join it.[282]

3.148 As explained above, the DHSC used the retrospective sales and volume data supplied to the DHSC by Scheme M members to set the reimbursement prices for drugs in Category M, taking into account the agreed retained margin for community pharmacies.

3.149 Scheme M allowed its members to alter the price at which a medicine is sold to wholesalers or dispensing contractors without any requirement to discuss such changes with the DHSC in advance. The intention was that competition and pressure from pharmacies would restrain supplier pricing, consistent with the DHSC's policy that competition is the most effective 'regulator' of unbranded generic drug prices.

3.150 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*'.[283] They also provided that a Scheme M member could be required to provide on

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[280] Document LIO7822, DHSC's response to question 2 of the CMA's s.26 notice dated 18 July 2019.
[281] Document LIO7822, DHSC's response to question 3 of the CMA's s.26 notice dated 18 July 2019. Further detail is contained in document LIO7823, '*Category M method*', July 2016. However, decreases in ASP are not necessarily accompanied by corresponding decreases in reimbursement price, as margin adjustments may be applied for reasons unrelated to specific products (document LIO7822, DHSC's response to question 5 of the CMA's s.26 notice dated 18 July 2019).
[282] Sections 261(2) and 266(6) of the NHS Act 2006, and document PAD030, '*Revised long-term arrangements for reimbursement of generic medicines*', paragraph 4.
[283] Document PAD030, DHSC: '*Revised long-term arrangements for reimbursement of generic medicines*', paragraph 30.

reasonable request information regarding costs and/or profit margins.[284] 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.[285]

3.151 Since Scheme M was voluntary, a Scheme M Member was free to withdraw from the Scheme M arrangements at any time.[286] The provisions of Scheme M only applied to Scheme M members.

3.152 It is unclear whether Advanz's Liothyronine Tablets were covered by Scheme M during the Infringement Period,[287] although they were not in Category M and Advanz did not provide data submissions under Scheme M to the DHSC.[288] If Liothyronine Tablets were not covered by the scheme then it would have no further relevance to this Decision. However, the CMA assesses the potential impact of Scheme M on the assumption that it applied (see in particular paragraphs 5.11ff of Annex 5).

3.153 In June 2018, the DHSC gave notice of its intention to end Scheme M and replace it with new information regulations.[289] Scheme M expired on 30 June 2019 and pricing information is now collected under the Health Service Products (Provision and Disclosure of Information) Regulations 2018, which

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[284] Document PAD030, DHSC: '*Revised long-term arrangements for reimbursement of generic medicines*', paragraph 31.
[285] Document PAD030, DHSC: '*Revised long-term arrangements for reimbursement of generic medicines*', 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.
[286] Document PAD030, DHSC: '*Revised long-term arrangements for reimbursement of generic medicines*', paragraph 44. It would do so by withdrawing consent for the voluntary Scheme to be treated as applying to it.
[287] Advanz informed the CMA that it did not provide data for Liothyronine Tablets under Scheme M during the Infringement Period because, although certain entities within the Advanz group were members of Scheme M during the Infringement Period, the selling entity and MA holder for Liothyronine Tablets within the Advanz group – Mercury Pharmaceuticals Limited – was not a Scheme M reporting entity (Document LIO2665, Advanz's '*2. Source system data mapping.xlsx*', and document LIO4427, Advanz's response to question 2 of the CMA's s.26 notice dated 25 September 2017; Document LIO2589, Advanz's response to question 12 of the CMA's s.26 notice dated 27 February 2017). However, Advanz has subsequently informed the CMA that Mercury Pharma (Generics) Limited's status as a Scheme M reporting entity was understood by the DHSC to be a '*group registration*' (Document LIO6361.5, [✂] witness statement, paragraphs 27 and 28, and Annex 2) and the DHSC has confirmed that it is for a participating company to determine how it wishes to provide information, and it may do so on an individual or group basis (Document LIO6878, DHSC's response to question 1 of the CMA's s.26 notice dated 2 July 2018).
[288] The DHSC has confirmed that Advanz did not send it any information relating to Liothyronine Tablets under Scheme M during the Infringement Period (Document LIO6878, DHSC's response to questions 2 and 3 of the CMA's s.26 notice dated 2 July 2018); when the CMA asked Advanz to provide all '*voluntary quarterly data submissions to the DH*' referring to Liothyronine Tablets, Advanz provided three quarterly submissions, all dating from after the end of the Infringement Period (Document LIO7459, Advanz's response to question 23 of the CMA's s.26 notice dated 21 August 2018; and documents LIO7469, LIO7470 and LIO7471, Advanz's '*Annex 5 - Relevant voluntary quarterly data submissions that refer to Liothyronine Tablets*' for 1 April to 30 June 2018, 1 October to 31 December 2017, and 1 January to 31 March 2018).
[289] Document PAD164, DHSC: '*Legal requirements to provide information about health service products*', June 2018, paragraphs 1.1-1.5.

also provide for quarterly submissions of information to the DHSC (see paragraph 3.166 below).[290]

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

3.154 The Secretary of State 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 National Health Service Act 2006 (as amended) ('**NHS Act**'). The Secretary of State's role is discharged through the DHSC, and so this section refers to the DHSC.

3.155 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.

3.156 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**').

3.157 The Statutory Scheme that was in force during the Infringement Period only applied to branded medicines.[291] Since Liothyronine Tablets were de-branded in October 2007, the Statutory Scheme is not relevant.

3.158 The application of the Reserve Power to Advanz's sales of Liothyronine Tablets has now changed because of statutory reforms which came into force on 7 August 2017, after the end of the Infringement Period. This section will therefore discuss separately the position prior to 7 August 2017, and subsequently.

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[290] Document LIO7822, DHSC's response to question 3 of the CMA's s.26 notice dated 18 July 2019.
[291] 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, 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 (see Regulations 1 and 2 of the Health Service Branded Medicines (Control of Prices and Supply of Information) (No.2) Regulations 2008, and Regulations 2 and 3 of the Health Service Medicines (Information Relating to Sales of Branded Medicines etc.) Regulations 2007).

i. The position during the Infringement Period

3.159 Prior to 7 August 2017, the Reserve Power did not apply to Advanz's sales of Liothyronine Tablets. Until 7 August 2017, the Reserve Power was not exercisable in relation to a member of a voluntary scheme: until that date section 262(2) stated 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*'. As explained above, Advanz entities – and specifically Mercury Pharmaceuticals Limited – were members of the voluntary PPRS throughout the Infringement Period.[292]

3.160 This position was amended from 7 August 2017, as discussed at paragraphs 3.161 to 3.167 below, to address concerns that '*[a]lthough 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*'.[293]

ii. Statutory reforms – the position after the end of the Infringement Period

3.161 From 7 August 2017, the regulatory position changed. On that date, the Health Service Medical Supplies (Costs) Act 2017 (the '**Costs Act**') entered into force.[294]

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

(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;[295] and

(b) allowing for regulations requiring licence holders to provide cost and other financial information to the DHSC upon request.[296]

3.163 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:

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[292] The statutory power in section 261(8) NHS Act to prohibit a manufacturer or supplier to whom a voluntary scheme applies from increasing the prices of drugs covered by the scheme was also not available, since that provision was not in force until 7 August 2017, when it was brought into force by the Health Act 1999 (Commencement No 17) Order 2017.
[293] Document PAD035, Debate - Health Service Medical Supplies (Costs) Bill, page 10.
[294] By virtue of the Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017.
[295] Section 4 of the NHS 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).
[296] Section 8 of the Act inserted a new section 264A into the NHS Act 2006, allowing for such regulations for purposes including '*the exercise by the Secretary of State of any powers under section 260 to 264 and 265*'.

(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.

3.164 The Secretary of State stated that this was because:

> '[T]here 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. We cannot allow this practice to continue unchallenged. My Department has been working closely with the Competition and Markets Authority to alert it to any cases where there may be market abuse and provide evidence to support this, but we also need to tackle it within our framework for controlling the cost of medicines and 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'.[297]

3.165 The Secretary of State also explained that the Costs Act was designed 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'.[298]

3.166 As a result of the Costs Act, since 7 August 2017 (after the end of the Infringement Period), the Reserve Power has been available in relation to

[297] Document PAD035, Debate - Health Service Medical Supplies (Costs) Bill, page 10.
[298] Document PAD035, Debate - Health Service Medical Supplies (Costs) Bill, page 12.

Advanz's sales of Liothyronine Tablets. Further regulations have since come into force, giving the DHSC supporting powers.[299]

3.167 The Reserve Power is silent as to the method the DHSC should use to determine a price limit. The DHSC has publicly stated that it will consult with the relevant industry bodies (the BGMA and the Healthcare Distribution Association) in relation to its policy and procedures for using the Reserve Power.[300] Although in January 2019 the DHSC told the Public Accounts Committee that it was preparing a framework for use of the power and would consult on it with industry, in May 2019 it was reported that the consultation was delayed because the DHSC '*wants to ensure the proposals are sufficiently robust beforehand*'.[301] The DHSC has yet to issue any public consultation on use of the Reserve Power at the date of this Decision. The DHSC is also required under section 262(1) of the NHS Act to consult with the relevant industry body before making a particular price determination using the Reserve Power.

D. The Manufacture of Advanz's Liothyronine Tablets and Development Projects

3.168 During the Infringement Period, Advanz [✂].

I. Advanz's [✂]

3.169 During the Infringement Period, Advanz operated [✂].[302]

3.170 [✂] is (and was throughout the Infringement Period) Advanz's [Contract Manufacturing Organisation ('CMO')] for Liothyronine Tablets.[303] [✂].[304]

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[299] 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 (Regulations 25, 26 and 32).

[300] Document PAD164, DHSC: '*Legal requirements to provide information about health service products*', June 2018, page 35.

[301] The Pharmaceutical Journal: '*Government delays consultation with pharmaceutical industry over generics price limiting powers*', available at: https://pharmaceutical-journal.com/article/news/government-delays-consultation-with-pharmaceutical-industry-over-generics-price-limiting-powers

[302] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum_vF.docx*', page 18; document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', pages 62-64; document LIO0769, '*Project Armour CIM_v72.pdf*', page 38; document LIO1096, Advanz's response to question 7 of the CMA's s.26 notice dated 25 October 2016.

[303] [✂].

[304] Advanz's agreement with [✂] does not only cover the production of Liothyronine Tablets, but governs the entire manufacturing relationship between the two parties. For the Infringement Period, '*[t]wo Manufacturing and Supply Agreements have existed … one from Nov 2007 and another from June 2014 covering a range of products including Liothyronine … tablets 20mcg*': document LIO1228.1, [✂]'s response to question 3 of the CMA's s.26 notice dated 25 November 2016.

a. Relevant contractual terms

3.171 Advanz's agreement with [✂] required [✂] to supply a range of pharmaceutical products to Advanz on an exclusive basis, including Liothyronine Tablets.[305] [✂].[306] [✂].[307]

b. Manufacturing and development difficulties

3.172 According to the MHRA, the manufacture of Liothyronine Tablets '*is challenging due to the low amount of active substance in the product and potential sensitivity of liothyronine to apparently minor changes in processing technology*'.[308] The MHRA further explained that the '*manufacture of liothyronine products is to be considered complex despite using conventional blending, granulation and compression technology*'. Potential entrants have confirmed these difficulties and added that developing reliable clinical trials is difficult because the active substance is endogenous to the human body in varying quantities.[309]

3.173 These difficulties are apparent from the challenges faced by Advanz in producing a consistently stable product over the Infringement Period, resulting in the MHRA requiring Advanz to apply for a batch specific variation in respect of every batch of product that it produces.[310]

3.174 There appear to be a limited number of suppliers of the API required for manufacturing Liothyronine Tablets worldwide.[311] [✂] supplied the API to Advanz until 2013, when it stopped production. This resulted in shortages of Liothyronine Tablets in the UK.[312] Advanz subsequently replaced [✂] with [✂], which was the only other manufacturer of the API in the EU at that time. [✂] remains the non-exclusive API supplier for Advanz's Liothyronine Tablets.[313]

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[305] Document LIO1228.1, [✂]'s response to question 10 of the CMA's s.26 notice dated 25 November 2016.
[306] Document LIO1228.1, [✂]'s response to question 11(e)(i) of the CMA's s.26 notice dated 25 November 2016.
[307] Document LIO1228.1, [✂]'s response to question 11(e)(i) of the CMA's s.26 notice dated 25 November 2016.
[308] Document LIO1862, MHRA's response to question 5 of the follow-up questions to the CMA's s.26 notice dated 28 November 2016.
[309] Document LIO3232, Morningside's response to question 2 of the CMA's s.26 notice dated 7 July 2017; document LIO3445, [PE2]'s response to question 2 of the CMA's s.26 notice dated 7 July 2017.
[310] Document LIO3061, Advanz's response to question 7(b) of the CMA's s.26 notice dated 25 January 2017; document LIO1414, [✂]'s response to question 4 of the follow-up questions to the CMA's s.26 notice dated 26 November 2016.
[311] Document LIO2195, Teva's response to question 8 of the CMA's s.26 notice dated 28 February 2017.
[312] Document LIO0399, Advanz's '*Liothyronine 20 microgram tablets_ continuity of supply and potential need f.pdf*'; document LIO3061, Advanz's response to questions 11 and 17 of the CMA's s.26 notice dated 25 January 2017.
[313] Document LIO3061, Advanz's response to questions 11 and 28 of the CMA's s.26 notice dated 25 January 2017.

3.175 [✂].[314]

c. Strategic relationship [✂]

3.176 [✂].[315]

3.177 [✂].[316] [✂]:

(a) [✂];

(b) [✂];

(c) [✂]; and

(d) [✂].[317]

II. Advanz's liothyronine development projects

3.178 As set out at paragraph 3.21 above, Advanz only supplies a 20mcg strength of Liothyronine Tablets and this was the only licensed strength in the UK throughout the Infringement Period. However, as explained above (paragraph 3.34), endocrinologists have indicated that this often results in patients taking a dose of liothyronine which is too high, when Liothyronine Tablets are prescribed in combination with Levothyroxine Tablets as the recommended combination dose is 5mcg of liothyronine twice daily. A management consultant presentation produced for Advanz cited one endocrinologist estimating that a lower dose of liothyronine would be suitable for 75% of patients.[318]

a. Development of other strengths

3.179 In 2013 Advanz decided to start developing product variations of Liothyronine Tablets in 5mcg and 10mcg, not only to meet clinical demand[319] but also to counter the competition that Advanz expected to enter the UK market.[320] Advanz asked [✂] to start development of the new strengths.[321]

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[314] Document LIO2195, Teva's response to question 8 of the CMA's s.26 notice dated 28 February 2017.
[315] Document LIO1228.1, [✂]'s response to question 3 of the CMA's s.26 notice dated 25 November 2016.
[316] Document LIO0190, Email exchange between [✂] dated 20 April 2012.
[317] Document LIO1228.1, [✂]'s response to question 3 of the CMA's s.26 notice dated 25 November 2016.
[318] Document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 41.
[319] Advanz noted that Liothyronine Tablets were often prescribed in 5mcg or 10mcg doses in combination with Levothyroxine and currently tablets were crushed or split (leading to inaccurate dosing) or specials were purchased which was expensive; document LIO0402, '*PPRM_Liothyronine.pptx*', page 2.
[320] Document LIO0704, '*Liothyronine 5mcg and 10mcg UK - 1PS.DOCX*', page 2.
[321] Document LIO0618, '*PPRM - Liothyronine new strengths.pptx*', page 2.

3.180 [✂].[322]

3.181 However, as part of the acquisition of Primegen Limited (‘**Primegen**’) (see paragraphs 3.185 to 3.187 below), Advanz also acquired a development project for new strengths of liothyronine tablets, [✂].

b. Acquisition of Focus Pharmaceuticals

3.182 On 1 October 2014, Advanz acquired Focus Pharmaceuticals Ltd (‘**Focus**’), a UK-based company founded in 2003, for [✂].[323] Focus specialised in branded and generic niche medicines and made sales of just under £40 million at the time of the acquisition, predominantly in the UK.[324]

3.183 Focus was described by Advanz as having ‘*a very similar operating model to [Advanz]*’.[325] Advanz considered that the acquired products would ‘*increase [Advanz’s] strength in the UK market, which should leave it better positioned with wholesalers and retail chains*’.[326]

3.184 Focus’s pipeline products included 20mcg Liothyronine Tablets, although Advanz has told the CMA that development was at an early stage and it considered them ‘*negligible in the context of the overall acquisition*’.[327] [✂],[328] [✂].[329] [✂].[330] [✂].[331]

c. Acquisition of Primegen Limited

3.185 On 2 June 2015, Advanz acquired Primegen for [✂].[332] Primegen was a UK-based company founded in 2014, which was engaged in the sale of a number of niche medicines. At the time of the acquisition, Advanz described the Primegen business as ‘*an attractive pipeline of UK and international registrations*’.[333]

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[322] Document LIO0704, '*Liothyronine 5mcg and 10mcg UK - 1PS.DOCX*', page 1.
[323] Document LIO3980, Advanz's response to question 1 of the CMA’s s.26 notice dated 25 July 2017; see also document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 17.
[324] Document PAD085, ‘*AMCo acquisition of Focus Pharma*’.
[325] Document LIO0449, '*Focus Pharmaceuticals Commercial Due Diligence Report*', page 2.
[326] Document LIO0449, '*Focus Pharmaceuticals Commercial Due Diligence Report*', page 3.
[327] Document LIO3980, Advanz's response to question 1 of the CMA’s s.26 notice dated 25 July 2017.
[328] Document LIO0449, '*Focus Pharmaceuticals Commercial Due Diligence Report*', page 5.
[329] Document LIO3980, Advanz's response to question 1 of the CMA’s s.26 notice dated 25 July 2017.
[330] Document LIO0449, '*Focus Pharmaceuticals Commercial Due Diligence Report*', page 4.
[331] Document LIO0449, '*Focus Pharmaceuticals Commercial Due Diligence Report*', page 8.
[332] Document LIO3980, Advanz's response to question 1 of the CMA’s s.26 notice dated 25 July 2017, and document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 17.
[333] Document PAD084, ‘*AMCo acquisition of Primegen*’.

3.186 Through the Primegen acquisition, Advanz inherited a development project for different liothyronine strengths.[334] [✂].[335] [✂].[336]

3.187 [✂].[337] [✂].[338] [✂].

E. Pricing and volumes of Liothyronine Tablets

3.188 This section sets out the evolution of Advanz's monthly ASPs and the NHS Reimbursement Price, as well as volume trends in Liothyronine Tablets.[339] It also sets out pricing and volume trends for Liothyronine Tablets after the Infringement Period following entry by Morningside and Teva, and relevant information regarding other hypothyroidism treatments.

3.189 As set out below, Advanz repeatedly increased its prices for Liothyronine Tablets between November 2007 and July 2017. Advanz's prices were at all times profitable, including prior to the start of the price increases when the price was around £4 per pack.[340]

I. Trends in Advanz's ASPs and the NHS Reimbursement Price

3.190 Figure 3.2 below sets out Advanz's ASPs[341] and the monthly average NHS Reimbursement Price for packs of Liothyronine Tablets between January 2007 and July 2017. The key trends are as follows:

(a) Average prices prior to de-branding remained fairly flat between January and September 2007 at an average of £3.92 (for example, in January 2007,

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[334] Document LIO0618, '*PPRM - Liothyronine new strengths.pptx*', page 2.
[335] Document LIO0596, Email from [✂] to [✂] and [✂] of Advanz, dated 21 October 2015.
[336] Document LIO0704, '*Liothyronine 5mcg and 10mcg UK - 1PS.DOCX*', page 1; see also document LIO0802, '*2016-02-04-AMIL-Board-Pack.pdf*', page 3, and document LIO0596, Email from [✂] to [✂] and [✂] of AMCo, dated 21 October 2015.
[337] Document LIO3980, Advanz's response to question 1 of the CMA's s.26 notice dated 25 July 2017.
[338] Document LIO0618, '*PPRM - Liothyronine new strengths.pptx*', pages 2, 4, 8 and 10.
[339] The NHS Reimbursement Price is the price that is reimbursed to pharmacies by the NHS for medicines dispensed (see paragraph 3.121 above). As the Drug Tariff for Category C medicines is based on the prices charged by the manufacturer (see paragraphs 3.141-3.146 above), the NHS Reimbursement Price during the Infringement Period closely followed the changes in Advanz's ASPs (see Figure 3.2 below). Following Liothyronine Tablets being placed in Category M, the prices charged by wholesalers and/or manufacturers remain an input into the NHS Reimbursement Price, although the correlation is less close. In this section, the NHS Reimbursement Prices are based on PCA data for England, which accounts for 86 to 87% of the total UK supply of Liothyronine Tablets over the Infringement Period and is dispensing data.
[340] Document LIO0010, Advanz's '*UK Retail Brands Business Plan.doc*', page 2.
[341] Advanz's ASPs for Liothyronine Tablets are monthly ASPs per pack, calculated as the revenue generated in a particular month divided by the number of packs sold in that month. No rebates were applied to sales of Liothyronine Tablets during the Infringement Period in the UK, therefore there has been no adjustment for rebates. Document LIO1727, Advanz's response to question 4 of the CMA's s.26 notice dated 20 December 2016. Advanz invoiced wholesalers at ex-factory prices and wholesalers received a 4% discount calculated by reference to Advanz's list price. However, Advanz recognises revenues net of discount in its financial accounts. Document LIO1727, Advanz's response to question 3 of the CMA's s.26 notice dated 20 December 2016, and document LIO4936, Advanz's supplemental response to question 3 of the CMA's s.26 notice dated 20 December 2016.

Advanz's ASP per pack was £3.90 and in September 2007 Advanz's ASP was £4.05).[342]

(b) Advanz's ASP immediately after de-branding in October 2007 was £8.05. Advanz's ASPs steadily and repeatedly increased[343] over the course of the following 10 years. As a result, Advanz's ASPs and NHS Reimbursement Prices in July 2017 were respectively 6,021%,[344] [345] and 5,692%[346] higher than prices in September 2007 (the month prior to de-branding).

(c) The NHS Reimbursement Price closely tracked the changes in Advanz's ASPs throughout the Infringement Period.

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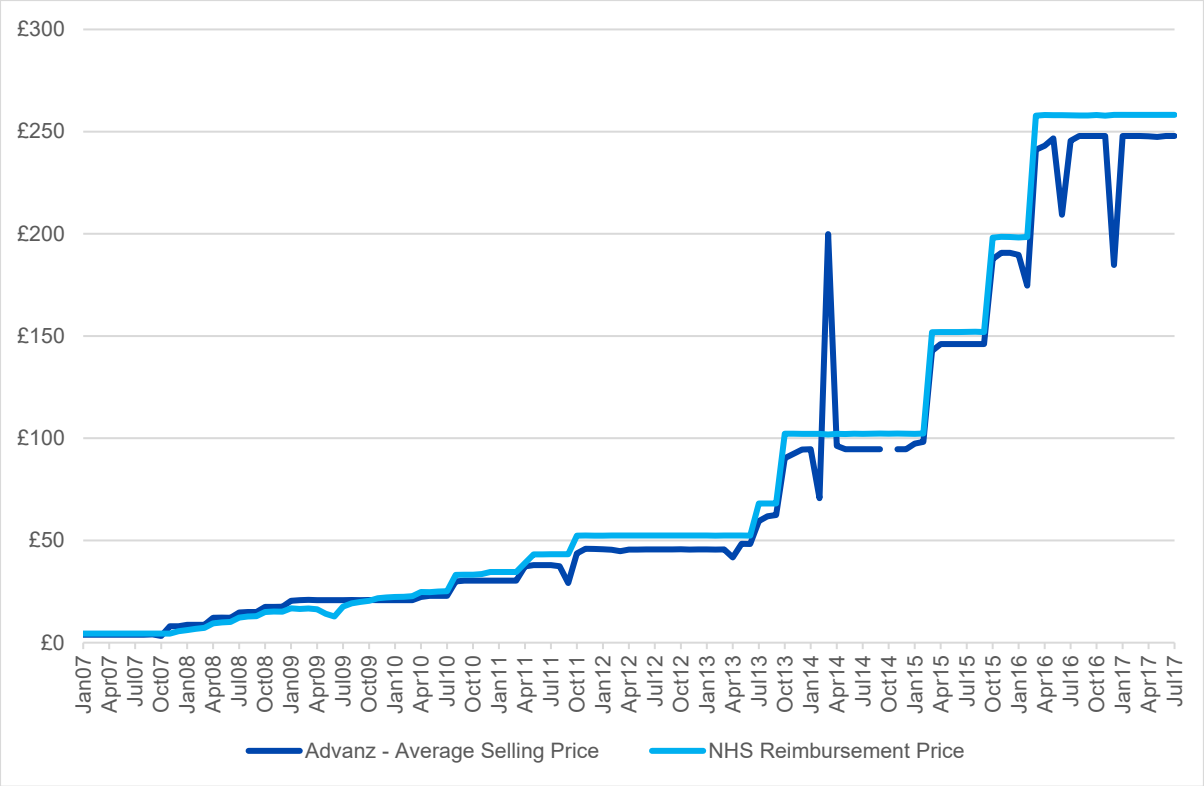
[342] In October 2007, at the same time as de-branding, Advanz switched from selling Liothyronine Tablets in packs of 100 tablets to packs of 28 tablets: '*From October 2007 … the pack size was 28 tablets. … Since October 2007, Liothyronine Sodium 20mg has never been marketed with any other pack size*': document LIO1521, Advanz's response to question 1 of the follow-up questions to the CMA's s.26 notice dated 25 October 2016. In order to allow a comparison of prices per pack before and after the change in pack-size, the CMA has adjusted the price and the number of packs dispensed to 28-tablet pack-size equivalents. As a result, prices per pack reported for the period from January 2007 to October 2007 are expressed in 28-tablet pack-size equivalents. On this basis the CMA has assumed that all packs dispensed since November 2007 contain 28 tablets per pack.
[343] The outliers to this trend, which can be seen in Figure 3.2 below, relate to particularly large orders in particular months. Document LIO2988.3, '*Annex 3 - Liothyronine Tablets sold*'.
[344] Price of £4.05 in September 2007 and £247.87 in July 2017.
[345] The reimbursement figures presented in this Decision are rounded to the nearest penny. However, the percentage increase calculations presented in this Decision are calculated using the more precise data. The percentage figures in this Decision will therefore sometimes differ slightly compared to calculations performed using the rounded figures.
[346] Price of £4.46 in September 2007 and £258.19 in July 2017. See also footnote 345.

Figure 3.2: Advanz's monthly ASP and average NHS Reimbursement Price of Liothyronine Tablets (January 2007 – July 2017)



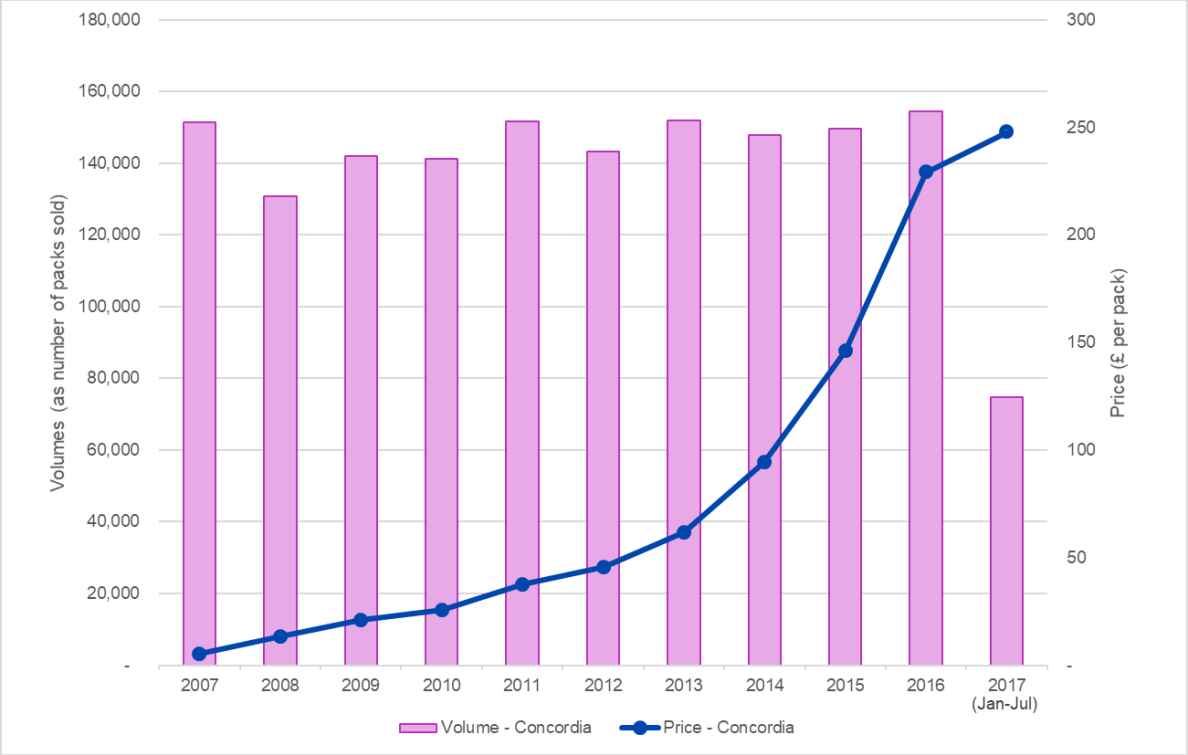
Note: Advanz's price data for October 2014 unavailable.
Source: CMA analysis of data submitted by Advanz and PCA data for England [347]

II. Trends in volumes of Liothyronine Tablets sold in the UK

3.191 Figure 3.3 below shows the volumes of Liothyronine Tablets Advanz sold from 2007 to July 2017, as well as Advanz's annual ASPs for comparison.[348] Over the same period that Advanz's ASPs increased by 6,021%,[349] annual volumes sold have been broadly stable.[350]

[347] See document PAD042, NHS BSA: '*Prescription Cost Analysis*'.
[348] The data for 2017 includes the months from January to July only.
[349] Price of £4.05 in September 2007 and £247.87 in July 2017.
[350] Figure 3.3 below shows that there was a small drop in volumes between 2007 and 2008. As explained at paragraph 3.22 above, in October 2007 Advanz de-branded and changed to a 28 tablets pack size. Given the uncertainty over when 100 tablet packs stopped being dispensed, the volume of packs sold in 2007 may represent an under-estimate.

Figure 3.3: Advanz's ASPs and volumes (number of packs sold) (January 2007 – July 2017)



Note: The data for 2017 include the months from January to July only.
Source: CMA analysis of data submitted by Advanz.

III. Trends in volumes of Liothyronine Tablets and Levothyroxine Tablets dispensed in the UK

3.192 Table 3.3 below shows volumes of Liothyronine Tablets together with other treatments for hypothyroidism (Levothyroxine Tablets and unlicensed liothyronine) dispensed between 2007 and 2017. The volumes of Liothyronine Tablets and unlicensed liothyronine dispensed in the UK are very low relative to the volumes of Levothyroxine Tablets: on average in each year between 2007 and July 2017, Levothyroxine Tablets accounted for 99.7% of units dispensed, while Liothyronine Tablets accounted for less than 0.3%.

Table 3.3: Number of items dispensed of Levothyroxine Tablets and capsules, Liothyronine Tablets, unlicensed liothyronine and NDT

Year	Levothyroxine Tablets and capsules	Liothyronine Tablets	Unlicensed liothyronine	NDT
2007	1,063,580,033	3,701,100	17,287	174,740
2008	1,123,091,532	3,425,903	15,996	139,819
2009	1,172,490,342	3,615,017	43,384	160,104
2010	1,219,476,505	3,926,094	76,681	216,215
2011	1,258,897,842	4,344,774	133,350	300,158
2012	1,312,102,761	4,543,068	201,662	385,125
2013	1,333,922,888	4,489,650	308,217	441,139
2014	1,357,442,687	4,477,166	430,753	465,281

Year	Levothyroxine Tablets and capsules	Liothyronine Tablets	Unlicensed liothyronine	NDT
2015	1,382,791,963	4,329,752	572,313	454,725
2016	1,413,559,375	4,121,434	624,528	422,330
2017 (Jan to July)	874,074,357	2,224,974	428,337	249,233

Notes:
a) No monthly data available for Northern Ireland and Scotland, so annual data applied pro-rata for 2017 (January to July).
b) Levothyroxine Tablets 25mcg, 50mcg, and 100mcg account for around 99% of the total number of Levothyroxine Tablets and levothyroxine capsules dispensed in each year.

Source: CMA analysis based on PCA data for England, Wales, Scotland, and Northern Ireland.

IV. Prices of Liothyronine Tablets following entry by Morningside and Teva

3.193 Figure 3.4 below sets out ASPs by MA holder and monthly average NHS Reimbursement Price for packs of Liothyronine Tablets up to February 2021.[351] The key facts are as follows:

(a) In July 2017, the last month of the Infringement Period, the ASP for packs of Liothyronine Tablets was £247.87. By February 2021, the average price across suppliers had dropped to [✂], a percentage change of [✂]. Each manufacturer's ASP fell during this period:

(i) Advanz's ASP was £247.87 in July 2017. In February 2021, Advanz's ASP was equal to [✂], a percentage drop of [✂].

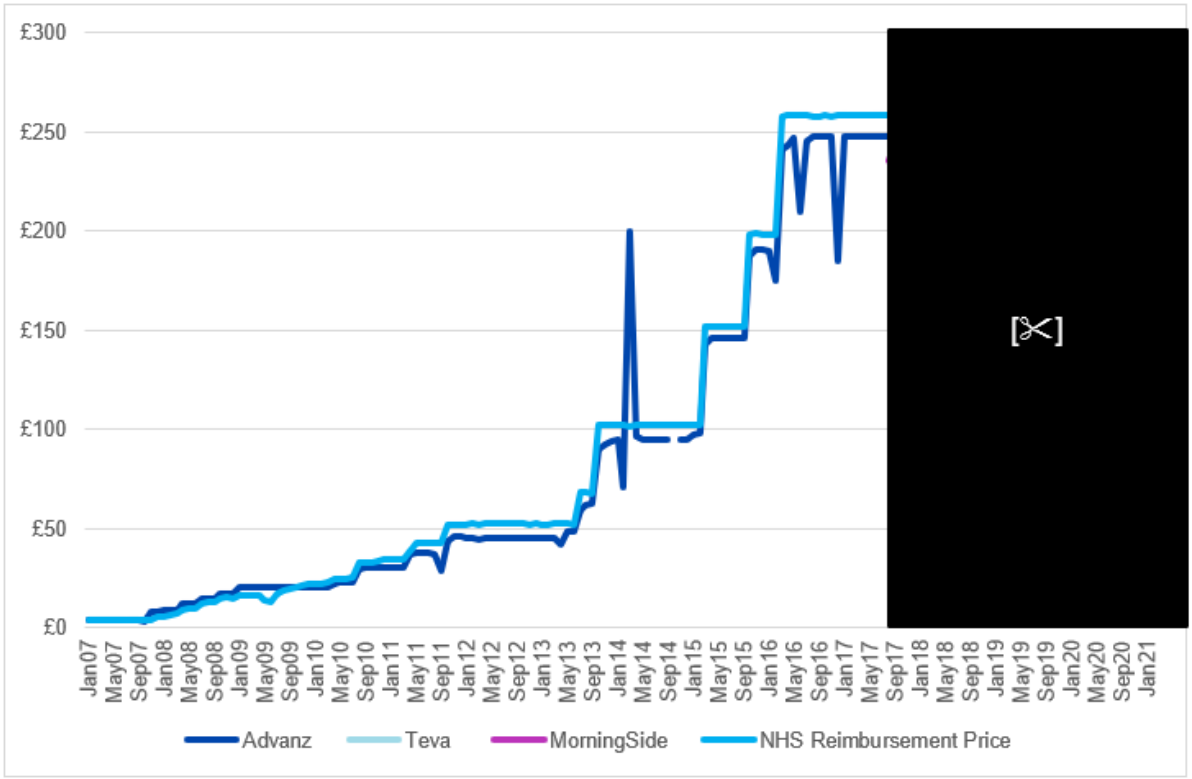
(ii) Morningside entered the market in August 2017 with an ASP of [✂]. In February 2021 Morningside's ASP was equal to [✂], a percentage drop of [✂].

(iii) Teva entered the market in September 2017 with an ASP[352] of [✂]. In February 2021 Teva's ASP was equal to [✂], a percentage drop of [✂].

(b) Between July 2017 and February 2021 the average NHS Reimbursement Price[353] changed from £258.19 to £137.70, a percentage decrease of 47%.

[351] The latest data available to the CMA.
[352] [✂]
[353] This is based on PCA data for England only.

Figure 3.4: Liothyronine Tablet ASPs by manufacturer and average NHS reimbursement price (January 2007 – February 2021)



Source: CMA analysis of data provided by Advanz, Teva, Morningside and PCA data for England.

F. The supply of Levothyroxine Tablets

3.194 This section sets out information regarding the supply of Levothyroxine Tablets, in order to inform the comparative exercise that the CMA carries out in its assessment later in this Decision.

I. Suppliers of Levothyroxine Tablets

3.195 There are currently four companies supplying Levothyroxine Tablets in the UK, across a number of strengths: AUK, Advanz, Teva and Wockhardt UK Limited ('**Wockhardt**'). Each of these companies currently supplies the strengths set out in Table 3.4 below. Advanz is the only company supplying a branded version of Levothyroxine Tablets (Eltroxin).

Table 3.4: Companies supplying various strengths of Levothyroxine Tablets in the UK[354]

Company	12.5mcg	25mcg	50mcg	75mcg	100mcg
AUK			Generic		Generic
Advanz		Generic Eltroxin	Generic Eltroxin		Generic Eltroxin
Teva	Generic	Generic	Generic	Generic	Generic
Wockhardt		Generic			

Source: CMA summary of information provided by different parties.

3.196 Levothyroxine Tablets were first developed in 1927. The current market participants have all been present in the market since prior to the start of the Infringement Period:

(a) AUK has supplied 50mcg and 100mcg strengths since shortly after 8 June 1978;[355]

(b) Advanz acquired the UK product rights to Levothyroxine Tablets in 1992. These included rights to the branded Eltroxin product as well as unbranded generic Levothyroxine Tablets;[356]

(c) Teva has supplied 50mcg and 100mcg strengths since around November 1980.[357] Teva sourced 25mcg tablets from Advanz from prior to the start of the Infringement Period until 2016 and it sourced 50mcg and 100mcg tablets from Advanz between 2012 and 2016;[358] and

(d) Wockhardt has supplied 25mcg tablets in the UK since at least 2007.[359]

3.197 In 2013, Advanz withdrew the supply of Eltroxin. It reintroduced Eltroxin in 2016, [✂].[360] Sales of Eltroxin across the three strengths [✂] over the Infringement Period. Advanz's volume of sales in 2007 was 623,000 packs of

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[354] The 12.5mcg and 75mcg strengths were introduced by Teva in 2016. Previously, only the 25mcg, 50mcg and 100mcg strengths were available in the UK: document LIO7456, Teva's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[355] Document LIO7453, AUK's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[356] Document LIO7459, Advanz's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[357] Document LIO7456, Teva's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[358] In February 2012, the MHRA suspended Teva's MA for the 50mcg and 100mcg strengths, following an increase in reports from patients and healthcare professionals, raising concerns that Teva's Levothyroxine Tablets might not be equivalent to, or as effective as, Levothyroxine Tablets from other manufacturers. The MHRA concluded that the manufacture of Teva's product was not in regulatory compliance with its MAs and the MHRA could no longer be assured that all aspects of manufacture were appropriately controlled. In 2016, the suspension of Teva's MA for the 50mcg and 100mcg strengths was lifted. At this time, Teva was also granted MAs for 12.5mcg, 25mcg and 75mcg tablets, which it has since started supplying: document LIO7456, Teva's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[359] Document LIO7473, Wockhardt's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[360] Document LIO7459, Advanz's response to question 10 of the CMA's s.26 notice dated 21 August 2018.

Eltroxin, while in 2017 its volume of sales [✂].[361] Advanz's sales of unbranded Levothyroxine Tablets increased over the same period: in 2007 Advanz sold 8.6 million packs, [✂].[362]

3.198 In general terms, the pricing framework for Levothyroxine Tablets is the same as for Liothyronine Tablets. However, unlike Liothyronine Tablets, the principal strengths of Levothyroxine Tablets were in Category M of the Drug Tariff during the Infringement Period. As a branded product, Eltroxin was subject to the PPRS throughout the Infringement Period.[363] The PPRS is discussed at paragraphs 3.138 to 3.140 above.

II. Levothyroxine Tablet prices over time

3.199 Table 3.5 and Figure 3.5 below set out the ASPs for 25mcg, 50mcg and 100mcg Levothyroxine between 2007 and 2018. 25mcg, 50mcg and 100mcg have been the main strengths of Levothyroxine Tablets since 2007 and the only strengths with at least two manufacturers. The key facts are as follows:

(a) Since the start of the Infringement Period, the [✂] ASP of the main strengths of Levothyroxine Tablets was in 2009, when the 50mcg and 100mcg strengths had a price per pack[364] of [✂]. The [✂] ASP was in 2016 when the 25mcg strength reached a price of [✂] per pack.

(b) Prior to Teva's MA suspension in 2012, ASPs were on average [✂], [✂], and [✂] per pack for 25mcg, 50mcg and 100mcg Levothyroxine Tablets respectively.

(c) Between 2012 and 2016 (i.e. the years when Teva's MAs were suspended), ASPs [✂] and were on average [✂], [✂], and [✂] per pack for 25mcg, 50mcg and 100mcg Levothyroxine Tablets respectively.

(d) Between 2017 and September 2018, following Teva's re-entry into the market, ASPs [✂] and were on average [✂], [✂], and [✂] for 25mcg, 50mcg and 100mcg Levothyroxine Tablets respectively.

Table 3.5: Levothyroxine Tablet ASPs (2007-2018)

	2007	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017	2018
Levothyroxine Tablets 25 mcg	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]

[361] Document LIO7459, Advanz's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[362] Document LIO7459, Advanz's response to question 1 of the CMA's s.26 notice dated 21 August 2018.
[363] Document LIO7459, Advanz's response to question 8 of the CMA's s.26 notice dated 21 August 2018.
[364] Specifically, ASPs in this section have been expressed as equivalent to the price of a pack of 28 tablets.

Levothyroxine Tablets 50 mcg	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Levothyroxine Tablets 100 mcg	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]

Notes:
a) ASPs expressed as equivalent to the price of a pack of 28 tablets.
b) ASPs have been calculated as weighted averages.
c) 2018 includes data from January to September inclusive.
d) [✂].
e) Only MA holders' prices to wholesalers have been considered. As such, sales to pre-wholesalers or cross-supplies (e.g. from Advanz to Teva during its MA suspension) were excluded
f) Teva's MAs were suspended in January 2012 and reinstated in September 2016 (Teva re-entered in late October 2016). For the purpose of the table Teva was excluded from 2012 to 2016 (inclusive).
g) Albeit cross-supplied by Advanz, between 2007 and 2009 (inclusive) Teva's data on Levothyroxine 25mcg tablets have been reported as this is the only data available to the CMA for that period.

Source: CMA analysis of data provided by Advanz, Teva, AUK and Wockhardt.

Figure 3.5: Levothyroxine Tablet ASPs (2007-2018)

[✂]

Notes:
a) ASPs expressed as equivalent to the price of a pack of 28 tablets.
b) ASPs have been calculated as weighted averages.
c) 2018 includes data from January to September inclusive.
d) [✂]
e) Only MA holders' prices to wholesalers have been considered. Thus, sales to pre-wholesalers or cross-supplies (e.g. from Advanz to Teva during its MA suspension) were excluded
f) Teva's MAs were suspended in January 2012 and reinstated in September 2016 (Teva re-entered in late October 2016). For the purpose of the table Teva was excluded from 2012 to 2016 (inclusive).
g) Albeit cross-supplied by Advanz, between 2007 and 2009 (inclusive) Teva's data on Levothyroxine 25mcg tablets have been reported as this is the only data available to the CMA for that period.
Source: CMA analysis of data provided by Advanz, Teva, AUK and Wockhardt.

4. Market Definition and Dominance

A. Summary

4.1 The CMA concludes that the relevant market is for the supply of Liothyronine Tablets in the UK and that Advanz was dominant in that market from at least 1 November 2007 to 31 July 2017.

I. Market definition

4.2 The CMA concludes that the relevant market is for the supply of Liothyronine Tablets in the UK.

4.3 Defining the relevant market is not an abstract exercise; it is done to facilitate the assessment of alleged dominance.[365] As explained in detail below, market definition involves looking at relevant factors, taking into account the economic context of the case.[366] The key consideration in the definition of a product market is that of a competitive constraint: that is, the extent to which other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm.[367]

4.4 In reaching its conclusion on the scope of the relevant market, the CMA has rejected Levothyroxine Tablets, unlicensed liothyronine and NDT as sufficient substitutes for Liothyronine Tablets in the treatment of hypothyroidism.[368]

4.5 The qualitative and quantitative evidence both confirm that no alternative products acted as a competitive constraint on the conduct of Advanz, the monopolist supplier of Liothyronine Tablets which held a 100% UK market share throughout the Infringement Period.

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[365] See OFT guidance on market definition, adopted by the CMA ('**OFT403**'), paragraph 2.1. See also *Paroxetine I* [2018] CAT 4, paragraph 397.
[366] See section 4.B.I. below.
[367] See *Aberdeen Journals v DGFT* [2002] CAT 4, paragraphs 96 to 97 cited with approval in *Paroxetine I* [2018] CAT 4, paragraph 382 and *Phenytoin CAT* [2018] CAT 11 paragraph 115.
[368] Advanz also supplies powder which can be formulated to liothyronine injections. However, given: (i) the limited volumes of this product sold; (ii) the fact that it is primarily used for indications other than the treatment of hypothyroidism (see paragraph 3.56 above), and (iii) that it is sold at a price above that of Liothyronine Tablets, the CMA does not consider it plausible that it could impose a constraint on Liothyronine Tablets. See document LIO0225, Advanz's '*Glacier - Reforecasted SKUs - Questions for management.xlsx*' and document LIO0460, Advanz's '*Final Endocrinology Market Overview – BD&L – 16.10.14*', page 35.

a. Product market

i. Qualitative evidence

4.6 The qualitative evidence (Section 4.B.III.a) demonstrates that neither unlicensed liothyronine and NDT nor Levothyroxine Tablets are sufficiently substitutable to act as a significant competitive constraint on the pricing of Liothyronine Tablets. In particular:

(a) Advanz's internal documents demonstrate its clear internal view that, as the exclusive supplier of Liothyronine Tablets, it had the ability to set prices independently of effective competitive pressure from alternative products. Internal documents show Advanz implementing numerous significant price increases over a period of 10 years without expecting or experiencing any competitive reaction which would have a significant impact on its volumes. Rather, the internal documents frequently remark upon the absence of competition from other suppliers of Liothyronine Tablets with no suggestion that price rises might lead to patients switching to NDT, unlicensed liothyronine or Levothyroxine Tablets. Moreover, Advanz implemented these significant price increases with negligible promotional activity.

(b) Differences in the regulatory environment for unlicensed liothyronine and NDT indicate that these products are not close substitutes for Liothyronine Tablets (consistent with Advanz's own perception that these products did not constrain its market power).

(c) Evidence relevant to doctors' prescribing decisions demonstrates that Levothyroxine Tablets are not a close substitute for patients who are prescribed Liothyronine Tablets. In particular, medical recommendations and NHS guidelines indicate that Levothyroxine Tablets are the primary treatment for hypothyroidism and that Liothyronine Tablets are prescribed in circumstances where patients do not respond adequately to Levothyroxine Tablets. This means that for patients prescribed Liothyronine Tablets, Levothyroxine Tablets are not perceived as a substitutable product.

(d) Actual and potential competing generic suppliers of Liothyronine Tablets do not regard alternative products as constraining pricing of Liothyronine Tablets.

ii. Quantitative evidence

4.7 The quantitative evidence (Section 4.B.III.b) concerning actual consumption patterns corroborates the qualitative evidence. Following de-branding in September 2007, Advanz profitably implemented numerous significant price increases without experiencing a significant impact on its volumes. Even after

the introduction of revised, stricter prescribing guidance in 2015 (see paragraphs 3.74 above and 5.37 below), volumes of Liothyronine Tablets remained broadly stable, declining by only a few percent at the end of the Infringement Period.

4.8 Following the entry of other generic Liothyronine Tablets suppliers, Liothyronine Tablet prices have fallen considerably (and continue to fall). Observed pricing patterns show that the constraints on Liothyronine Tablets from other products were insignificant compared to the constraint that generic suppliers of Liothyronine Tablets place on each other.

b. Geographic market

4.9 It is necessary to obtain a UK-wide MA in order to sell Liothyronine Tablets in the UK and the relevant regulatory framework for prescription drugs like Liothyronine Tablets (including the price at which CCGs reimburse pharmacies for prescriptions) is specific to the UK.

II. Dominance

4.10 The CMA concludes that Advanz held a dominant position in the relevant market from at least 1 November 2007 to 31 July 2017. In particular, this is demonstrated by:

(a) Advanz's market share of 100% throughout that period;

(b) Advanz's pricing behaviour and financial performance, as reflected by the fact that Advanz has been able consistently to profitably raise prices; and

(c) The lack of sufficient constraint from potential entry owing to high barriers to entry and the lack of countervailing buyer power.

B. Market definition

4.11 For the reasons set out in this section (which are summarised at paragraphs 4.2 to 4.9 above), the CMA concludes that the relevant market is for the supply of Liothyronine Tablets in the UK.

I. Legal framework

4.12 In order to determine whether an undertaking holds a dominant position, it is first necessary to define the relevant market in which the undertaking operates.[369]

4.13 Market definition is a step in assessing dominance rather than an end in itself; it is a tool to identify and define the boundaries of competition between undertakings. The essential purpose is to identify the competitive constraints to which the allegedly dominant firm is subject.[370] As such, the definition of the relevant market should not be an abstract exercise detached from the question of dominance.[371]

4.14 There are generally two dimensions to a relevant market: (i) a product and (ii) a geographic dimension. A further possible dimension to market definition is time.[372] A firm may find itself exposed to competitive constraints at one point in time but may be free from them at another.

4.15 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.[373]

4.16 A key question when assessing the relevant market is whether the products concerned are '*close enough*' substitutes to be sensibly regarded as belonging to the same market. The process of defining a market therefore typically begins by establishing the closest substitutes to the product that is the focus of the investigation (i.e. the focal product – see paragraph 4.24 below).

4.17 Functional interchangeability or similarity of characteristics will not, in themselves, be sufficient to determine whether two products are demand substitutes, because the responsiveness of customers to relative changes in

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[369] *Europemballage Corporation and Continental Can Company v Commission*, 6/72, EU:C:1973:22, paragraph 32. *United Brands*, 27/76, EU:C:1978:22, paragraph 10. *Hoffmann-La Roche v Commission* 85/76, EU:C:1979:36, paragraph 21. *Aberdeen Journals* [2002] CAT 4, paragraph 88.
[370] *Albion Water (Dominance and other issues)* [2006] CAT 36, paragraph 90. See also paragraph 2 of the European Commission's notice on the definition of relevant market for the purposes of Community competition law OJ [1997] C 372/5 (97/C 372/03) (the '**Commission Notice on Market Definition**').
[371] *Aberdeen Journals* [2002] CAT 4, paragraph 101. This passage was cited with approval by the CAT in *Phenytoin CAT* [2018] CAT 11 at paragraph 115.
[372] OFT403, paragraph 5.1.
[373] *Aberdeen Journals* [2002] CAT 4, paragraph 96.

price may be determined by other considerations as well.[374] In this respect, the European Commission has repeatedly rejected the proposition that pharmaceutical products used to treat the same medical condition are necessarily to be regarded as demand substitutes.

4.18 For example, in its *AstraZeneca* decision, 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 different medicines are prescribed for the same general illness or disease'.[375]

4.19 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?'.[376]

4.20 In *AstraZeneca* the European Commission used price data and price developments to assess whether other products constrained the price of a pharmaceutical product. [377] The General Court, on appeal, rejected an argument that '*price-related indicators are inappropriate for competition analysis purposes where competition on the market is not based on price*',[378] holding that '*... the specific features which characterise competitive mechanisms in the pharmaceutical sector do not negate the relevance of*

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[374] Commission Notice on Market Definition, paragraph 36.
[375] Case COMP/A.37.507/F3 – *AstraZeneca*, European Commission decision of 15 June 2005 ('***AstraZeneca* decision**'), paragraph 381.
[376] *Aberdeen Journals* [2002] CAT 4, paragraph 97 (emphasis added). See also *Paroxetine I* [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'*.
[377] See, for example, *AstraZeneca* decision, paragraphs 423 and 428-431.
[378] *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraph 112.

price-related factors in the assessment of competitive constraints, although those factors must be assessed in their specific context'.[379]

4.21 Similarly, in *Servier* the General Court confirmed that price-related factors are relevant to consider in the assessment of competitive constraints, although these must be assessed '*in their own context*':

> 'It is also clear from the case-law that the specific features of competition mechanisms in the pharmaceutical sector do not remove the price-related factors from their relevance in the assessment of competitive constraints, although those factors must be assessed in their own context (judgment of 1 July 2010, AstraZeneca v Commission, T 321/05, EU:T:2010:266)'.[380]

4.22 In terms of specific qualitative factors that should be taken into account, in *Servier* the General Court set out a list of eight categories of information that it thought should be considered in that case:

> 'It is necessary to examine all the relevant elements making it possible to assess whether perindopril was perceived by prescribing doctors as being such that other ACE inhibitors could be substituted therapeutically for it. In the present case, account will be taken, in turn, of the following: [i] the basic information concerning that medicinal product set out in the contested decision, [ii] the ATC classification system, [iii] medical guidelines, [iv] medical studies, [v] policies implemented by certain local authorities in the United Kingdom, [vi] internal documents from Servier, [vii] the Commission's survey of prescribers and [viii] the responses of producers of other ACE inhibitors to the questions asked by the Commission'.[381]

4.23 There is no set '*hierarchy*' of evidence in EU or UK law on issues such as market definition.[382] 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.[383] The CAT has also held that evidence of how the

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[379] *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraph 183. See also *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1385.
[380] *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1411.
[381] *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1421.
[382] *Aberdeen Journals v DGFT* [2003] CAT 11, paragraph 127.
[383] Commission Notice on Market Definition, paragraph 38. In *Paroxetine* the CAT found that – despite limited switching in response to pricing differences – certain other anti-depressant drugs exerted some competitive constraint on the patent-protected product in question (Seroxat) in that they stimulated GSK's promotional efforts to persuade doctors to prescribe paroxetine. However, the CAT accepted that post-genericisation the relevant

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*'.[384]

II. Focal Product

4.24 The '**Focal Product**' of this Decision (i.e. the product under investigation) is Liothyronine Tablets (that is, UK-licensed 20mcg liothyronine sodium tablets). As set out at section 3.B.II.a above, Liothyronine Tablets are primarily used to treat hypothyroidism. Given that the use of Liothyronine Tablets to treat other illnesses is relatively small in volume terms, the CMA's analysis focuses on the treatment of hypothyroidism.[385]

III. Relevant product market

4.25 The CMA finds that the relevant product market is no wider than the supply of Liothyronine Tablets.[386] In reaching this conclusion, the CMA has considered the following products as potential substitutes for Liothyronine Tablets in the treatment of hypothyroidism:[387]

(a) Levothyroxine Tablets;[388] and

(b) Unlicensed liothyronine and NDT.

4.26 In the following sections, the CMA first sets out the qualitative evidence and then turns to quantitative evidence of actual consumption patterns in response to price changes.

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market was that of the paroxetine molecule alone. See *Paroxetine I* [2018] CAT 4 paragraphs 384 and 402 and *Paroxetine II* [2021] CAT 9, paragraph 90.

[384] *Aberdeen Journals* [2002] CAT 4, paragraphs 103-104.

[385] To the extent that any potential substitutes for Liothyronine Tablets for other illnesses do not also treat hypothyroidism, any switching to such products would not be significant enough to constrain Advanz's behaviour in regard to the majority of its Liothyronine Tablet sales.

[386] Advanz told the CMA that the product market should include Levothyroxine Tablets, unlicensed liothyronine: document LIO6288, Advanz RSO, Schedule 2, paragraphs 2.78ff.

[387] Advanz also supplies powder which can be formulated to liothyronine injections. However, given: (i) the limited volumes of this product sold; (ii) the fact that it is primarily used for indications other than the treatment of hypothyroidism (see paragraph 3.56 above), and (iii) that it is sold at a price above that of Liothyronine Tablets, the CMA does not consider it plausible that it could impose a constraint on Liothyronine Tablets. See document LIO0225, Advanz's '*Glacier - Reforecasted SKUs - Questions for management.xlsx*' and document LIO0460, Advanz's '*Final Endocrinology Market Overview – BD&L – 16.10.14*', page 35.

[388] Levothyroxine Tablets were the only alternative treatment for hypothyroidism that Advanz identified: document LIO3061, Advanz's response to question 1(c) of the CMA's s.26 notice dated 25 January 2017.

a. Qualitative evidence

4.27 The CMA has reviewed the following categories of qualitative evidence to inform its market definition assessment:[389]

(a) the ATC classification;

(b) Advanz's internal documents and submissions;

(c) evidence on unlicensed liothyronine and NDT;

(d) factors that influence doctors' prescribing of Liothyronine Tablets and Levothyroxine Tablets, namely:

(i) chemical composition and mode of action;

(ii) medical recommendations;

(iii) NHS policies at the national and local level; and

(iv) medical studies;

(e) views of third-party manufacturers of Liothyronine Tablets.

4.28 The qualitative evidence which the CMA considers to be particularly informative includes: Advanz's internal documents and submissions; medical recommendations; and NHS policies at the national and local level.

4.29 As summarised at paragraph 4.6 above, the qualitative evidence demonstrates that neither unlicensed liothyronine and NDT nor Levothyroxine Tablets are sufficiently substitutable to act as a significant constraint on the pricing of Liothyronine Tablets.

i. ATC Classification

4.30 The Anatomical Therapeutic Chemical ('**ATC**') classification system is an internationally recognised system for drug utilisation monitoring and research.[390] The CMA has used the ATC classification system in this investigation as a starting point to help identify potential substitutable products which may belong in the relevant market in this case. This is in line with the

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[389] See *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1422. The CMA does not propose to include survey evidence, which it does not consider is needed to substantiate its case.
[390] The ATC classification system is recognised and used by the European Pharmaceutical Market Research Association ('**EPhMRA**'), and the corresponding system maintained by the World Health Organization ('**WHO**'). The ATC classification system is used to help improve quality of drug use: document PAD183, WHO: '*Purpose of the ATC/DDD system*'.

approach adopted by the CMA[391] and European Commission[392] in previous investigations in the pharmaceutical sector and it is an approach which has been approved by the Courts on appeal.[393]

4.31 The ATC classification system groups active substances in a hierarchy of five different levels.[394]

(a) The third-level of the ATC classification system (ATC3) groups together pharmaceutical products by reference to their therapeutic indications. At ATC3 liothyronine sodium belongs within the 'Thyroid Preparations' group along with Levothyroxine, NDT and other medicines.

(b) The fourth-level class (ATC4) normally takes into consideration the mode of action. In this case ATC4 includes a smaller set of medicines including liothyronine, levothyroxine, combinations of levothyroxine and liothyronine, tiratricol and thyroid gland preparations within the 'Thyroid hormones' group.[395]

(c) The fifth-level class (ATC5) comprises individual active substances and in this case consists solely of liothyronine sodium.

4.32 Levothyroxine Tablets, unlicensed liothyronine and NDT (which all fall within ATC3) have been raised by the Parties as potential substitutes. They are considered in further detail below. The CMA has not seen any evidence that other products listed within the ATC3 group or any other products outside that group are potential substitutes for Liothyronine Tablets, nor have the Parties or third parties suggested that they are.[396] On this basis other products are not considered further.

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[391] 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.
[392] 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.
[393] See *Genzyme v OFT* ('***Genzyme***') [2004] CAT 4 paragraphs 198-199. Judgment of 1 July 2010, *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraphs 154–156, upheld by the Court of Justice in its Judgment in *AstraZeneca v Commission*, C-457/10 P, EU:C:2012:770.
[394] At the second level, the system groups active substances according to either pharmacological or therapeutic groups. The third and fourth level identifies further sub-categories according to chemical, pharmacological or therapeutic subgroups and the fifth level is the chemical substance.
[395] Document PAD181, WHO: '*WHOCC – ATC/DD Index: Systemic hormonal preparations, excl. sex hormones and insulins*'.
[396] Document LIO3061, Advanz's response to question 1(c) of the CMA's s.26 notice dated 25 January 2017. Advanz also supplies powder which can be formulated to liothyronine injections. However, given: (i) the limited

ii. Advanz's internal documents and submissions

4.33 The CMA has reviewed contemporaneous documents and submissions provided by Advanz containing information on its strategy in relation to Liothyronine Tablets. Advanz's assessment provides useful insight into the extent to which it considered that prices or sales of Liothyronine Tablets were constrained by other products or competitor activity in developing hypothyroidism treatments, or by changes to guidance in the treatment area. The CAT has previously said that evidence as to how the allegedly dominant undertaking views its competitors may be of '*decisive importance*'.[397] The evidence of most relevance to the CMA's assessment is objective evidence regarding parameters of competition. This may include considerations such as how Advanz responds to competitor behaviour, commentary around how a new product launch is affecting sales, or assessments of how changes to Advanz's own product portfolio may have an impact upon the sales and strategies of its competitors.

4.34 Advanz's internal documents demonstrate its view that, as the exclusive supplier of Liothyronine Tablets, it had the ability to set prices independently of effective competitive pressure from alternative products. In the absence of competition from other suppliers of Liothyronine Tablets, Advanz implemented numerous significant price increases over a period of several years without expecting or experiencing a significant impact on its volumes. There is also evidence in Advanz's internal documents that there were no significant constraints of a non-price nature on Liothyronine Tablets. Advanz implemented significant price increases with negligible promotional activity.

4.35 The CMA has assessed Advanz's internal documents and other evidence in relation to:

(a) substitution from Liothyronine Tablets to other treatments;

(b) constraints on Advanz's pricing conduct; and

(c) constraints on Advanz's non-pricing conduct such as promotional activity and product development.

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volumes of this product sold; (ii) the fact that it is primarily used for indications other than the treatment of hypothyroidism (see paragraph 3.56 above), and (iii) that it is sold at a price above that of Liothyronine Tablets, the CMA does not consider it plausible that it could impose a constraint on Liothyronine Tablets. See document LIO0225, Advanz's '*Glacier - Reforecasted SKUs - Questions for management.xlsx*' and document LIO0460, Advanz's '*Final Endocrinology Market Overview – BD&L – 16.10.14*', page 35. See also the medical and wider NHS evidence as well as the regulatory context set out later in this section.

[397] *Aberdeen Journals* [2002] CAT 4, paragraphs 103-104.

- *No substitution from Liothyronine Tablets to other treatments*

4.36 Advanz has informed the CMA that Levothyroxine Tablets were the main treatment constraining its supply of Liothyronine Tablets.[398] However, there is no evidence in Advanz's internal documents that Advanz systematically reviewed competitor activity in relation to Levothyroxine Tablets, unlicensed liothyronine or NDT, or that it considered competitive responses to changes within the treatment area.[399]

4.37 On the contrary, when describing Liothyronine Tablets, Advanz's internal documents highlight features which mean they are differentiated from Levothyroxine Tablets, and indicate that they are without substitute. For example:[400]

(a) In one presentation to investors dated May 2012, Liothyronine Tablets are described as having '*a more rapid onset of action than levothyroxine and is rapidly metabolised*'.[401]

(b) In response to an email dated October 2015 from [Advanz CEO] asking for confirmation that Liothyronine Tablets had no alternatives, an Advanz employee replied that the alternative would be: '*levothyroxine if liotyronine* [sic] *not available. Slow onset and again, very unsatisfactory 2nd best*'.[402]

(c) An investor question and answer presentation dated November 2015 stated: '*No alternative product for treatment so no comparator pricing other than for some patient cohorts Levothyroxine can be used*'.[403]

(d) An email chain dated May 2016 explains that there is no lower-priced alternative for Liothyronine Tablets: '*[I]s it typical to have lower cost alternatives to our higher priced generics? If not "typical" is "in many*

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[398] Document LIO3061, Advanz's response to question 7(a) of the CMA's s.26 notice dated 25 January 2017. See also question 16: Advanz does not refer to unlicensed products as a constraint on Liothyronine Tablets. Further, Advanz said that it was unaware of which companies currently supply unlicensed liothyronine in the UK. Advanz informed the CMA that it had not taken any action during the Infringement Period to influence the level of imports of unlicensed liothyronine and NDT into the UK, see document LIO3061, Advanz's response to questions 19 of the CMA's s.26 notice dated 25 January 2017.
[399] One internal email appears to suggest that unlicensed liothyronine sales are large enough to warrant consideration, though the response is to start '*with the products where we face genuine UK licensed competition*': document LIO4424, Email from [Vice President UK & Ireland Commercial, Advanz] to [Director UK Generics, Advanz] dated 13 February 2017.
[400] The CMA notes that there is broad consistency in information across Advanz's investor-facing documents and other internal documents.
[401] Document LIO0308, '*Project Glacier - 798108 - Final Report - 210512 (IMS).pdf*', page 73. See also the memorandum to investors dated September 2012: document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62.
[402] Document LIO3815, Email from [Advanz employee] to [Advanz CEO] dated 13 October 2015.
[403] Document LIO0601, '*Investor Q&A info pack - DRAFT 12Nov2015.pptx*', page 2.

instances" fair? In many cases yes but in some cases like liothyronine the answer is no, we are exclusive supplier and it is essential'.[404]

- *No constraints on Advanz's pricing conduct*

4.38 Advanz's internal documents indicate that other treatments did not constrain Advanz's pricing of Liothyronine Tablets. Advanz frequently refers to itself as being the sole or exclusive supplier of Liothyronine Tablets and explains that this gives it a strong market position in relation to its ability to raise prices. For example:[405]

(a) In a spreadsheet modelling future price rises emailed from [✂] (then Head of Marketing) to [✂] (then Chief Operating Officer) and [✂] (then UK Head of Pharmaceuticals) dated November 2008, Advanz comments '*Goldshield is sole supplier. Price increase is possible. We have already increased price from £8.72 (Mar'08) to £20.80 (Jan'09)*' and further states that '*[i]n year 2008 Goldshield sales has not decreased inspite* [sic] *of price increase*'.[406]

(b) In a budget preparation document dated March 2011 emailed to [✂] (then Chief Executive Officer), Liothyronine Tablets are listed as one of the products for which: '*Prices have been increased on sole supply products which have been taken out of the PPRS scheme*'.[407]

(c) A memorandum to investors dated September 2012 states that '*Mercury Pharma has a strong market position as the only supplier of Liothyronine tablets in the UK market … Through its position as sole market provider in the UK, Mercury Pharma has strong pricing power. Over the last 3 years, Mercury Pharma has doubled the price of Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases, with volumes growing from FY2010 to FY2012 at a CAGR of 2%*'.[408]

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[404] Document LIO0662, Email from [Advanz Global Marketing Director] to [Vice President of Investor Relations and Communications, Advanz] and others dated 4 May 2016.
[405] The CMA notes that there is broad consistency in information contained in investor-facing documents with Advanz's other internal documents.
[406] Document LIO0043, '*Proposed - Price Increase Model 2009-10.xls*', attached to document LIO0042, Email from [Goldshield Head of Marketing Brands and Generics India] to [Goldshield Founder and Group Board Director] dated 28 November 2008. In document LIO0043, Advanz's '*Proposed - Price Increase Model 2009-10.xls*', page 3, Advanz notes that Liothyronine Tablets have '*a 1.6% market share out of the total Thyroid preparations*'. However, the CMA notes that the proposed price increase assumed no impact on Liothyronine Tablet volumes indicating no substitution to alternative products.
[407] Document LIO0112, '*Budget 2011-2012_15_03_2011_version 2.docx*', attached to document LIO0111, Email from [Advanz employee] to [Advanz CEO] dated 18 March 2011.
[408] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62; see also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 30, and document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf*', page 47.

(d) In a draft question and answer pack prepared for investors dated 12 November 2015, a slide relating to Liothyronine Tablets states: '*No direct competitor … Non-branded, therefore free pricing … Volumes have been stable historically, with consistent price increases achieved*'.[409]

4.39 Advanz's internal documents record that it experienced limited or no impact in terms of volume decline in response to its price rises. For example:[410]

(a) A presentation to investors in November 2012 stated that '*[b]etween FY 2010-12, stable historical volume growth reflects the market's acceptance of price increases*'.[411]

(b) A ratings agency presentation in September 2014 stated, under the heading of '*price optimisation*', that there were '*[c]ontinued price increases y-o-y [year-on-year] (not just one-offs). Below is the example of Liothyronine where volumes have remained stable over past 5 years while we were able to take four annual price increases*'.[412]

(c) In 2015, an internal presentation prepared for inclusion in a management summary stated: '*[p]rice increased, historical trends indicate there will be no impact on volumes, as no alternative product*'.[413]

4.40 When considering future pricing, Advanz did not consider that its proposed price rises would reduce the volumes of Liothyronine Tablets it would sell, as it perceived that it faced little or no price competition. For example:[414]

(a) In January 2008, Advanz planned three price rises for Liothyronine Tablets over the period from April 2008 to March 2009, representing a cumulative price rise of over 60% in the price it charged wholesalers. Over the same period, Advanz forecasted that the volume of sales of the product would rise (from 12,250 to 12,500 packs sold monthly).[415]

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[409] Document LIO0601, '*Investor Q&A info pack - DRAFT 12Nov2015.pptx*', page 14.
[410] The CMA notes that there is broad consistency in information contained in investor-facing documents with Advanz's other internal documents.
[411] Document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf.pdf*', page 47.
[412] Document LIO0455, '*AMCo Sep14 - RAP_Final.pdf*', page 32. See also document LIO0794, '*20150802 Atoll Management Presentation vDRAFT.pdf*', page 24; document LIO3087, '*Annex 18 - Amdipharm Mercury Management Presentation dated August 2015.PDF*', page 21. A monthly report for April 2014 states that Liothyronine Tablet sales are under budget and attributes this to the price increase of Liothyronine Tablets. The CMA notes that this observation relates to a limited time period and the significant majority of Advanz's internal documents show a trend for no or limited impacts following price increases: see document LIO0415, Advanz's '*Monthly Report - April 2014*', page 25.
[413] Document LIO0542, '*20150722 Atoll MP Shell_JEFF_v14.pptx*', attached to document LIO0541, Email from [Advanz Director of Strategic Finance] to [Advanz Chief Financial Officer] dated 27 June 2015.
[414] The CMA notes that there is broad consistency in information contained in investor-facing documents with Advanz's other internal documents.
[415] Document LIO0029, '*Achieve 2 Million in Gross Margin in 2008-09 - 3 Price Changes*', attached to document LIO0028, Email from [Advanz employee] to [Goldshield Head of pharmaceuticals UK] dated 18 January 2008.

(b) In October 2011, Advanz observed in a presentation that past price rises had been profitable: '*[i]ncreasing sales trend is observed in … Liothyronine tablets*'. The presentation also explained that the price increase '*served its purpose giving high returns*'.[416]

(c) An internal email dated 28 May 2013 sets out proposed price increases for Liothyronine Tablets of 30% in the context of 2013 financial performance overall, following a request from [Advanz CEO], noting that the price increase was low risk.[417]

(d) A memorandum to investors dated October 2014 explains that '*[p]rice optimisation has driven revenue growth in the UK, notably on five key molecules;* [✂]*, Liothyronine and* [✂] *where there is limited or no pricing competition and restrictions under the PPRS*'.[418]

(e) An internal presentation dated April 2015 sent to [✂] (then Chief Financial Officer) lists Liothyronine Tablets as an '*example of success*', stating '*20-50% p.a. [per annum] price increase since 2010 with stable volumes. Similar increase planned for next year*'.[419]

(f) An internal pricing analysis presentation dated August 2015 includes a graph on Liothyronine Tablet prices and volumes which has been annotated to show that price has increased but without there being a volume effect. Additional commentary states that: '*IMS volumes consistent over 2 yrs at circa 13.5k/month … Price rises have had no effect on volumes … Further price increase possible, 5% assumed in 2017*'.[420]

(g) When Advanz planned a 50% price rise in 2015, the assumption was made that there would be no corresponding volume decline.[421]

4.41 As explained at paragraph 3.74 above, in 2015 PrescQIPP updated the DROP-List to include a recommendation that Liothyronine Tablets should not be prescribed to treat hypothyroidism in most cases. Advanz's responses to this development indicate that it considered that this change had only a

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[416] Document LIO0148, '*13 Oct am - UK Primary Care presentation combined.ppt*', page 9.
[417] Document LIO0300, Email between [Advanz CEO] and others dated 28 May 2013, part of email chain dated between 24 May and 5 June 2013. See also document LIO0292, Email from Advanz employee to various dated 29 May 2013, part of email chain dated between 29 May and 31 May 2013.
[418] Document LIO0773, '*2014.10.15_Project Armour CIM_vF.pdf*', page 80.
[419] Document LIO0530, '*AMCo company overview - DRAFT unredacted PARR_Concordia 27Apr2015.pptx*', page 9, attached to document LIO0529, Email from [Advanz Director of Strategic Finance] to [Advanz Chief Financial Officer] dated 16 July 2015.
[420] Document LIO0562, '*20150810 AMCo Run Rate Analysis v09.pdf*', page 5.
[421] Document LIO0495, '*UK 2015 Price increase model_141209.xlsx*'.

negligible impact on its volumes and profitability and it did not influence Advanz's behaviour as regards Liothyronine Tablets:

(a) Advanz confirmed to the CMA that it did not take any action in response to the guidance.[422]

(b) In an internal email dated 6 June 2016 an Advanz employee referred to a newspaper article which highlighted price increases for Liothyronine Tablets and asked: '*What do you think is meant by NHS encouraged docs to stop prescribing lio? Is it biz as usual for us for this product, or is there likely a big impact?*' [✂] (then Global Marketing Director and UK Commercial Director) responded: '*Business as usual. We have seen a very small volume decline over the last 18 mths but it is very small (1-2%). So we characterise the market and volumes as flat!*'[423]

(c) In an internal email dated 29 June 2016 discussing the impact of the DROP-list, [Advanz Global Marketing Director] stated that the list '*was published a year ago and our volumes remain flat. Thus it has had no impact on the sales volumes. […] It does likely mean that new initiations will be minimal but some KOL's may still initiate if they disagree with this evidence and some do.*'[424]

4.42 As set out at paragraphs 3.76 to 3.79 above, in 2017 the NHS consulted on further guidance recommending that Liothyronine Tablets cease to be prescribed in most cases. Advanz's internal documents indicate that it was aware of this proposed consultation and was starting to see a modest impact on its volumes. For example:

(a) A monthly report for March 2017 stated that '*[a]nnouncements from NHS England that they will produce national guidelines on certain products (including Liothyronine Tabs) has put further pressure on Liothyronine use in CCGs. This has triggered a number of patient complaint letters this month, raising concerns about their inability to source the product. Volumes seem to have declined slightly over the last 6mths vs the 1st half of 2016*'.[425]

(b) A monthly report in April 2017 stated that there was '*[n]o further clarification on NHS England's plans to amend National Prescribing Guidelines following*

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[422] Document LIO3061, Advanz's response to questions 21 and 22 of the CMA's s.26 notice dated 25 January 2017.
[423] Document LIO0687, Email from [Advanz Global Marketing Director] to [Vice President of Investor Relations and Communications, Advanz] dated 6 June 2016.
[424] Document LIO0820, Email from [Advanz Global Marketing Director] to [Vice President of Investor Relations and Communications, Advanz] dated 29 June 2016, part of email chain dated between 22 June and 29 June 2016.
[425] Document LIO3489.69, Advanz's '*Annex 22 - Liothyronine UK Monthly Reports - 2017 Reports - UKI Commercial Summary Monthly Report_Mar 17 Final*', page 2. See also document LIO3489.71, Advanz's '*Annex 22 - Liothyronine UK Monthly Reports - 2017 Reports - UK I Commercial Summary Monthly Report_May 17 Final*', page 3.

media speculation, despite this it appears some CCGs and GPs are making attempts to reduce usage' and '*[p]ressure on Liothyronine usage within CCGs despite no formal change to clinical guidelines. This is impacting in market volume*'.[426] Having observed a decline in quarterly average volumes from June 2016 onwards, the document then states: '*Work is underway with local patient groups to help counter this, reinforcing the clinical value and patient benefit of Liothyronine*'.[427]

4.43 While this evidence suggests that there may be some constraint on Advanz's sales of Liothyronine Tablets, any switching away from Liothyronine Tablets needs to be seen in the context of prices which are at supra-competitive levels and which increased from £4.05 in September 2007 (the month before de-branding) to £247.87 in July 2017 (see paragraph 3.190 above). As noted in paragraphs 4.97(b) and 4.102 below, annual volumes declined only modestly from their peak during 2012-2014 (when prices were between around £45 and around £90) and in 2016 (by which time prices had reached their peak of around £248) volumes were only around 5% below the level that would be expected taking into account the growth in the population of patients with hypothyroidism.

4.44 There is a clear contrast between the way in which Advanz assessed the possible competitive constraint from other suppliers of Liothyronine Tablets (produced by generics manufacturers) and the assessment it made of other products as discussed above. There is only some limited evidence that Advanz perceived a threat of entry in the initial years after debranding and in the early part of the Infringement period (see items listed at (a) to (c) below). In the latter part of the Infringement Period, Advanz's documents indicate that it became aware of potential entry by other generic suppliers of Liothyronine Tablets (see items listed at (d) to (i) below). Advanz's forecasts predict significant price, profit and market share erosion associated with new entry (although this did not deter Advanz from increasing its prices). These assessments demonstrate that Advanz considered that competition from generic Liothyronine Tablets would be more effective than competition from other treatments for hypothyroidism in constraining prices and profits for Liothyronine Tablets.[428] For example:

(a) In January 2008, an internal email suggested that Liothyronine Tablet revenues of £1 million to £2 million might trigger entry. [✂] (then Chief

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[426] Document LIO4441, '*UK Commercial Summary Monthly Report April 2017 Final*', pages 2-3; see also document LIO3718.29, Advanz's '*Annex 17 - Mercury Pharma Minutes - MPGL - Board Minutes - 1 June 2015*', page 15.
[427] Document LIO4441, '*UK Commercial Summary Monthly Report April 2017 Final*', page 2.
[428] As noted in paragraph 4.143 below, Advanz's awareness of potential entry did not prevent Advanz from repeatedly raising its prices throughout the Infringement Period.

Operating Officer) estimated that it would probably be two to three years before entry. [429]

(b) A due diligence report prepared in August 2009 for HgCapital in advance of the 2009 management buyout stated under the heading '*expected market environment*': '*Competitors likely to enter due to continued growth*'.[430]

(c) A spreadsheet modelling pricing scenarios in May 2013 suggested excluding Liothyronine Tablets from further price rises because it was '*alredy* [sic] *a £8M product and further price increase might attract competition*'.[431]

(d) Internal projections of the impact of entry of other suppliers of generic Liothyronine Tablets covering the period 2017 to 2020 assumed that Advanz would lose [65-85%] of the market and experience price erosion of [65-85%][432] within three years of entry by the first supplier and assuming two further suppliers also commence supply of Liothyronine Tablets. In each of these scenarios Advanz forecast that its gross profit would drop to [0-20%] of 2016 levels by 2019.[433]

(e) Board papers from 2014 stated: '*Liothyronine 20mcg tablets…we learned that* [✂] *has developed the product for another UK company; they have either submitted or are soon to submit in the UK, posing a threat to our current market share. We are working with the partner to secure more favourable terms for the new strengths and have reflected the impact of the competition in our company sales forecast figures*'.[434]

(f) In February 2015, an email from [✂] (Advanz) to [✂] (Advanz) noted as an assumption: '*[a]ssume generic entry on liothyronine in 2017 – 50% volume loss*'.[435]

(g) A sales projection dated May 2015 modelled volume falls of 50% in July 2017 due to competition.[436]

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[429] Document LIO0025, Email from [Goldshield Founder and Group Board Director] to [Goldshield Head of pharmaceuticals UK] and [Goldshield Head of Marketing Brands and Generics India], dated 11 January 2008.
[430] Document LIO0733, Hg's '*20090814 Trojan Final Commercial DD Report 1600 SENT.PDF*'.
[431] Document LIO0288, '*Price increase scenarios 30May 2013.xlsx*'. See also document LIO0279, Email from Advanz employee to [Advanz Commercial Servies Director] dated 29 May 2013.
[432] The exception is '*Scenario 1c: 'Upside - Late entry competition*' for which the price erosion is 57%: document LIO3718.25, '*Annex 2 - Question 2 Documents - Morningside – 005*'.
[433] Document LIO3718.25, '*Annex 2 - Question 2 Documents - Morningside – 005*'.
[434] Document LIO0802, '*2016-02-04-AMIL-Board-Pack.pdf*', page 14.
[435] Document LIO0488, Email from [Advanz Director of Strategic Finance] to [Advanz employees] dated 7 February 2015.
[436] Document LIO0513, Advanz's '*Finance Model 2015 - 2019 GD inputs.xlsx*'. The same spreadsheet models price rises of 50% in 2017 which is stated in '*Assumptions – 24 Feb*' tab as being '*just prior to generic competition*'. An internal Advanz spreadsheet dated July 2010 containing the projected future price increases

(h) In February 2016, Advanz board papers noted that '*we learned that* [✂] *has developed* [Liothyronine Tablets] *for another UK company; they have either submitted or are soon to submit in the UK, posing a threat to our current market share*'.[437]

(i) In July 2016, an internal presentation evaluating new strengths stated that Advanz expected '*competition to enter the market on the 20mcg in 2017'*[438] and in May 2016 Advanz predicted that competition in 2017 would lead to *'volume declining by 40% and then 50% in 2018*'.[439]

4.45 The difference between these assessments of the competitive impact of other suppliers of generic Liothyronine Tablets, and the assessments made of the competitive impact of other products, point to the boundary of the product market being that of Liothyronine Tablets only.

- *No constraints on Advanz's non-pricing conduct*

4.46 There is no evidence that there were significant constraints of a non-price nature on Liothyronine Tablets. As set out below, Advanz's promotional expenditure on Liothyronine Tablets was negligible and the CMA found no evidence of Advanz reacting to competitive pressure from other products in a non-price way, e.g. by innovating or making material improvements to the product.

4.47 In *Servier,* the General Court found that the fact that Servier had spent a significant amount of money on marketing showed that it was subject to competitive constraints of a non-price nature from other companies. The General Court described Servier's promotional spending as highlighting the benefits of perindopril over other drugs.[440] It found that other companies also incurred considerable expenditure on promotional activities for the benefits of their competing products and that this acted as a competitive constraint.[441] The General Court noted that Servier had itself spent a significant proportion of its perindopril revenues on promotional activities: '*The Commission does not explain the reasons why a dominant operator such as Servier should, in*

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noted the existence of a '*[l]ong term risk as product £4m may encourage a niche generics player or a manufacturer such as* [✂] *(once we pull out) to obtain a licence*'. See document LIO0066, Advanz's '*Proposed - Price Increase Model 2010-11 option 1 (2)*', 'Proposed – Price Increase Model' tab.

[437] Document LIO0802, '*2016-02-04-AMIL-Board-Pack.pdf*', page 14.

[438] Document LIO0618, '*PPRM - Liothyronine new strengths.pptx*', page 4.

[439] Document LIO0680, Email from [✂] to [✂] dated 16 May 2016, part of email chain dated between 16 May and 19 May 2016.

[440] *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1474, stated: '*While the company, like other companies marketing IEC, has tried to positively promote and differentiate perindopril through complimentary communication, this strategy has not, according to these documents, been able to differentiate sufficiently perindopril from other IEC*.'

[441] *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1556.

the absence of significant competitive pressure, need to spend such a part of its overall turnover for such a long time on promotion'.[442]

4.48 Advanz's approach to promotional expenditure for Liothyronine Tablets stands in contrast to the facts in *Servier*. There is no evidence of Advanz responding to any constraints from other treatments through significant promotional expenditure. On the contrary, Advanz's promotional spend on Liothyronine Tablets was negligible, at considerably less than 1% of the revenue it made on Liothyronine Tablets.[443, 444]

4.49 While Advanz has made some investments that may be relevant to Liothyronine Tablets (as well as other investments relating to Advanz's wider business, which might equally benefit Liothyronine Tablets and other drugs), the CMA has not seen evidence that these investments were in response to competitive pressure from other products and the scale of these investments is not material compared to the scale of the price increases of Liothyronine Tablets (see paragraphs 5.364 to 5.367 below). Rather than being a response to competitive pressures, the investments which were specific to Liothyronine Tablets were driven by regulatory concerns. For example, Advanz had to apply for batch specific variations due to its Liothyronine Tablets failing to comply with the regulatory specifications of its MA (see paragraph 3.173 above); there was also significant interruption to the supply of Liothyronine Tablets in 2013 which led to further investment on the part of Advanz (see paragraph 3.177 above). Advanz's Liothyronine Tablets are the same formulation as Glaxo's Tertroxin product, sold in the UK from the 1950s onwards, and Advanz has not launched any new strengths of Liothyronine Tablets.[445]

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[442] *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1563.
[443] CMA analysis of Advanz's promotional spend from 2014 to 2017, allocating spend from the following cost categories (in the CMA's Cost Plus Model) to Liothyronine Tablets on the basis of the number of packs: Global Marketing; Global Market Director and UK Promoted Product. This results in promotional expenditure of 3p to 7p per pack in each year over this period, equivalent to 0.02 to 0.05% of the ASPs of Liothyronine Tablets. Over earlier years in the Infringement Period (2009 to 2013), this promotional spend of 3p to 7p per pack would amount to no more than 1% of the ASP of Liothyronine Tablets.
If promotional spend is allocated on the basis of the activity-based costing model that Advanz submitted in response to the 2017 SO (see paragraph 5.122 below), the promotional spend on Liothyronine Tablets is also negligible at 7p to 22p per pack from 2014 to 2017, equivalent to 0.07% to 0.11% of the ASP of Liothyronine Tablets over this period.
[444] Advanz's overall promotional expenditure was less than 2% of its global revenues from 2014 to 2017: document PAD171, Advanz: '*2017 Annual Report*', page 15.
[445] Advanz has considered investments in new strengths (see paragraphs 3.179 to 3.187 above) but this has not resulted in the launch of new strengths. They also appear to be in response to clinical demand and to counter competition that Advanz expected from entry into the supply of Liothyronine Tablets rather than in response to a significant competitive constraint from another treatment (see paragraph 3.179 above). See also document LIO0618, '*PPRM - Liothyronine new strengths.pptx*', pages 3-4. When considering plans to invest in new strengths of Liothyronine Tablets, this presentation refers to Advanz facing no competition until the expected entry of a UK licensed manufacturer of Liothyronine Tablets:

iii. Unlicensed liothyronine and unlicensed NDT

4.50 As explained at paragraphs 3.52 to 3.57 above, unlicensed forms of liothyronine are available as (a) synthetic tablets and capsules of differing strengths, referred to as unlicensed liothyronine and (b) unlicensed NDT. While there may be clinical benefits to prescribing liothyronine in lower strengths than the 20mcg tablets supplied by Advanz, the clinical evidence strongly recommends against prescribing unlicensed NDT (see paragraph 3.52 above).[446]

4.51 Both products remain unlicensed in the UK and their bioequivalence has not been established. As set out at paragraphs 3.81 to 3.83 above, the relevant guidance states that unlicensed medicines should only be used where there is no licensed product available that would meet the patient's special needs. A prescriber has to take direct responsibility for prescribing an unlicensed product. The extent of interchangeability between products was raised in May 2013 when there was a shortage of Liothyronine Tablets in the UK. The MHRA suggested at that time that patients be prescribed unlicensed liothyronine[447] but stated that the interchangeability of Liothyronine Tablets and unlicensed liothyronine cannot be guaranteed and it noted that patients should see their GP if symptoms changed.[448]

4.52 There is also no evidence in Advanz's internal documents that it considered unlicensed liothyronine and NDT to be a competitive constraint. On the contrary, Advanz's response to patient groups emphasised that Liothyronine Tablets may not be interchangeable with unlicensed liothyronine.[449]

iv. Prescribing of Liothyronine Tablets and Levothyroxine Tablets

4.53 As set out at paragraphs 3.61 to 3.62 above, the decision as to whether to treat hypothyroidism with Liothyronine Tablets, Levothyroxine Tablets, or with a combination of the two medicines is taken by prescribers based on a range

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- Next to the heading '*competition*' at page 3, Advanz stated '*Concordia only – We do however no* [sic] *that another product is under registration*'.
- Next to the '*competitors*' assumption at page 4, Advanz stated '*Only Concordia then we expect competition to enter the market on the 20mcg in 2017*'.

[446] Despite this, patient groups have stated that some patients have a preference for NDT: document LIO2268, TPA's response to question 6(d) of the CMA's s.26 notice dated 13 February 2017, and document LIO2114.1, Thyroid UK's response to question 6(e) of the CMA's s.26 notice dated 08 February 2017.

[447] The MHRA gave the rationale for the substitution as follows: '*there is an interruption of supply of a patient's usual medicine, and there is no alternative UK licensed product which that patient could take instead*.': document PAD099: MHRA: '*Liothyronine (Tertroxin) 20 microgram tablets - continuity of supply – update*'.

[448] Document PAD099: MHRA: '*Liothyronine (Tertroxin) 20 microgram tablets - continuity of supply – update*'.

[449] Document LIO0669, Email from [Advanz Global Marketing Director] to [Advanz Vice President Global Medical] dated 09 May 2016. Advanz's response to patient groups states: '*The UK formulation of liothyronine is unique and not interchangeable with other formulations that maybe [sic] available in other markets. Every batch of liothyronine has to proceed through a "batch specific variation" in collaboration with the UK regulatory authorities to ensure the modern safety and quality standards are met*.'

of factors, including therapeutic substitutability. This sub-section assesses the following factors:

(a) chemical composition and mode of action;

(b) medical recommendations;

(c) NHS guidelines and policies at the national level;

(d) NHS guidelines and policies at the local level; and

(e) medical studies.

4.54 The CMA considers that in this case, the medical recommendations and NHS guidelines and policies at national and local level are particularly informative for the assessment of the relevant product market.

- *Chemical composition and mode of action*

4.55 Liothyronine Tablets and Levothyroxine Tablets have differing modes of action. This evidence by itself is insufficient to determine whether or not Levothyroxine is a close substitute for Liothyronine Tablets. However, the differing modes of action indicate a degree of therapeutic differentiation between Liothyronine Tablets and Levothyroxine Tablets. This is consistent with the further analysis below which finds that there is a cohort of patients for whom Levothyroxine is not considered as a substitute for Liothyronine Tablets.

4.56 Reviewing the chemical composition and mode of action of different medicines may inform market definition, as differences can suggest that the medicines are not readily substitutable.

4.57 As explained at paragraph 3.20 above, hypothyroidism is caused by a deficiency of thyroid hormone. There are two relevant thyroid hormones: T3 and T4 (strictly, a pro-hormone, which is the pre-cursor of T3). Hypothyroidism is treated by prescribing synthetic forms of these thyroid hormones: Liothyronine Tablets are a synthetic version of T3, and Levothyroxine Tablets and capsules are a synthetic version of T4.

4.58 The two products have different chemical compositions and act differently: levothyroxine needs to be converted into T3 by the body whereas liothyronine does not. Moreover, the shorter half-life of Liothyronine Tablets compared to

Levothyroxine Tablets (see paragraph 3.48[450] above) means that Liothyronine Tablets need to be used in lower strengths but taken more frequently than Levothyroxine Tablets when treating hypothyroidism[451] (see paragraph 3.33 above). The rapid onset of action of Liothyronine Tablets is noted in the SMPC, submissions by the Society of Endocrinology and documents provided by Advanz and Teva[452] (see paragraphs 3.39, 3.48 and 4.37(a) above).

- *Medical recommendations*

4.59 Medical recommendations indicate that Levothyroxine Tablets are not a close substitute for many patients who are prescribed Liothyronine Tablets (see in particular paragraphs 4.62(c) and (d) below).

4.60 Clinical practice guidelines and recommendations provide advice on the prescription of Liothyronine Tablets and alternative products to treat hypothyroidism and are therefore useful in informing product market definition. As set out at paragraphs 3.31 to 3.34 above, Liothyronine Tablets may be prescribed either alongside or instead of Levothyroxine Tablets, depending on specific patient responses to the different treatments.

4.61 The guidance is clear that Levothyroxine Tablets are the first line treatment for hypothyroidism (see e.g. paragraph 3.51 above) and Liothyronine Tablets are prescribed to patients who have not adequately responded to treatment with Levothyroxine Tablets alone.

4.62 The CMA has assessed guidelines produced by the Royal College of Physicians, the British Thyroid Association (BTA), NICE and information provided by the Society of Endocrinology. Key points highlighted by these guidelines are as follows:

(a) Levothyroxine Tablets are recommended as the primary (or first line) treatment for hypothyroidism.

(b) The prescription of Liothyronine Tablets has tended to be restricted, and they are generally initiated by endocrinology specialists and then continued by GPs (see paragraphs 3.38 and 3.51 above).

(c) In some circumstances, when patients do not respond adequately to Levothyroxine Tablets prescribed on their own, a trial of Liothyronine Tablets

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[450] PrescQIPP bulletin published in February 2016 cites the differences in half-life as a reason that Liothyronine Tablets are not routinely recommended. See document PAD083, PrescQIPP Bulletin 121, February 2016.
[451] Conversely, when treating thyroid cancer, the shorter half-life of Liothyronine Tablets means that patients remain in a hypothyroid state for a shorter period of time (see paragraph 3.30(a) above).
[452] The only two manufacturers who currently supply both Liothyronine Tablets and Levothyroxine Tablets.

may be prescribed in combination with Levothyroxine Tablets, or, more rarely, on their own.[453, 454] Prescribing doctors will initiate a trial of Liothyronine Tablets only if alternative causes of ill-health are not found (see paragraph 3.79 above). This indicates that Levothyroxine Tablets may not be a substitute treatment for at least a substantial portion of the cohort of patients who are prescribed Liothyronine Tablets because Levothyroxine may be ineffective for these patients.

(d) Conversely, it is not recommended that Liothyronine Tablets be withdrawn from patients who are established on them.[455] Again, this indicates that Levothyroxine Tablets may not be a substitute treatment for at least a substantial portion of the cohort of patients who are prescribed Liothyronine Tablets.

- *NHS guidelines and policies at the national level*

4.63 Consistent with the medical recommendations assessed above, NHS guidelines and policies at the national level indicate that Levothyroxine Tablets are not a close substitute for many patients who are prescribed Liothyronine Tablets.

4.64 Since around 2015, in response to repeated price increases, NHS guidelines and policies at a national level have encouraged prescribers to review patients taking Liothyronine Tablets for suitability for switching to Levothyroxine Tablets.[456] The guidelines recommend that all 'suitable' patients be switched to Levothyroxine, but they acknowledge that there remains a cohort of patients for whom continued treatment with Liothyronine Tablets is the most appropriate course.

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[453] Document LIO2152, BTA's response to question 4 of the CMA's s.26 notice dated 13 February 2017; document LIO2157, '*BTA Executive Committee Information for members on prescribing Liothyronine (L-T3)*', December 2016, page 1; document PAD098, 'Management of primary hypothyroidism: statement by the BTA Executive Committee', page 3; document LIO2114.2, '*Management of Primary Hypothyroidism - Statement by BTA Exec Committee*', page 4; document LIO1504, Society for Endocrinology's response to question 4(a) of the CMA's s.26 notice dated 20 December 2016; document PAD207, NICE guideline: 'Thyroid disease: assessment and management', 20 November 2019, page 34.

[454] Document LIO2154, Wiersinga, W M, Duntas, L, Fadeyev, V, et al.: '*2012 ETA Guidelines: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism*', European Thyroid Journal, 2012, page 55. This study reports that 5 to 10% of patients treated with Levothyroxine continue to experience symptoms of hypothyroidism. A trial of liothyronine may be suitable in certain cases, although the trial should be discontinued after 3 months if there is no improvement.

[455] Document LIO2157, '*BTA Executive Committee Information for members on prescribing Liothyronine (L-T3)*', December 2016, page 2.

[456] Or switching to levothyroxine monotherapy where liothyronine was previously prescribed in combination with levothyroxine.

(a) In July 2015, when the NHS Reimbursement Price had increased to £152.01 (from £4.46 in September 2007),[457] PrescQIPP updated the DROP-List,[458] stating that Levothyroxine Tablets are recommended as a monotherapy for the treatment of hypothyroidism and advising that patients taking Liothyronine Tablets should be reviewed for suitability to switching to Levothyroxine Tablets (see paragraphs 3.73 to 3.74 above). In February 2016 (by which point the NHS Reimbursement Price had increased to £198.47), PrescQIPP published an updated bulletin on Liothyronine Tablets that highlighted the high cost of prescribing the drug.[459] The bulletin renewed its recommendation that patients taking Liothyronine Tablets be reviewed for suitability for switching to Levothyroxine Tablets, although it acknowledged the BTA advice that some patients '*who have unambiguously not benefited*' from Levothyroxine Tablets may benefit from a trial of Liothyronine Tablets.[460]

(b) Subsequently, in July 2017, the NHSCC identified a number of drugs (including Liothyronine Tablets) that were expensive or ineffective, and consulted on recommendations that they should not routinely be prescribed (see paragraphs 3.76 to 3.79 above).[461] The outcome of this consultation published on 30 November 2017[462] resulted in the proposed recommendations being revised to state that Liothyronine Tablets '*should still be prescribed for a small cohort of patients*' for the treatment of hypothyroidism and '*that deprescribing in "all" patients is not appropriate as there are recognised exceptions*'.[463] The consultation set out that it expected CCGs to take the guidance into account in formulating local polices and that '*the guidance does not remove the clinical discretion of the prescriber in accordance with their professional duties*'.[464] Following concerns that the

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[457] NHS Reimbursement Price per 28-tablet pack of Liothyronine Tablets increased 3,310% from September 2007 to July 2015.
[458] Document PAD021, PrescQIPP Bulletin 117, July 2015.
[459] Document PAD083, PrescQIPP Bulletin 121, February 2016.
[460] Document PAD083, PrescQIPP Bulletin 121, February 2016, page 2.
[461] For example, Liothyronine Tablets are categorised as an item which is '*clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation*': document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', page 5.
[462] Document LIO7789.15, NHSCC: '*Items which should not be routinely prescribed in primary care: Consultation Report of Findings*', page 29. This states that '*[c]omments from clinicians reflect the view that Liothyronine should be available for new patients but that the product should be available in exceptional circumstances.*'
[463] Document PAD127, NHSCC guidance, pages 8 and 19-20. The final guidance was published on 30 November 2017 after the end of the Infringement Period, however the outcome that some patients may be prescribed liothyronine under certain conditions is consistent with the PrescQIPP February 2016 statement and the BTA December 2016 statement. Morningside notes that the NHS consultation's proposal to '*restrict patient access to Liothyronine was reconsidered following submissions by organisations that supported its use and a lack of medical evidence supporting a blanket ban*': See also document LIO6435.1, Morningside's response to question 3(a) of the CMA's s.26 notice dated 24 May 2018.
[464] Document PAD127, NHSCC guidance, page 4; document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', page 4. CCGs have taken varying approaches to their recommendations regarding prescribing Liothyronine (see paragraphs 3.70-3.71 above).

NHSCC guidance was not being followed by CCGs,[465] in June 2019 the NHS Regional Medicines Optimisation Committee[466] published updated guidance which stated that '*[t]he majority of patients suffering from hypothyroidism can be treated effectively with levothyroxine alone, but liothyronine is perceived to be an important medicine for a small proportion of patients in order to maintain health and wellbeing*'.[467] It made more detailed recommendations aimed at ensuring that both prescribing and withdrawal of Liothyronine Tablets should '*only be undertaken by, or with the oversight of, an NHS consultant endocrinologist*'.[468]

4.65 Recommendations to switch patients from Liothyronine Tablets have been opposed by the BTA, which highlights the risks of moving patients away from a treatment on which they are stabilised.[469] The BTA issued a statement in December 2016 which acknowledged the pressure to switch patients away from Liothyronine Tablets due to recent price increases, but argued that such changes of treatment may result in significant instability of thyroid status and potentially undesirable clinical outcomes, and therefore advised that the decision to continue or stop Liothyronine Tablets should be based on clinical need above other considerations.[470]

4.66 While the national level recommendations and policies described in this section indicate that there is a cohort of patients for whom Levothyroxine Tablets are perceived as being ineffective and therefore not an appropriate substitute for Liothyronine Tablets, the guidance does not itself reveal what proportion of patients prescribed Liothyronine Tablets fall into this category. The quantitative evidence (see paragraphs 4.87ff below) reveals that in 2016 (the last full year of the Infringement Period), volumes of Liothyronine Tablets were only around 5% below the level that would be expected taking into account the growth in the population of patients with hypothyroidism. Similarly, Advanz's internal documents show that its perception was that the guidance had resulted in only a very small decline in volumes (see paragraph

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[465] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaughnessy*', pages 3 and 4.
[466] The Regional Medicines Optimisation Committee system for England has been developed to address Medicine Optimisation issues which have current impact on practice and where a national steer would be beneficial to the system: document PAD208, SPS NHS: '*What are the RMOCs?*'.
[467] Document PAD206, SPS NHS: '*Guidance - Prescribing of Liothyronine*', June 2019, page 3.
[468] Document PAD206, SPS NHS: '*Guidance - Prescribing of Liothyronine*', June 2019, page 3.
[469] In December 2016 the BTA issued a statement that it does not support the sudden withdrawal of Liothyronine Tablets and noted that '*[in] such cases a change of treatment may result in significant instability of thyroid status and potentially undesirable clinical outcomes.*': document LIO2157, '*BTA Executive Committee, Information for members on prescribing Liothyronine (L-T3)*', December 2016, pages 1 and 2. The European Thyroid Association ('**ETA**') recommends that patients who are started on Liothyronine Tablets should be reassessed after three months and that treatment should be continued if the patient is deriving benefit as determined by a quality of life tool: document LIO2152, BTA's response to question 7(c) of CMA's s.26 notice dated 13 February 2017.
[470] Document LIO2157, '*BTA Executive Committee Information for members on prescribing Liothyronine (L-T3)*', December 2016, pages 1 and 2.

4.41(b) above). This suggests that a significant proportion of patients prescribed Liothyronine Tablets are not considered suitable for switching to Levothyroxine.[471]

4.67 The CMA notes that the PrescQIPP DROP-List was first published in 2012 and has been updated several times since then, but it was not until 2015 (after more than seven years of increasing prices and three years after the DROP-List was first published)[472] that Liothyronine Tablets were included in the DROP-List. The scale of the price increases for Liothyronine Tablets and the length of time it took for PrescQIPP to amend the DROP-List to include Liothyronine Tablets, demonstrates a lack of sensitivity to prices within prescribing guidance. To the extent that prescribers rely on such guidance when making their prescribing decisions, those prescribing decisions may display a similar lack of responsiveness to price changes (see also paragraph 3.61 above).

- *NHS guidelines and policies at the local level*

4.68 Consistent with the medical recommendations and the national NHS guidelines and policies discussed above, the NHS guidelines and policies at the local level indicate that Levothyroxine Tablets are not a close substitute for many patients who are prescribed Liothyronine Tablets.

4.69 At a local level, mirroring national guidance, prescribers have been encouraged, following repeated price increases, to review patients taking Liothyronine Tablets for suitability for switching to Levothyroxine Tablets. Local guidance generally continues to permit the prescribing of Liothyronine Tablets, which indicates that there is a cohort of patients for whom Levothyroxine Tablets are ineffective.

4.70 In response to repeated price increases, some CCGs have amended local guidelines regarding prescription of Liothyronine Tablets during the Infringement Period.[473] NHS policies at the local level (through CCGs) vary regarding prescribing Liothyronine Tablets (see paragraphs 3.70 to 3.71 above). Recommendations tend to state that Levothyroxine Tablets are the

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[471] This appears to be the most likely explanation for the relatively slow decline in volumes of Liothyronine Tablets from 2015 onwards. Liothyronine Tablets have long been a second line treatment, which means that they would generally only have been prescribed where Levothyroxine Tablets (then first-line treatment) were perceived as being ineffective.
[472] By December 2012, the monthly average NHS Reimbursement Price of Liothyronine Tablets had increased to £52.44 from £4.46 in September 2007, a percentage increase of 1,076% (see footnote 345). As set out at paragraph 4.67 above, between September 2007 and July 2015 when the PrescQIPP Guidance was published, the monthly average NHS Reimbursement Price of Liothyronine Tablets increased from £4.46 per pack to £152.01 per pack, an increase of 3,310%.
[473] See paragraph 3.69 above.

primary treatment for hypothyroidism and either (a) omit reference to Liothyronine Tablets or (b) recommend Liothyronine Tablets only as a second line treatment or specify usage is restricted in some way (for example only to be prescribed by a specialist or only to existing patients but not new patients).

4.71 Evidence submitted to Parliament in October 2018 noted concerns that not all local health authorities were following national policies permitting Liothyronine Tablets to be prescribed in exceptional cases.[474] The report advised that patients who remain well on Liothyronine Tablets and wish to continue taking Liothyronine Tablets should not have their treatment disrupted and that patients that benefited from treatment with Liothyronine Tablets, and have had it withdrawn, should have it reinstated.[475]

- *Medical studies*

4.72 Contrary to the arguments of the Parties, medical studies do not suggest that patients who have been prescribed Liothyronine Tablets can readily be switched to Levothyroxine Tablets. Rather, the evidence from medical studies is equivocal. In any case, it is not as informative for market definition as the evidence from medical recommendations, and NHS guidelines and policies.

4.73 Cinven argues that medical studies demonstrate that treatment with Levothyroxine Tablets would be as therapeutically effective as Liothyronine Tablets (alone or in combination with Levothyroxine Tablets).[476] Advanz also argues that this demonstrates that Liothyronine Tablets and Levothyroxine Tablets are therapeutically substitutable and there are no patients for whom Liothyronine Tablets are the only effective treatment.[477]

4.74 The CMA considers that qualitative evidence reflecting actual behaviour, such as medical guidance and internal documents, is more insightful than academic papers for the purposes of defining the relevant market. Identifying the relevant market requires consideration of how prescribing doctors behave and substitute between treatments in practice.

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[474] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*'. National guidance permits Liothyronine Tablets to be prescribed in exceptional cases. However, the report states that this was not being followed in many cases by CCGs (page 2 and 3). It found that most local policy documents did not signpost to statements in national guidance that treatment for patients stabilised on (and benefiting from) treatment with Liothyronine Tablets should not be disrupted (page 5 and 9).
[475] Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaughnessy*', pages 5 and 6.
[476] Document LIO7791, Cinven RSSO-2019, Section 4.
[477] Document LIO7781, Advanz RSSO-2019, Section 3.

4.75 The CMA nevertheless recognises that the medical studies may contain relevant evidence and has reviewed them accordingly. In this case, the CMA finds that the evidence from medical studies is equivocal. The studies compare the treatment of hypothyroid patients with Levothyroxine Tablets alone versus a combination of Levothyroxine Tablets plus Liothyronine Tablets (combination therapy). A number of the studies themselves suggest that caution in interpretation is needed as they report limitations with the approach used in the clinical trials carried out. Moreover, the studies have not provided clear results on the treatment of hypothyroidism with Liothyronine Tablets.

4.76 In 2005, a paper which reviewed published controlled clinical trials found that combination treatments did not appear to have a clear advantage over Levothyroxine Tablets on their own, and the use of Levothyroxine Tablets alone should remain the standard treatment.[478] However, it reported limitations in some of the medical studies reviewed[479] and noted that in some studies patients expressed a preference for combination therapy.

4.77 In 2006, a paper examining a number of clinical trials[480] also found no statistically significant difference in the effectiveness of combination treatments versus Levothyroxine Tablets alone across a number of indicators.[481] The paper also noted that a proportion of patients experience persistent symptoms despite normal TSH (that is, the concentration of thyroid-stimulating hormone in the blood), a finding reported by a number of studies.[482]

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[478] Document LIO2158, Escobar-Morreale, H F, Botella-Carretero, J I, et al.: '*Treatment of Hypothyroidism with Combinations of Levothyroxine plus Liothyronine*', The Journal of Clinical Endocrinology & Metabolism, 21 May 2005, page 2.

[479] Including variability across patients in the severity and duration of hypothyroidism and their pre-study Levothyroxine requirements. The paper stated that the lack of proven beneficial effects of combination treatments over Levothyroxine alone might depend on these confounding factors. Document LIO2158, Escobar-Morreale, H F, Botella-Carretero, J I, et al.: '*Treatment of Hypothyroidism with Combinations of Levothyroxine plus Liothyronine*', The Journal of Clinical Endocrinology & Metabolism, 21 May 2005, page 2.

[480] The paper presented the results of a metanalysis of controlled clinical trial. See document LIO0299, Grozinsky-Glasberg, S, Fraser, A, Nahsoni, F, at al.: '*Thyroxine-Triiodothyronine Combination Therapy Versus Thyroxine Monotherapy for Clinical Hypothyroidism: Meta-Analysis of Randomized Controlled Trials*', The Journal of Clinical Endocrinology & Metabolism, 2 May 2006. The data extraction method identified 11 randomized trials, performed between the years 1999 and 2005.

[481] Document LIO0299, Grozinsky-Glasberg, S, Fraser, A, Nahsoni, F, at al.: '*Thyroxine-Triiodothyronine Combination Therapy Versus Thyroxine Monotherapy for Clinical Hypothyroidism: Meta-Analysis of Randomized Controlled Trials*', The Journal of Clinical Endocrinology & Metabolism, 2 May 2006, page 2593. Indicators included patient symptoms such as bodily pain, fatigue, anxiety, depression and quality of life measure as well as cognitive performance, biochemical indicators, adverse effects, and weight changes.

[482] Document LIO0299, Grozinsky-Glasberg, S, Fraser, A, Nahsoni, F, at al.: '*Thyroxine-Triiodothyronine Combination Therapy Versus Thyroxine Monotherapy for Clinical Hypothyroidism: Meta-Analysis of Randomized Controlled Trials*', The Journal of Clinical Endocrinology & Metabolism, 2 May 2006, page 2592; see also document LIO2154, Wiersinga, W M, Duntas, L, Fadeyev, V, et al.: '*2012 ETA Guidelines: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism*', European Thyroid Journal, 2012, page 55; document PAD098, '*Management of primary hypothyroidism: statement by the British Thyroid Association Executive Committee*',

4.78 Later in 2011[483] and 2012,[484] further literature reviews also suggested that there was insufficient evidence that combination therapy was better than monotherapy. They stated that treatment with Levothyroxine Tablets should remain the standard treatment. The 2011 paper again highlighted limitations of the approach used in a number of trials.[485] It also noted that a small but significant proportion of patients remain dissatisfied with treatment with Levothyroxine Tablets and some patients may derive benefit from combination therapy with Liothyronine Tablets.[486]

4.79 A paper published in 2014[487] reported clinical study results showing that inadequate thyroid hormone replacement was found in over a third of hypothyroid patients treated with Levothyroxine Tablets and also that a number of studies had proposed a rationale for treatment with Liothyronine Tablets alongside Levothyroxine Tablets, although this was controversial.[488] The paper reported results from a clinical trial (also mentioned in the 2011 paper) which found that patients with certain genetic characteristics experienced greater improvement in symptoms with combination treatment with Liothyronine Tablets than with treatment with Levothyroxine Tablets alone.[489]

4.80 In 2016, another review of published controlled trials[490] found that the benefits of a combined liothyronine and levothyroxine treatment were uncertain, and that while it is theoretically probable that certain genetically predisposed individuals will benefit from combination therapy, the existing evidence is as yet limited.

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page 1; document LIO2162, Eligar, V, Tylor, P N, Okosieme, OE, et al.: '*Thyroxine replacement: a clinical endocrinologist's viewpoint*', Annals of Clinical Biochemistry 0(0) 1–13, 2016, pages 8-10.

[483] Document LIO2163, Okosieme, OE: '*Thyroid hormone replacement: current status and challenges*', Expert Opin Pharmacother, 2011, page 8.

[484] Document LIO2154, Wiersinga, W M, Duntas, L, Fadeyev, V, et al.: '20*12 ETA Guidelines: The Use of L-T4 + L-T3 in the Treatment of Hypothyroidism*', European Thyroid Journal, 2012.

[485] Limitations including the dosage of Levothyroxine and Levothyroxine used. Document LIO2163, Okosieme, OE: '*Thyroid hormone replacement: current status and challenges*', Expert Opin Pharmacother, 2011, page 8.

[486] The paper also reported results from a 2009 clinical trial which found that patients with certain genetic characteristics had a better response to combination therapy with Liothyronine Tablets than treatment with Levothyroxine Tablets alone. The paper recommended additional research to confirm these results and clarify variation in results across studies. This could result from factors including incongruent patient recruitment criteria, differences in statistical approach, and the limitations of small sample size in some studies. Document LIO2163, Okosieme, OE: '*Thyroid hormone replacement: current status and challenges*', Expert Opin Pharmacother, 2011, pages 1, 8 and 9.

[487] The paper noted that although TSH (thyroid stimulating hormone) level is commonly used to monitor treatment in hypothyroid patients, it is not an optimal indicator of adequate thyroid hormone replacement therapy in all hypothyroid patients. Document LIO2161, Biondi, B, Wartofsky, L.: '*Treatment with thyroid hormone*', Endocrine Reviews, 2014, pages 2 and 60.

[488] Document LIO2161, Biondi, B, Wartofsky, L.: '*Treatment with thyroid hormone*', Endocrine Reviews, 2014, page 2.

[489] Document LIO2161, Biondi, B, Wartofsky, L.: '*Treatment with thyroid hormone*', Endocrine Reviews, 2014, pages 36 and 60.

[490] Document LIO2162, Eligar, V, Tylor, P N, Okosieme, OE, et al.: '*Thyroxine replacement: a clinical endocrinologist's viewpoint*', Annals of Clinical Biochemistry 0(0) 1–13, 2016.

4.81 The limitations of controlled trials are further noted in a study published in the Lancet, Diabetes and Endocrinology in January 2019. This study expressed concerns about '*the limitations (small size, short duration, inconsistent dosage) of previous studies*' and concluded that '*specialist society guidance recognises that a trial of liothyronine might be appropriate in selected patients*'.[491]

v. Views of third party manufacturers of Liothyronine Tablets

4.82 Consistent with the other qualitative evidence analysed above, the evidence from third party manufacturers of Liothyronine Tablets indicates that Levothyroxine Tablets, unlicensed liothyronine and NDT are not close substitutes for Liothyronine Tablets.

4.83 The CMA has asked third party suppliers of Liothyronine Tablets for their views on competitive constraints. Teva is the only manufacturer other than Advanz which supplies both Liothyronine Tablets and Levothyroxine Tablets. The CMA asked Teva to provide a list of any existing or potential new products which compete with, or may compete with, Liothyronine Tablets in the UK. While Teva told the CMA that it was unable to comment, '*as this is a decision which is the sole responsibility of the prescribing physician*', it nevertheless stated that it understood Levothyroxine Tablets were commonly used as an alternative to Liothyronine Tablets; it also cited NDT as a treatment but noted this is unlicensed in the UK.[492] A Teva internal document dated 25 November 2014[493] prepared as part of Teva's assessment of whether to develop Liothyronine Tablets states: '[✂]'.[494] Accordingly, although Teva has noted similarities between Liothyronine Tablets and Levothyroxine Tablets and NDT, it has also acknowledged important distinctions between them.

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[491] Document PAD169, Taylor, P N, Razvi, S, Muller, I, et al.: '*Liothyronine cost and prescriptions in England*', Lancet Diabetes Endocrinol 2019. See also documents LIO2162, Eligar, V, Tylor, P N, Okosieme, OE, et al.: '*Thyroxine replacement: a clinical endocrinologist's viewpoint*', Annals of Clinical Biochemistry 0(0) 1–13, 2016, page 10, which states that '*[t]he limitations of these RCTs have been highlighted including the use of non-physiological T3:T4 dose ratios, heterogeneity in the studied population and the lack of long-term safety and efficacy data*'; and LIO2158, Escobar-Morreale, H F, Botella-Carretero, J I, et al.: '*Treatment of Hypothyroidism with Combinations of Levothyroxine plus Liothyronine*', The Journal of Clinical Endocrinology & Metabolism, 21 May 2005, page 4946, which states that although TSH is widely used to monitor levothyroxine replacement, it is just a single indicator of thyroid hormone action and may not be fully accurate in all cases. Document PAD207, NICE guideline: '*Thyroid disease: assessment and management*', 20 November 2019, page 34, review RCT evidence stating these suggested combination treatment does not offer any important health benefits compared with levothyroxine alone. The guidelines also state liothyronine is sometimes prescribed where levothyroxine treatment fails and liothyronine could potentially have greater benefit for patients still unwell following treatment with levothyroxine alone than in the general population with hypothyroidism. The guidelines note the limited evidence in this area and made a recommendation for research to help inform future guidance.
[492] Document LIO2195, Teva's response to question 10 of the CMA's s.26 notice dated 25 January 2017.
[493] Document LIO2196, Teva's '*45117645_1_Annex 1.pdf *Liothyronine Presentation*'.
[494] Document LIO2196, Teva's '*45117645_1_Annex 1.pdf *Liothyronine Presentation*', page 5.

4.84 Notably, since entering the market, Teva [✂].[495]

4.85 Morningside told the CMA that when it considered entry, it thought that the NHSCC proposal to '*restrict patient access to Liothyronine was reconsidered following submissions by organisations that supported its use and a lack of medical evidence supporting a blanket ban*'.[496]

4.86 In addition, the actual and proposed entry of generic suppliers of Liothyronine Tablets (see section 3.V.c above) indicates that potential suppliers of Liothyronine Tablets did not foresee substantial substitution to Levothyroxine Tablets.

b. Quantitative evidence

4.87 The CMA has also considered actual consumption patterns[497] to determine whether other products were capable of exerting a significant competitive constraint on Liothyronine Tablets.[498]

4.88 Consistent with the General Court's judgment in *Servier*, price-related factors are relevant to the CMA's assessment of the relevant market. The small but significant and non-transitory increase in price ('**SSNIP**') test provides a standard 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.[499] If such an increase in the price of the Focal Product would be profitable, the test is complete and the Focal Product sold by the hypothetical monopolist is (usually) the relevant market.[500]

4.89 In this case, the CMA does not need to hypothesise that there is a single supplier of the Focal Product as Advanz was the only supplier of Liothyronine Tablets in the UK until August 2017. In addition, given the repeated and

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[495] Document LIO2195, Teva's response to question 5 of the CMA's s.26 notice dated 25 January 2017; document LIO3870, Teva's response to question 2 of the CMA's s.26 notice dated 6 September 2017.
[496] Document LIO6435.1, Morningside's response to question 3a of the CMA's s.26 notice dated 24 May 2018.
[497] Commission Notice on Market Definition, paragraph 38, explains that evidence of actual substitution would be fundamental to defining markets where this evidence is available.
[498] See *Servier v Commission*, T-691/14, EU:T:2018:922, paragraph 1411, which confirms the relevance to pharmaceuticals market definition of price-related factors when assessed in their own context.
[499] This increase is usually referred to as a small but significant non-transitory increase in price or SSNIP.
[500] 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 paragraphs 15-19 of the Commission Notice on Market Definition.

significant price rises for Liothyronine Tablets, the CMA has not needed to conduct a hypothetical SSNIP test as it can observe as an empirical matter the response to actual price increases.

4.90 The CMA has considered the observed competitive responses to price increases to determine whether other products impose a significant enough competitive constraint in practice to warrant being included in the relevant product market. Observed actual consumption patterns provide evidence on how much switching has occurred in practice. Although the CMA is relying on the observed competitive responses to price increases rather than carrying out a hypothetical test, the framework used is consistent with the SSNIP framework.

4.91 When assessing the effect of Advanz's price increases, caution is required. Where an undertaking has substantially increased prices, one may observe consumers switching to other products. However, it may be incorrect in those circumstances to conclude that the undertaking lacks market power and to include those other products in the relevant market, since the undertaking may well already have used its market power to raise prices above competitive levels.[501] The CMA has been mindful of this when assessing observed substitution patterns in this case.

4.92 The quantitative evidence clearly demonstrates that Advanz has profitably implemented numerous significant price increases without experiencing a significant impact on its volumes. Advanz's ASP increased by 6,021%[502] since de-branding Liothyronine Tablets, while volumes broadly increased, peaking in 2012 with a small decline from 2014.[503] The lack of adverse impact on the volumes and profitability of Advanz is clearly indicative of the fact that Liothyronine Tablets did not suffer any form of significant competitive constraint prior to the arrival of competition from other Liothyronine Tablet suppliers.

4.93 In particular, there has been relatively low consumption of unlicensed liothyronine and NDT, and an absence of significant substitution from Liothyronine Tablets to Levothyroxine Tablets despite a significant divergence in Liothyronine and Levothyroxine Tablet prices between November 2007 and July 2017. In conjunction with the qualitative findings on price and non-price parameters of competition, the observed consumption patterns strongly

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[501] This is commonly known as the 'Cellophane fallacy' following the *US v EI Du Pont de Nemours & Co* [1956] 351 US 377 case. See also OFT403, paragraph 5.5.
[502] Advanz's ASP per 28-tablet pack equivalent increased from £4.05 in September 2007 to £247.87 in July 2017.
[503] This is based on PCA data (see Table 3.3 above); information provided by Advanz shows greater stability, with volumes in fact increasing slightly in 2016 (see Figure 3.3 above). The choice of dataset does not materially affect the CMA's conclusions.

indicate that other products do not exert a sufficient competitive constraint on the supply of Liothyronine Tablets to warrant widening the relevant product market.

4.94 The CMA's findings in relation to actual consumption patterns corroborate the evidence in Advanz's own documents which are contemporaneous with its price increases. As described above, these documents indicate that Advanz perceived itself as a sole supplier facing limited competition in relation to the supply of Liothyronine Tablets and show Advanz implementing numerous price increases over a period of several years without expecting or experiencing a significant impact on its volumes, in the absence of competition from other suppliers of Liothyronine Tablets.

4.95 In addition, following the entry of other generic Liothyronine Tablets suppliers, Liothyronine Tablet prices have fallen. Observed pricing patterns, supported by Advanz's own internal documents, demonstrate that the constraints on Liothyronine Tablets from other products are insignificant compared to the constraints that generic suppliers of Liothyronine Tablets place on each other.

4.96 The quantitative evidence below examines the observed effect of price increases on Liothyronine Tablet volumes; consumption patterns of Levothyroxine Tablets, unlicensed liothyronine, NDT and Levothyroxine Tablets; the impact of generic Liothyronine Tablet entry on pricing; and finally the impact of the steady increase in the number of people diagnosed with hypothyroidism.

i. Liothyronine Tablet pricing and volumes

4.97 Figure 4.1 below presents the yearly average NHS Reimbursement Price[504] of Liothyronine Tablets and the yearly number[505] of packs[506] of Liothyronine Tablets dispensed from 2007 to July 2017.[507] The key trends[508] are that:

(a) Prices rose consistently and significantly from November 2007 to July 2017. The NHS Reimbursement Price of Liothyronine Tablets increased from £11.55 per pack on average in 2008 to £246.51 per pack on average in 2016, a 2,034% percentage increase.[509]

(b) The number of packs of Liothyronine Tablets dispensed each year broadly increased between November 2007 and July 2017, peaking in 2012 with a small decline from 2014.[510] The annual number of packs dispensed rose from 122,354 in 2008 to 147,194 in 2016, a 20% increase.[511]

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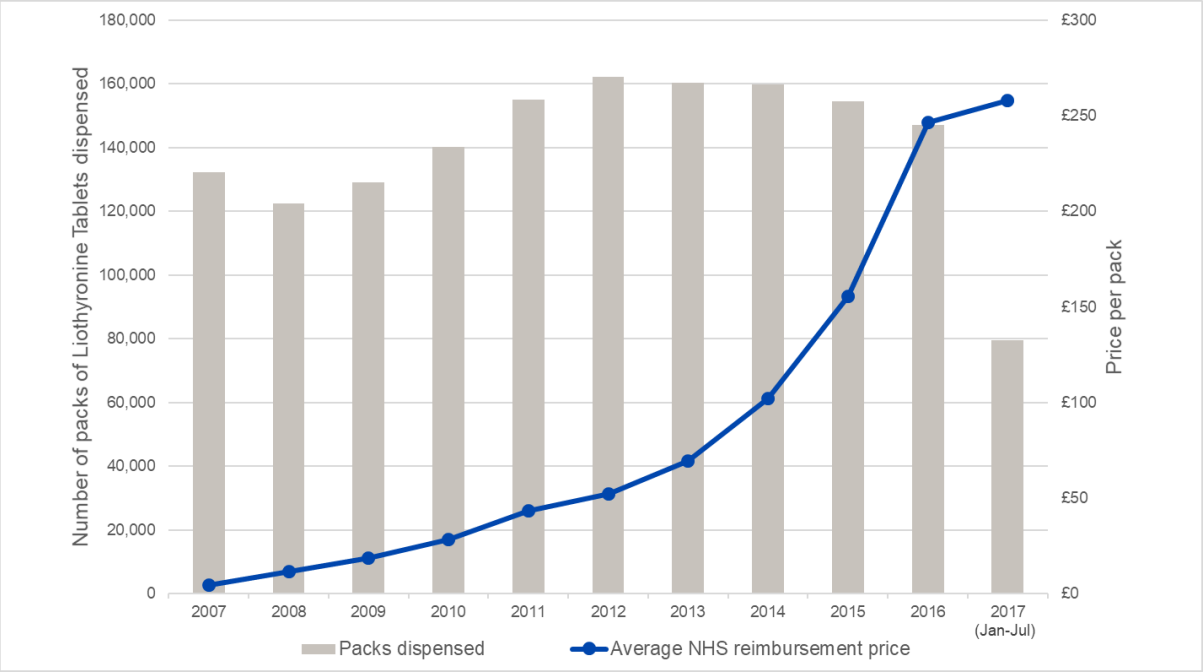
[504] The NHS Reimbursement Price is used for this analysis because it is published monthly and is available to prescribers. Prescribers are unlikely to be aware of the ASPs to wholesalers and pharmacies.
[505] Presenting this data on an annual basis smooths out the unsystematic monthly variation in prescription volumes.
[506] CMA analysis based on PCA data for England, Wales, Scotland and Northern Ireland which reports volumes in terms of number of tablets dispensed. As explained at paragraph 3.22 above, in October 2007 Advanz de-branded and reduced the pack size of its Liothyronine Tablets from 100 to 28 tablets. This resulted in a significant increase in the number of packs of Liothyronine Tablets dispensed in 2008. To take this change into account, the CMA has estimated (and reported in Figure 4.1 below) the number of 28-tablet pack-size equivalents of Liothyronine Tablets dispensed in 2007. However, given the uncertainty over when 100 tablet packs stopped being dispensed, the volume of packs sold in 2007 may represent an under-estimate.
[507] The CMA's analysis focuses on sales through the pharmacy channel. Liothyronine Tablets are primarily distributed through pharmacies rather than through hospitals (see paragraph 3.59 above) and the CMA considers that the limited sales being made in the hospital channel could not have affected overall prices and volumes in pharmacies in any appreciable way. The NHS Reimbursement Price is based on PCA data, which cover pharmacies and dispensing doctors, but not medicines dispensed in secondary care (hospitals).
[508] Generally in this section, when assessing changes using annual data, comparison is made between 2008 (the first full year following the implementation of Advanz's price optimisation strategy in respect of Liothyronine Tablets) and 2016 (the last full year for which volume data are available within the Infringement Period).
[509] The increase in the NHS Reimbursement Price using monthly price data was even greater: an increase of 5,692% from £4.46 per pack in September 2007 (the month before de-branding) to £258.19 per pack in July 2017. The NHS Reimbursement Price closely tracked the changes in Advanz's ASPs between at least November 2007 and July 2017 (see paragraph 3.190 above). Regarding these percentage calculations see footnote 345.
[510] As noted at footnote 503, this is based on PCA data. Advanz's own data indicate greater volume stability.
[511] CMA analysis based on PCA data for England, Wales, Scotland and Northern Ireland which reports volumes in terms of number of tablets dispensed. As explained at paragraph 3.22 above, in October 2007 Advanz de-branded and reduced the pack size of its Liothyronine Tablets from 100 to 28 tablets. This resulted in a significant increase in the number of packs of Liothyronine Tablets dispensed in 2008. To take this change into account, the CMA has estimated (and reported in this paragraph) the number of 28-tablet pack-size equivalents of Liothyronine Tablets dispensed.

Figure 4.1: Liothyronine Tablets – NHS Reimbursement Prices and number of packs dispensed (January 2007 – July 2017)



Notes:
a) A pack size of 28 tablets per pack has been applied for the whole period.
b) No monthly data available for Northern Ireland and Scotland and so annual data applied pro-rata for 2017 (January to July).
Source: CMA analysis of PCA data for England, Wales, Scotland, and Northern Ireland.

4.98 Advanz's ASP for Liothyronine Tablets in July 2017 (£247.87) was 6,021% higher than its ASP in September 2007 (£4.05) (the month before de-branding). Advanz's significant price increases of Liothyronine Tablets increased its profits (see paragraphs 5.185 to 5.186 below). The fact that Advanz carried out multiple, profitable price increases strengthens the CMA's conclusion that other products did not impose a significant competitive constraint on Advanz.

ii. Switching to Levothyroxine Tablets

4.99 Advanz and Cinven[512] told the CMA that Liothyronine Tablet volumes have decreased relative to Levothyroxine Tablets, demonstrating a constraint from Levothyroxine Tablets. The Parties cite a report[513] that finds from August 2013 to July 2018 (beyond the Infringement Period) there was a median 37%

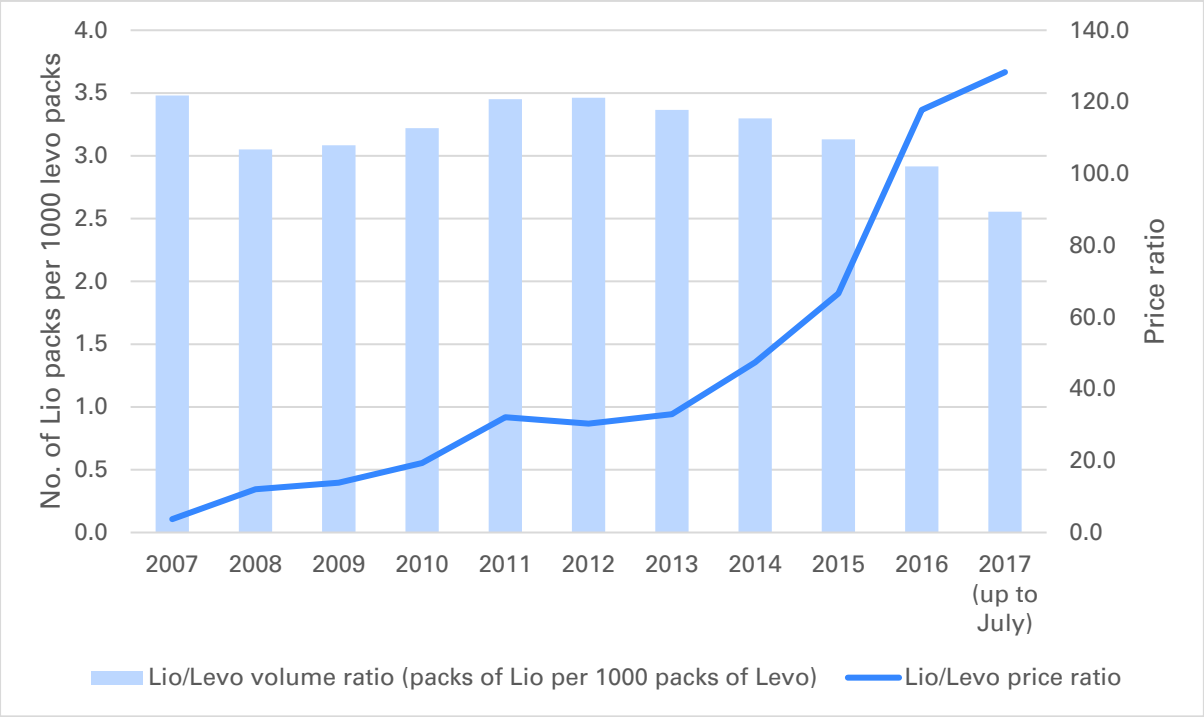
[512] Document LIO7781, Advanz RSSO-2019, paragraphs 3.15 and 3.74; document LIO7791, Cinven RSSO-2019, paragraphs 4.3b and 4.22-4.23.
[513] The report examines the monthly number and cost of Liothyronine Tablet prescriptions for each CCG. Document PAD169, Taylor, P N, Razvi, S, Muller, I, et al.: '*Liothyronine cost and prescriptions in England*', Lancet Diabetes Endocrinol 2019; 7: 11–12.

decrease in Liothyronine Tablet prescriptions per 1,000 Levothyroxine Tablet prescriptions nationwide.[514]

4.100 From November 2007, the significant rise in prices of Liothyronine Tablets resulted in a growing divergence in prices between Liothyronine Tablets and Levothyroxine Tablets. This is set out in Figure 4.2 below, which shows that Liothyronine Tablets increased from being around 12 times more expensive than Levothyroxine Tablets in 2008 to over 100 times more expensive in 2016. The number of Liothyronine Tablets per 1,000 Levothyroxine Tablets displays an upward trend from 2008, peaking in 2012, and then slowly declines.[515] While there is a substantial divergence in the price ratio between Liothyronine Tablets and Levothyroxine Tablets, the ratio of the volumes of Liothyronine Tablets to Levothyroxine Tablets declined only slightly between 2008 and 2016. Even as the ratio of prices increased very significantly from 2013 until July 2017, the ratio over that period between volumes reduced only gradually. In absolute terms, between November 2007 and 31 July 2017, the number of packs of Liothyronine Tablets dispensed each year broadly increased, with a flattening of this trend from 2012 and a slow decline from 2014 (see paragraph 4.97(b) and Figure 4.1 above).

[514] The report cites the largest changes in prescribing occurred in early 2016, coinciding with the most substantial increase in cost of Liothyronine Tablets.
[515] As noted at footnote 503, this is based on PCA data. Advanz's own data indicate greater volume stability.

Figure 4.2: Number of Liothyronine Tablets dispensed per 1,000 Levothyroxine Tablets dispensed and ratio of Liothyronine Tablet to Levothyroxine Tablet NHS Reimbursement Price per pack (January 2007 – July 2017)



Source: CMA analysis of PCA data for England, Wales, Scotland and Northern Ireland.

4.101 Had Levothyroxine Tablets been a close enough substitute to Liothyronine Tablets to form part of the same relevant product market then such a price divergence would not have been sustainable, because switching to Levothyroxine Tablets would have made it unprofitable to increase the price of Liothyronine Tablets to such an extent. Volume changes have not been sufficient to prevent Advanz from sustaining significant profitable price rises. This supports the CMA's assessment that Levothyroxine Tablets did not sufficiently constrain Liothyronine Tablets to warrant inclusion in the product market.

iii. The steady increase in the number of people diagnosed with hypothyroidism

4.102 The CMA has also considered the possibility that, in the absence of the price rises for Liothyronine Tablets, volumes of Liothyronine Tablets may have increased by a greater amount than they actually did, given the steady increase in the number of people that have been diagnosed with hypothyroidism across the UK.[516] Had the volume of Liothyronine Tablets dispensed increased in line with the growing number of patients diagnosed

[516] Document LIO1504, Society for Endocrinology's response to question 1(b) of the CMA's s.26 notice dated 20 December 2016.

with hypothyroidism in the UK, this would have led to an increase of around 27%[517] from 2008 to 155,222 packs being dispensed in 2016. The 147,194 packs of Liothyronine Tablets that were actually dispensed in 2016[518] represent approximately 5% less than the 155,222 packs that might have been expected to be dispensed had the prescribing of Liothyronine Tablets followed overall trends in prescribing treatments for hypothyroidism. Given the scale of the significant price rises in Liothyronine Tablets between November 2007 and July 2017 (an increase of 6,021%[519] in Advanz's average selling price), a 5% difference in volumes is relatively small. Accordingly, even if Advanz might have sold slighter larger volumes if it had not significantly raised its prices, overall its conduct (much higher pricing on volumes which might have been slightly reduced) was highly profitable in any event.

iv. Switching to unlicensed liothyronine and NDT

4.103 Cinven submits that there has been a substantial increase in the volumes of unlicensed liothyronine and NDT and a decrease in volumes of Liothyronine Tablets.[520]

4.104 Figure 4.3 below shows that the increase in unlicensed liothyronine and NDT volumes dispensed is small relative to the volumes of Liothyronine Tablets dispensed between January 2007 and July 2017. Liothyronine Tablet prices significantly increased without any significant impact on volumes. This finding is consistent with the qualitative evidence above, which demonstrates differences in the regulatory environment and no evidence in Advanz's internal documents to demonstrate that it considered unlicensed liothyronine and NDT as a competitive constraint. Together, the quantitative and qualitative evidence indicate that unlicensed liothyronine and NDT do not sufficiently constrain Liothyronine Tablets to warrant inclusion in the product market.

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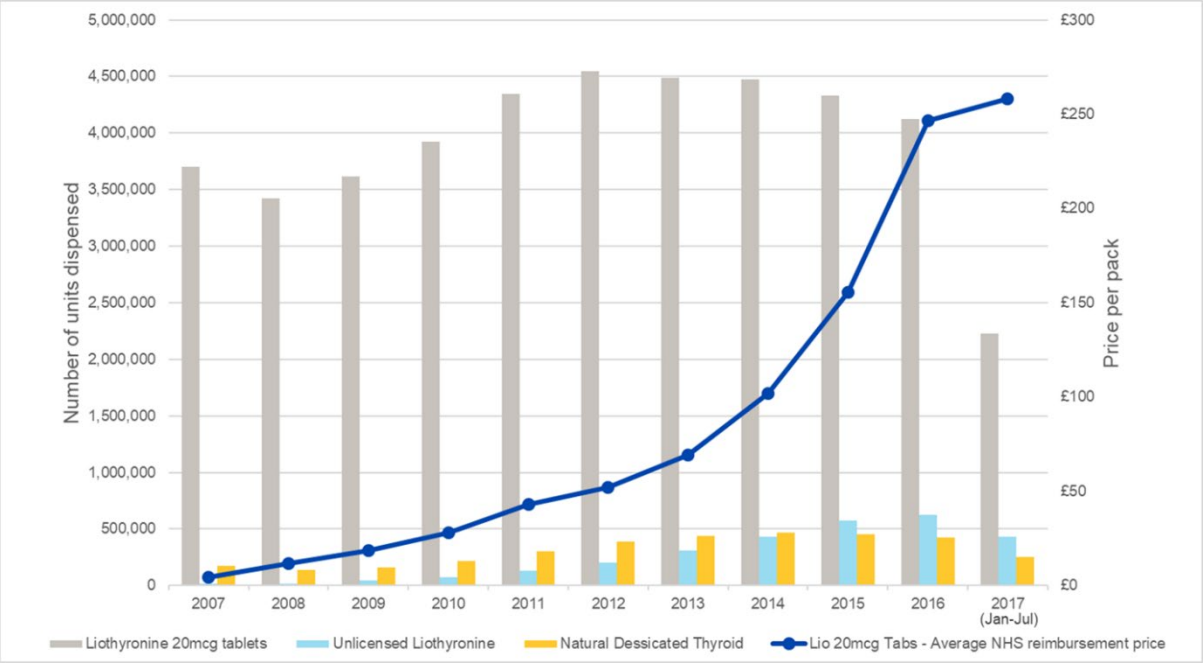
[517] The number of thyroid hormone tablets (Liothyronine Tablets (20mcg), Levothyroxine Tablets (25mcg, 50mcg, and 100mcg) and other preparations (unlicensed liothyronine)) dispensed in the UK has increased from 1,118 million in 2008 to 1,418 million in 2016, an increase of 27%. The micrograms of Liothyronine Tablets and Levothyroxine tablets (specifically 25mcg, 50mcg, and 100mcg tablets - this covers 99.2% of all formulations of Levothyroxine) dispensed in the UK (CMA analysis of PCA data for England, Wales, Scotland and Northern Ireland).
[518] CMA analysis based on PCA data for England, Wales, Scotland and Northern Ireland which reports volumes in terms of number of tablets dispensed. The CMA has converted the units to number of packs dispensed by assuming a 28-tablet pack-size for Liothyronine Tablets across the period of analysis. As noted in footnote 503, information provided by Advanz shows greater stability: Advanz's data indicates that 154,514 packs were sold during 2016.
[519] Advanz ASP per 28-tablet equivalent pack increased from £4.05 in September 2007 to £247.87 in July 2017.
[520] Document LIO7791, Cinven RSSO-2019, Sections 3 and 4; document LIO6330, Cinven RSO, Section 4. See also document LIO6288, Advanz RSO, Schedule 1, paragraph 1.74.

Figure 4.3: Liothyronine Tablets, unlicensed liothyronine and NDT – NHS Reimbursement Prices and number of units dispensed (January 2007 – July 2017)



Notes:
a) No monthly data available for Northern Ireland and Scotland and so annual data applied pro-rata for 2017 (January to July)
b) A unit dispensed corresponds to a tablet, if the drug is in tablets form, a capsule if in capsules form.
Source: CMA analysis based on PCA data for England, Wales, Scotland, and Northern Ireland.

v. The impact of new entry on Liothyronine Tablet prices

4.105 Given that there was entry in the supply of Liothyronine Tablets in 2017 (see paragraphs 3.100 and 3.106 above), it is also informative to compare the prices of Liothyronine Tablets before and after this entry.[521] Advanz's ASPs of Liothyronine Tablets prior to entry were £229 in 2016 and just under £248 from January to July 2017, earning Advanz substantial profits.[522] These prices were [✂] and [✂] higher than the post-entry ASP of Liothyronine Tablets in February 2021 ([✂]).[523] When Advanz was a sole supplier of Liothyronine Tablets, it was able profitably to sustain prices that were significantly higher

[521] The CAT has noted that market definition is contextual and '*should reflect relevance to the issue under consideration*' (*Paroxetine I* [2018] CAT 4, paragraph 403). The CAT decided in favour of Professor Shapiro's approach that the relevant market should be defined as the focal product alone because generic entry had a demonstrably large impact on the price of the focal product, demonstrating that the competitive constraint generic entry far outweighed any pressure from other products, notwithstanding the high degree of therapeutic equivalence of these alternatives (*Paroxetine I* [2018] CAT 4, paragraph 402 and 404). The CAT's conclusion on market definition was referred to the Court of Justice. In its further judgment following the Court of Justice's judgment, the CAT noted that this approach had not been supported by the Court of Justice or the Advocate General (*Paroxetine II* [2021] CAT 9 at paragraph 86). In any event, since the conduct in question concerns excessive prices resulting from a lack of normal and sufficiently effective competition, a comparison of prices before entry with prices when there was more competition should inform the market definition to be used in the competitive assessment. Prices following entry may take time to adjust however as set out in paragraphs 5.311 ff below.
[522] See Table 1.1 above.
[523] See paragraph 3.193 above.

than the prices set when there were other manufacturers.[524] This comparison shows that the constraints on Liothyronine Tablets from other products are insignificant compared to the constraints that generic manufacturers of Liothyronine Tablets place on each other.

IV. The relevant geographic market

4.106 The CMA concludes that the relevant geographic market in this case is national (UK-wide) in scope.

4.107 In previous cases in the pharmaceutical sector, including *AstraZeneca*, *Reckitt Benckiser*, *Paroxetine* and *Phenytoin*,[525] the relevant geographic market has been defined as national in scope. In these cases, this conclusion was reached on the basis of factors such as differences between countries in (i) the regulatory schemes for authorising and reimbursing medicines; (ii) marketing strategies used by pharmaceutical companies; (iii) doctors' prescribing practices; and (iv) prices.

4.108 The CMA concludes that it is similarly appropriate to define the geographic market as national in this case. In particular, in order to sell Liothyronine Tablets in the UK, it is necessary to obtain an MA from the MHRA, where the MA covers the whole of the UK (see paragraph 3.94 above). In addition, the regulatory framework which applies to Advanz's pricing (see section 3.C.VI above), including the NHS reimbursement price by which CCGs reimburse pharmacies, is specific to the UK.

C. Dominance

4.109 For the reasons set out in this section (which are summarised at paragraph 4.10 above), the CMA concludes that Advanz held a dominant position in the market for the supply of Liothyronine Tablets in the UK from at least 1 November 2007 to 31 July 2017.

I. Legal framework

4.110 The Chapter II prohibition requires that an undertaking holds a dominant position within the United Kingdom.

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[524] Advanz's prices in 2016 and January to July 2017 will be even higher than [✂] above Post-Entry Prices in the longer-term as the prices of Liothyronine Tablets are still falling (see Figure 3.4 above).
[525] *AstraZeneca* decision, paragraph 503; OFT Case No. CE/8931/08 *Reckitt Benckiser*, paragraphs 4.170-4.171; *Paroxetine I* [2018] CAT 4, paragraph 380 and *Paroxetine II* [2021] CAT 9, paragraph 90; and *Phenytoin CAT* [2018] CAT 11, footnote 28 referring to the reasoning in CE/9742-13 *Pfizer and Flynn Pharma*, CMA Decision of 7 December 2016, paragraphs 4.184-4.185.

4.111 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 giving it the power to behave to an appreciable extent independently of its competitors, customers and ultimately of consumers*'.[526] 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.[527]

4.112 An undertaking will not be in a dominant position unless it has substantial market power.[528] When assessing whether and to what extent market power exists, the CMA will consider the strength of any competitive constraints that prevent an undertaking from profitably sustaining prices above competitive levels.[529] Relevant considerations include:

(a) actual competition;

(b) the behaviour and financial performance of the undertaking in question;[530]

(c) potential competition (from new entrants who are not currently active in the relevant market);[531]

(d) countervailing buyer power;[532] and

(e) other relevant factors, such as the existence of economic regulation.[533]

4.113 Market shares are an important factor in determining whether an undertaking holds a dominant position.[534] The Court of Justice has held that:

> '[A]lthough the importance of the market shares may vary from one market to another the view may legitimately be taken that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position.
>
> An undertaking which has a very large market share and holds it for some time … is by virtue of that share in a position of strength which makes it an unavoidable trading partner and which, already

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[526] *United Brands*, 27/76, EU:C:1978:22, paragraph 65.
[527] *Hoffmann-La Roche*, 85/76, EU:C:1979:36, paragraph 39.
[528] OFT guidance on abuse of a dominant position, adopted by the CMA (OFT402), paragraph 4.11. OFT guidance on assessment of market power, adopted by the CMA ('**OFT415**'), paragraph 2.9.
[529] OFT415, paragraph 3.2.
[530] OFT415, paragraph 3.5.
[531] *United Brands*, 27/76, EU:C:1978:22, paragraph 122. *Hoffmann-La Roche*, 85/76, EU:C:1979:36, paragraph 48.
[532] OFT415, paragraphs 3.3 and 6.1-6.4. See also *National Grid v Gas and Electricity Markets Authority ('**National Grid**')* [2009] CAT 14, paragraph 60 and *Genzyme* [2004] CAT 4, paragraph 243.
[533] OFT415, paragraph 3.4.
[534] OFT415, paragraph 2.11.

because of this secures for it, at the very least during relatively long periods, that freedom of action which is the special feature of a dominant position'.[535]

4.114 In applying this principle, the Court of Justice has held that a market share of 50% constitutes, in itself, and save in exceptional circumstances, evidence of the existence of a dominant position.[536] A market share of 70 to 80% is, in itself, a clear indication of the existence of a dominant position.[537]

4.115 The European Courts have held that an undertaking's pricing conduct can also be a relevant factor in assessing whether it holds a dominant position.[538] Similarly, the CAT has held that an undertaking's pricing conduct may be indicative of market power.[539]

4.116 Specifically, an undertaking's pricing conduct and financial performance is a relevant factor:

> '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 costs, or persistently earned an excessive rate of profit'.[540]

4.117 The European Courts have held that the competitive constraint caused by potential competition may also be a relevant factor in determining whether an undertaking has market power.[541] An assessment of barriers to expansion and entry is instructive in relation to potential competition and market power.[542]

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[535] *Hoffmann-La Roche*, 85/76, EU:C:1979:36, paragraph 41. *AstraZeneca v Commission*, C-457/10P, EU:C:2012:770, paragraph 176. See also *Aberdeen Journals v DGFT* [2003] CAT 11. paragraph 310.
[536] *Akzo v Commission* ('***Akzo***'), C-62/86, EU:C:1991:286, paragraph 60. Undertakings with market shares of below 50% may still be dominant if other relevant factors mean that they still have substantial market power.
[537] *Telefonica v Commission*, T-336/07, EU:T:2012:172, paragraph 150. *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraph 243.
[538] *United Brands*, 27/76, EU:C:1978:22, paragraphs 66-68. *AstraZeneca v Commission*, T-321/05, EU:T:2010:266, paragraphs 261-269, subsequently confirmed in *AstraZeneca v Commission*, C-457/10P, EU:C:2012:770, paragraph 181.
[539] *Albion Water (Dominance and other issues)* [2006] CAT 36, paragraph 180.
[540] OFT415, paragraph 6.5.
[541] *United Brands*, 27/76, EU:C:1978:22, paragraph 122. *Hoffmann-La Roche*, 85/76, EU:C:1979:36, paragraph 48.
[542] See, for example, *National Grid* [2009] CAT 14 at 52-59. See also Decision of the Office of Rail Regulation on DB Schenker Rail (UK) Limited, August 2010, paragraph 45: '*A number of factors can be taken into account by competition authorities seeking to reach a conclusion on the existence or otherwise of market power ... Barriers to entry and buyer power are both also potentially key.*'

4.118 Where barriers to entry are low, it may not be profitable for an undertaking to sustain prices above competitive levels because this would attract entry which would drive the price down.[543] In order for potential competition to effectively constrain an undertaking, entry would need to have the potential to occur on a timely basis.[544]

4.119 An undertaking with significant market power may not be dominant if its customer has a sufficient degree of countervailing buyer power to effectively constrain the undertaking's conduct. In this context, it is not enough that a buyer has some market power – the question is *'not just the presence or absence of [countervailing buyer power] … but the* ***degree*** *of such [countervailing buyer power] and the extent to which it operated as a constraint on [the undertaking]'s ability to exert market power'*.[545]

4.120 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.[546]

4.121 In the context of pharmaceutical markets, the NHS generally 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 '*This aspect of countervailing buyer power is better described as a form of regulatory power.'*[547] However, the potential for economic regulation is not a competitive constraint in itself.[548] 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.[549]

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[543] OFT415, paragraph 5.2.
[544] OFT415, paragraph 5.31.
[545] *National Grid* [2009] CAT 14, paragraph 60 (emphasis in original).
[546] *Hutchison 3G (UK) v Ofcom* [2005] CAT 39, paragraphs 105(i), 110(c) and 126.
[547] *Phenytoin CAT* [2018] CAT 11, paragraph 205.
[548] OFT415, paragraph 3.4.
[549] In *Hutchison 3G (UK) v Ofcom* [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 Ofcom* [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*

4.122 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 the DHSC's powers as a question of statutory interpretation or otherwise.[550] The question is instead 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.[551] The CAT 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.'[552]

4.123 In its judgment on the appeal in *Phenytoin* on the issue of abuse, the Court of Appeal observed 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*'.[553]

4.124 In its order refusing permission for Pfizer to appeal the CAT's findings on dominance, the Court of Appeal confirmed that:

> '[T]he 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

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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* [2009] CAT 14, paragraph 80; *Napp Pharmaceutical Holdings Limited v DGFT* ('***Napp***')[2002] CAT 1, paragraphs 153-155 and 165-168. Similarly, in *Deutsche Telekom*, C-280/08P, EU:C:2010:603, Deutsche Telekom 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 that this meant it could not abuse its position, 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).

[550] *Phenytoin CAT* [2018] CAT 11, paragraph 207.

[551] *Phenytoin CAT* [2018] CAT 11, paragraph 207.

[552] *Phenytoin CAT* [2018] CAT 11, paragraph 203.

[553] [2020] EWCA Civ 339, paragraphs 192 and 217.

> have absolved the appellants from their "special responsibility not to allow their conduct to impair genuine undistorted competition"'.[554]

4.125 In *Deutsche Telekom* the Court of Justice had stated:

> '[T]he 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 [102 TFEU]'.[555]

II. Market shares

4.126 The CMA finds that Advanz held a market share in the relevant market of 100% from at least 1 November 2007 to 31 July 2017, reflecting the fact that it was the sole supplier of Liothyronine Tablets in the UK. Market shares are an important factor in the assessment of dominance. A market share at this level is a clear indication of the existence of a dominant position.[556]

4.127 Consistent with this, as set out at paragraphs 4.36 and 4.38 to 4.40 above, Advanz considered that as the sole or exclusive supplier of Liothyronine Tablets in the UK, it could raise the price of Liothyronine Tablets with only limited constraints.

III. Pricing behaviour and financial performance

4.128 From November 2017, Advanz was consistently able to profitably raise prices (as shown at section 3.E above).[557] The CMA concludes that Advanz was able to act to an appreciable extent independently of its competitors, customers and consumers in the market for Liothyronine Tablets in the UK from at least 1 November 2007 to 31 July 2017 and that it has been able to exercise significant market power.[558]

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[554] Document PAD172, *Flynn Pharma Limited & Ors v CMA*, Order made by the Rt. Hon. Lord Justice Newey, dated 12 December 2018 (emphasis in original).
[555] *Deutsche Telekom*, C-280/08, EU:C:2010:603, paragraph 84.
[556] *Telefonica v Commission*, T-336/07, EU:T:2012:172, paragraph 150; and *AstraZeneca v Commission*, EU:T:2010:266, paragraph 243. See also paragraphs 4.113 to 4.114 above.
[557] OFT415, paragraph 6.5.
[558] See IV/30.787 and 31.488 *Eurofix-Bauco v. Hilti*, Commission Decision of 22 December 1987, paragraph 71, and *Hilti AG v Commission*, T-30/89, EU:T:1991:70, paragraph 93. See also OFT415, paragraphs 6.5 and 6.6 and European Commission Communication: Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings,(the '**Commission Enforcement Priorities Guidance**') [2009] OJ C 45/7, 24.2.2009, paragraph 11.

4.129 Advanz has argued that it is inappropriate for the CMA to assess Advanz's conduct and financial performance in relation to a single product (Liothyronine Tablets).[559] Advanz told the CMA that it charged high prices for some of its established products (such as Liothyronine Tablets) in order to offset the very low or negative margins of other medicines in its portfolio ('portfolio pricing'). The CMA has considered and rejected this argument. Advanz's ability to charge higher prices on one product so that it offsets low returns on other products in its portfolio, as submitted by Advanz, reflects its market power in relation to the product for which it charges a higher price.[560] In any event, the commercial rationale that a firm may have for charging a high price for one product does not rebut the evidence that the firm is dominant in the market for that product.

4.130 In October 2007, Advanz de-branded Tertroxin (the former Liothyronine Tablets brand) and in doing so removed it from PPRS price controls (see paragraph 3.139 above). The CMA finds that, as a result of this strategy, Advanz has been able to profitably increase prices for Liothyronine Tablets over a sustained (10 year) period:

(a) As explained at paragraph 3.190 above, Advanz's ASP for Liothyronine Tablets increased by 6,021%[561] from the price prior to de-branding.

(b) Further, Advanz's prices have been consistently and significantly above an appropriate measure of its respective costs plus a reasonable rate of return throughout the Infringement Period. As is set out in more detail in paragraphs 5.178 to 5.194 below, Advanz's prices at all times exceeded its costs, including a reasonable rate of return, by at least 900%, with prices reaching 2,434% above cost by 2017 (the Differential rose from £18.72 per pack to £237.99 per pack).[562] These high returns are significantly above those which would be expected to prevail in a competitive market characterised by similar levels of risk.[563]

(c) Moreover, as set out at paragraphs 4.36 and 4.38 to 4.40 above, Advanz's internal documents confirm that previous price rises were profitable and that Advanz anticipated being able to undertake a series of profitable price increases. They also demonstrate that Advanz considered that its price rises would not reduce the volume of its sales of Liothyronine Tablets and the empirical evidence supports this.

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[559] Document LIO6288, Advanz RSO, Schedule 2, paragraph 2.10 and 2.20.
[560] OFT403, paragraph 2.2.
[561] An increase from £4.05 in September 2007 (the month prior to de-branding) to £247.87 in July 2017.
[562] See Table 5.4 below.
[563] OFT415, paragraph 6.6.

4.131 The fact that Advanz has been able to repeatedly increase its prices to such an extent and to profitably sustain such increases demonstrates that competitive constraints exerted on Advanz were insufficient to prevent it from holding a dominant position in the market for Liothyronine Tablets in the UK.

IV. Assessment of possible constraints on dominance

4.132 The CMA concludes that (a) significant barriers to entry prevented potential entrants from acting as an effective constraint on Advanz, and (b) Advanz was not effectively constrained by countervailing buyer power on the part of its customers.

a. Assessment of potential competition

4.133 The following analysis considers the barriers to entry faced by potential competitors seeking to develop Liothyronine Tablets. As the market has been defined as the supply of Liothyronine Tablets in the UK, this sub-section focuses on the potential introduction of other generic Liothyronine Tablets. While parallel imports could also potentially provide a source of competition, there were in fact no parallel imports of Liothyronine Tablets[564] because there is no sufficiently similar product in Europe.[565]

i. Technical and regulatory obstacles constituted significant barriers to entry to new entrants

4.134 In order to enter the market, potential entrants need to develop and manufacture Liothyronine Tablets, and obtain regulatory approval. However,

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[564] The MHRA has confirmed that no parallel import licences were granted for Liothyronine Tablets: document LIO1362, '*20161128 MHRA Forest s.26 data templates*', page 2. See also document LIO1983, MPT Pharma Limited's response to question 1 of Annex 3 of the CMA's s.26 notice dated 27 January 2017; document LIO2039, Primecrown Limited's response to question 1 of Annex 3 of the CMA's s.26 notice dated 27 January 2017; document LIO1931, Laxmi BNS Holding's response to question 1 of the CMA's s.26 Notice dated 27 January 2017; document LIO3011, OPD Laboratories' response to question 2 of the CMA's s.26 notice dated 15 June 2017; document LIO1782, Doncaster Pharmaceutical's Group Limited's response to question 1 of Annex 2 of the CMA's s.26 notice dated 27 January 2017; document LIO1912, Waymade Plc's response to question 1 of the CMA's s.26 notice dated 2 February 2017.

[565] Document LIO0669, Email from [Advanz Global Marketing Director] to [Advanz Vice President Global Medical] dated 09 May 2016. Advanz stated in a draft response to a patient association regarding its high prices: '*The UK formulation of liothyronine is unique and not interchangeable with other formulations that maybe available in other markets. Every batch of liothyronine has to proceed through a BSV [batch specific variation] in collaboration with the UK regulatory authorities to ensure the modern safety and quality standards are met*'. In addition, Doncaster Pharmaceuticals Group Limited stated that there was no '*equivalent product*' to Liothyronine Tablets available in Europe to import into the UK and that an equivalent product marketed by Goldshield in Italy was withdrawn on an unspecified date (document LIO1782, Doncaster Pharmaceutical's Group Limited's response to question 1 of Annex 2 of the CMA's s.26 notice dated 27 January 2017). Waymade Plc applied for a licence to parallel import 20mcg Tertroxin (branded Liothyronine Tablets) from Italy in 2007. However this application was unsuccessful due to '*potential therapeutic differences*' identified by MHRA between the Italian and UK versions of the tablet (document LIO1912, Waymade Plc's response to question 1 of the CMA's s.26 notice dated 2 February 2017).

the evidence demonstrates that doing so is difficult and typically takes several years, making barriers to entry high.

4.135 First, while it appears that the API is readily available to purchase, Liothyronine Tablets are difficult to manufacture, in particular due to the very small quantity of API used in each tablet. In fact, Advanz itself has had difficulty producing a consistently stable product, resulting in the MHRA requiring Advanz to apply for a batch specific variation in respect of every batch of product that it produces (see paragraph 3.173 above). Potential entrants have confirmed that Liothyronine Tablets are difficult to develop and manufacture (see paragraph 3.172 above).

4.136 Consistent with this, Advanz's internal documents indicate a contemporaneous view that the market for Liothyronine Tablets has high barriers to entry because the product is difficult to manufacture:[566]

(a) Numerous internal presentations, including presentations to investors, describe Liothyronine Tablets as '*difficult to manufacture*'[567] or '*extremely hard to make*'.[568]

(b) An internal presentation dated July 2012 states: '*The complex manufacturing process of Liothyronine, together with the relatively small size, discourages competitors from entering the market*'.[569]

(c) Under the heading '*Key Barriers to Entry*', a Company Overview presentation prepared in January 2015 sets out the reasons that Liothyronine Tablets are '*[d]ifficult to manufacture*', stating: '*Low dosage, insoluble API, requires dedicated & segregated hormone production suite*'.[570]

(d) A draft presentation prepared in August 2015 in relation to Concordia Healthcare Corporation's acquisition of AMCo describes Liothyronine Tablets as difficult to manufacture and cites an MHRA source: '*[K]nown to be a difficult to manufacture product - the complex manufacturing process represents a significant barrier to entry by competitors "… The main difficulties*

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[566] Inconsistently with its internal documents, Advanz submits in relation to barriers to entry, that the API and excipients are readily available, that there are no special production requirements, that there are multiple CMOs that could produce Liothyronine Tablets and that obtaining an MA in the UK is not unduly onerous for a company which already has an MA in another EU member state: document LIO3061, Advanz's response to question 28 of the CMA's s.26 notice dated 25 January 2017.
[567] Document LIO0188, Advanz's '*Project Glacier- Updated Draft Forecasts - 120412v2.pdf*', page 222; Document LIO0773, Advanz's '*2014.10.15_Project Armour CIM_vF.pdf*', page 58.
[568] Document LIO0535, Advanz's '*UK product slides - DRAFT 22 Jul 2015.pptx*', slide 3; document LIO0717, Advanz's '*150801 - Strategic plan presentationfinal.pptx*', slide 20.
[569] Document LIO0221, Advanz's '*Glacier Management Presentation_vFINAL.pdf*', page 30; See also Document LIO0740, Advanz's '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62.
[570] Document LIO0621, Advanz's '*Concordia Deck_Jan 27_Updated.pdf*', page 19. See also document LIO0794, Advanz's '*20150802 Atoll Management Presentation vDRAFT.pdf*', page 16.

of Liothyronine … tablets are due to the fact that it is a relatively unstable medicinal product, difficult to manufacture and with limited sources of active substances …" MHRA, August 2013'.[571]

4.137 Second, having developed a product which a company believes to be stable, there are strict regulatory standards to meet. The MHRA has confirmed that it has implemented rigorous pharmaceutical and clinical testing requirements for thyroid hormone products (including Liothyronine Tablets).[572] Consistent with this, views from companies seeking to enter the market for Liothyronine Tablets suggest that it may be difficult to meet the requirements for obtaining an MA in the UK.[573]

4.138 The evidence demonstrates that the technical and regulatory hurdles that must be overcome mean that successful entry in practice takes several years. For example, both Advanz and firms seeking to enter the market estimated that it could take around three to four years for a firm to enter the market.[574] The experience of companies seeking to launch Liothyronine Tablets suggests that the time taken is not less than three years and can be five years or more. For example:

(a) Morningside first began developing Liothyronine Tablets in 2012 and took five years to obtain an MA (see paragraph 3.100 above).

(b) Teva launched its project to develop Liothyronine Tablets in mid-2014 and took three years to obtain an MA (see paragraph 3.106 above).

(c) [PE1] initially anticipated commencing selling Liothyronine Tablets in 2019 but only submitted its application for an MA in May 2020, [✂] after it launched its initial development project (see paragraph 3.110 above). [PE1] compared this

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[571] Document LIO0588, Advanz's '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 41.
[572] Document LIO4154, MHRA background and clarification notes to be read alongside minutes from CMA for meeting of Thursday, 22 June 2017, point 9.
[573] Document LIO1906, [PE2]'s response to question 11 of to the CMA's s.26 notice dated 27 January 2017; document LIO3480, Teva's response to question 2 of the CMA's s.26 notice dated 07 July 2017; document LIO2017, Morningside's response to question 1 of the CMA's s.26 notice dated 25 January 2017. [PE10] stated that it is difficult to register products through the mutual recognition procedure (which is intended to facilitate obtaining MAs for the same medicinal product in different EU member states) where there are differences in registered indications for the same medicinal products in different EU member states: document LIO3541, [PE10]'s response to question 3 of the CMA's s.26 notice dated 11 July 2017.
[574] Advanz's estimate includes two to three years to develop a new Liothyronine Tablets product and one year for clinical trials. This process would be around six months faster for a firm with an existing MA in another EU country, as such firms could enter within two years using the mutual recognition procedure: document LIO3061, Advanz's response to question 28 of the CMA's s.26 notice dated 25 January 2017. [PE2] suggested it could launch Liothyronine Tablets three to four years after starting development: document LIO1906, [PE2]'s response to question 6 of the CMA's s.26 notice dated 27 January 2017. Morningside indicated it had taken more than four years to obtain an MA for Liothyronine Tablets: document LIO2017, Morningside's response to question 1 of the CMA's s.26 notice dated 25 January 2017. Teva and [PE3] both suggested it would take at least three years to obtain an MA: document LIO2195, Teva's response to question 6 of the CMA's s.26 notice dated 25 January 2017, and document LIO2206, [PE3]'s response to question 6 of the CMA's s.26 notice dated 25 January 2017.

to a more typical development time frame for generic drugs of 2.5 to 3.5 years from the start of development to market launch.[575]

(d) [PE16] launched its project to develop Liothyronine Tablets in 2016 and submitted an application for an MA in [✂]. Approximately [✂] years after initiating work on the project, [PE16]'s development remains pending (see paragraph 3.110 above).[576]

4.139 Successful entry is not guaranteed, and potential new entrants face uncertainty over whether they will be successful in their entry attempts.[577] The difficulty of developing a product that will meet regulatory standards is demonstrated by the fact that several companies have commenced but subsequently abandoned development projects (see paragraph 3.110 above):[578, 579]

(a) [PE3] applied for an MA in 2011, having identified the market for Liothyronine Tablets as an opportunity in 2010, but abandoned its application in 2013 [✂].

(b) [PE2] launched its project to develop Liothyronine Tablets in late 2014. [PE2] initially considered that it might be in a position to enter by Q1 2018 but, [✂].

ii. The high cost of entry meant that new entrants did not commence the long development process until Advanz had significantly increased its prices

4.140 The cost of entry, if it is high relative to the total size of a market, can also represent a barrier to entry. In relation to Liothyronine Tablets, the total costs (both estimated and actual) associated with entry, including developing the drug and obtaining all licences, range from around [<£500,000] to around [<£1 million],[580] compared to a total market size of approximately £800,000 in 2007 (in terms of gross sales).[581] Net profits available to a new entrant would be

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[575] Document LIO3321, [PE1]'s response to question 9 of the CMA's s.26 notice dated 30 June 2017.
[576] Document LIO6614, [PE16] response to question 1 of the CMA's s.26 notice dated 18 June 2018; Document LIO7846, [PE16] response to question 1 of the CMA's s.26 notice dated 21 August 2019; Document LIO12072, [PE16] response to question 1 of the CMA's s.26 notice dated 8 September 2020; Document LIO12179, [PE16] response to question 1 of the CMA's s.26 notice dated 24 February 2021.
[577] For example, Morningside stated, in February 2017, that it did not know whether it would be able to bring a product to market, given the regulatory requirements: document LIO2017, Morningside's response to questions 1 and 7 of the CMA's s.26 notice dated 25 January 2017. [✂].
[578] See also Annex 3, paragraph 3.197.
[579] The CMA notes that two companies which had commenced development of Liothyronine Tablets were acquired by Advanz: (a) Focus, which abandoned the project following failure of the manufacture of test batches (see paragraphs 3.182 to 3.184 above); and (b) Primegen, whose development project for 20mcg, 10mcg and 5mcg strengths remains ongoing (see paragraphs 3.185 to 3.187 above).
[580] See Annex 3 to this Decision.
[581] Potential entry costs vary significantly depending on whether the company has experience of supplying Liothyronine products in another country and the company's previous experience of developing other generic products. In an internal spreadsheet Advanz allocated [£300,000-£400,000] (Costs are expressed as [£200,000-£300,000] for development costs and [£100,000-£200,000] for a bioequivalence study: document LIO0552,

lower than £800,000 per annum given that: (i) the new entrant would incur ongoing costs in supplying the market; (ii) the new entrant would only likely win a share of the overall market, rather than capture the entire market; and (iii) new entry might itself lead to an erosion of supplier profit margins over time as a result of increased competition. In 2007, estimated entry costs were [✂] of the annual market size.[582] In contrast, by 2012 (when Morningside – the first successful entrant – commenced efforts to enter), entry costs were [✂][583] of the annual market size. By 2014 (when Teva – the second successful entrant – commenced efforts to enter), entry costs were just [✂][584] of the annual market size. Accordingly, the cost of entry in relation to the total market size was high in 2007, meaning that the relative cost of entry represented a significant barrier to entry at that time and subsequently until Advanz significantly increased its prices.

4.141 Advanz was aware that the small size of the market meant that the threat of entry was reduced. Advanz considered that '*[t]he Company's products are niche medications with sales typically under £5-10 million, falling below the radar of large generics companies. Given the sales potential of these products for a new competitor, it is not economically viable for new entrants to invest resources to develop these products*'.[585] More specifically, in 2012 Advanz focused on products with '*UK sales not much higher than £3M; therefore likely to be under the radar for larger companies*'.[586]

4.142 Consistent with Advanz's own view that entry was not attractive, there is no evidence of interest from potential competitors in entering the market until that of [PE3] in 2010 (whose efforts to enter were discontinued in 2013 – see paragraph 4.139 above).[587] The first successful entry attempts did not begin until 2012 (Morningside) and 2014 (Teva). The evidence indicates that these

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Advanz's '*Liothyronine evaluation_150731.xlsx*', '*Development costs'* tab.) as its own cost for developing new tablet strengths with [✂] (see paragraphs 3.179 to 3.180 above), and estimated total development costs of [£400,000-£500,000] for [✂] development of new tablet strengths (Consisting of [£150,000-£250,000] to date with a further [£150,000-£250,000] to follow. These estimates may overstate the UK development costs as they also include development of Liothyronine Tablets for the US and European markets: document LIO3980, Advanz's response to question 1 of the CMA's s.26 notice dated 25 July 2017, and document LIO3986, Advanz's '*Primegen Due Diligence Report 2 June 2015*', Annex 6, page 13).

[582] Entry costs of [<£0.5] to [<£1] million compared to annual market value of £800,000 in 2007, based on Advanz's sales values given the absence of other companies selling Liothyronine Tablets in 2007.

[583] Entry costs of [<£0.5] to [<£1] million compared to annual market value of £6.5 million in 2012, based on Advanz's sales values given the absence of other companies selling Liothyronine Tablets in 2012.

[584] Entry costs of [<£0.5] to [<£1] million compared to annual market value of £14 million in 2014, based on Advanz's sales values given the absence of other companies selling Liothyronine Tablets in 2014.

[585] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', pages 15-16; document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', pages 65-67; document LIO0769, '*Project Armour CIM_v72.pdf*', page 17. See also document LIO0546, Email from [✂] (then Global Marketing Director) to [✂] (then Chief Financial Officer) dated 30 July 2015, page 3.

[586] Document LIO0308, '*Project Glacier - 798108 - Final Report - 210512 (IMS).pdf*', page 42.

[587] This is consistent with the European Commission reporting that the high cost of obtaining regulatory approvals compared to the market size may constitute a barrier to entry for some generic medicines and that in very small generics markets the expected profits may be too small to attract entry. See document PAD137, OECD: '*Excessive Pricing in Pharmaceutical Markets - Note by the European Union*', 28 November 2018, paragraph 22.

entry attempts were stimulated by Advanz's pricing behaviour, which increased the market size (by sales value) with the result that entry became increasingly attractive in terms of the potential revenues they could earn.[588]

iii. Potential competition did not constrain Advanz's behaviour

4.143 Despite Advanz's awareness of the prospect of entry, the evidence shows that potential competition did not constrain Advanz's pricing behaviour:

(a) Advanz continued repeatedly to increase the price of Liothyronine Tablets. Even at times when Advanz's internal documents show it contemplating whether price increases would make entry more attractive (see documents referred to in paragraph 4.44 above), such views did not result in changes to its pricing conduct and Advanz continued implementing price rises.

(b) While acknowledging the threat of potential competition, Advanz decided to continue to raise prices to take advantage of the time before such competition emerged. In an email dated May 2013 [Advanz CEO] stated: '*[A]ctually think that we should continue with* [✂] *price increase because I am pretty sure that we are going to get competition within the next year or so. … Therefore we should take what we can from it now. I think Liothyronine maybe* [sic] *a similar story*'. Advanz increased the proposed price rise for Liothyronine Tablets in this instance from 20% to 30%.[589]

4.144 Advanz told the CMA that it made significant investments to manage the risk of competitive entry through enhancement of its manufacturing efficiency through dual sourcing.[590] While Advanz may have implemented a dual sourcing strategy the CMA does not consider there is evidence that this was a result of competitive pressure.

iv. Conclusion on potential competition

4.145 Overall, the CMA concludes that there are significant, but not insurmountable, barriers to entry in this market. The small size of the market relative to the cost of entry itself constituted a barrier to entry for a period and there were no

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[588] [✂]. In 2010 [PE3] estimated that the combined revenues it could achieve from sales of Liothyronine Tablets in the UK [✂] was [✂] per year. This was based on a price of [✂] for a 28 tablets pack, when the price in the UK at that time was more than three times that level: document LIO2206, [PE3]'s response to question 3 of the CMA's s.26 notice dated 25 January 2017. In 2014 [✂]: document LIO2195, Teva's response to question 3 of the CMA's s.26 notice dated 25 January 2017.

[589] Document LIO3779, Email chain between (i) [Advanz CEO] and [Advanz Commercial Servies Director] and (ii) [Advanz Commercial Servies Director] and [Advanz employee] dated between 30 May 2013 and 31 May 2013. Another internal document dated August 2014 shows that Advanz was aware that Focus was planning to launch its own Liothyronine Tablets in January 2017, see document LIO3718.5, Advanz's '*Annex 2 - Question 2 Documents - Focus - 002231405*', page 13.

[590] Document LIO6288, Advanz RSO, paragraph 2.92-2.93.

attempts at entry until Advanz's pricing behaviour made entry more attractive relative to the costs and risks of entry.[591] Even when prices became high enough to prompt the first successful entry attempts in 2012 (Morningside) and 2014 (Teva), the significant technical and regulatory barriers to entry that each undertaking faced meant that successful entry did not in fact occur until 2017. The result was that it took around 10 years for entry to succeed in response to Advanz's strategy in 2007 to de-brand and increase the price of Liothyronine Tablets. Despite numerous attempts at entry, Advanz continued to repeatedly raise its prices, which demonstrates that Advanz's behaviour was not constrained by the threat of entry overall. Rather, Advanz's ability to sustain high prices were a manifestation of its market power.

b. The absence of countervailing buyer power

4.146 The CMA concludes that Advanz was not constrained in its conduct by countervailing buyer power.

4.147 In this section, the CMA assesses the potential for countervailing buyer power from the NHS, and the DHSC as the government department responsible for the NHS, which must fund prescriptions for the drug and therefore generally ultimately bears the cost of Advanz's price rises (indirectly, via the reimbursement price that CCGs pay to pharmacies).[592]

4.148 Advanz argues that '*[a]t all times the DH/NHS held countervailing buyer power in its capacity as a monopsonist and a price regulator*'.[593] HgCapital also argues that Advanz was constrained '*by the DH, a monopsony purchaser with price control powers and the ability to issue guidance to change prescription practices in relation to Liothyronine*'.[594] Cinven argues that '*the NHS had countervailing buyer power and the DoH had the ability to regulate the price of Liothyronine Tablets during the Relevant Period*'.[595]

4.149 For the reasons explained in this section, the CMA rejects these arguments. Additional reasoning is set out in Annex 5. The CMA concludes that Advanz

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[591] See CMA merger guidelines paragraph 5.8.8 for relevant factors for assessing whether entry and/or expansion might act as an effective competitive constraint. This states that the Authorities will consider whether entrants are discouraged from entering by the small size of the market alongside the scale of barriers to entry. Even if barriers to entry are low, entrants may not have the incentive to enter due to the size of the market.
[592] As explained at paragraph 3.59 above, Liothyronine Tablets are primarily distributed through pharmacies rather than through hospitals and sales of Liothyronine Tablets directly to the NHS (in the form of hospitals and specialists) were therefore negligible.
[593] Document LIO7781, Advanz RSSO-2019, paragraph 1.6.5. In its representations on the SO, Advanz argued that '*the DH is in the unique position to be both the monopsonistic purchaser and the price regulator*' (document LIO6288, Advanz RSO, paragraph 2.96).
[594] Document LIO7798, HgCapital RSSO-2019, paragraph 229; document LIO6258, HgCapital RSO, paragraphs 161-183.
[595] Document LIO6330, Cinven RSO, paragraph 5.3.

was not constrained in its conduct by countervailing buyer power held by the DHSC or NHS.

4.150 As noted at paragraph 4.121 above, when refusing permission for Pfizer to appeal the CAT's *Phenytoin* judgment on dominance, the Court of Appeal 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*'.[596]

4.151 The absence of an effective constraint – whether from the DHSC/NHS or from Advanz's immediate customers – is clear from Advanz's pricing behaviour. An undertaking that increases its prices by over 6,000% without losing sales volumes is clearly not effectively constrained by countervailing buyer power.[597]

4.152 The absence of an effective constraint on Advanz's conduct from the NHS/DHSC is explained by factors including:

(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.

i. The fragmented composition of the NHS

4.153 As the CAT explained in *Genzyme*:

> 'The "NHS" does not […] exist as a corporate entity. In practice, the operation of the NHS is devolved to numerous executive or advisory bodies or agencies'.[598]

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[596] Document PAD172, *Flynn Pharma Limited & Ors v CMA*, Order made by the Rt. Hon. Lord Justice Newey, dated 12 December 2018 (emphasis in original). See also *National Grid* [2009] CAT 14, paragraph 60; *Hutchison 3G v Ofcom* [2005] CAT 39, paragraphs 105(i), 100(c) and 126.
[597] 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* [2004] CAT 4, paragraph 257.
[598] *Genzyme* [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 (CC) decision in the *Bournemouth/Poole* merger, in which the CC observed (in relation to hospital services) that in the 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).

4.154 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.[599]

4.155 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 and dispensing of drugs are not made by the entity responsible for paying for the drugs;

(b) The entity responsible for paying (the CCG) has no choice over whether to purchase or pay for drugs; and

(c) The price payable by the CCGs is not determined or agreed by the CCGs, even though they are responsible for paying. Indeed, the NHSCC, the membership organisation of CCGs, has informed the CMA that, 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.[600]

4.156 It is therefore overly simplistic to refer to '*the NHS*' as a '*customer*' or a '*monopsonist*': it is a collection of many individual customers, particularly CCGs, each of which has its own budget and priorities.[601] This was acknowledged in investor materials relating to Advanz's business prepared in preparation for Cinven's acquisition of the business from HgCapital:

'[✂].'[602]

ii. The inability of the NHS to exercise choice

4.157 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 countervailing buyer power. In order effectively to constrain a firm from exercising its market power, the buyer also typically has to have a choice as to whether to continue buying from the seller.[603]

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[599] *Genzyme* [2004] CAT 4, paragraph 251. Compare document LIO12042, Julie Lizbeth Wood's witness statement, paragraph 6.
[600] Document LIO3868, Note of call between the CMA and NHSCC dated 3 May 2017, paragraphs 13 and 37.
[601] Cf. the Cinven Entities' statement that the NHS was '*the sole end customer for Liothyronine Tablets in the UK*' (document LIO6330, Cinven RSO, paragraph 5.75) and Advanz's description of '*the DH/NHS*' as '*the monopsonistic purchaser*' (document LIO6288, Advanz RSO, paragraphs 2.103 and 2.106-2.109).
[602] Document LIO6490.3, *'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012'*, page 4 (emphasis added).
[603] OFT415, paragraph 6.1.

4.158 The CMA finds that neither the NHS nor any of its constituent parts was able to exercise such a choice.

4.159 As explained above, the pricing practices of Advanz in relation to Liothyronine Tablets themselves evidence the ability of Advanz to disregard the wishes of its customers and consumers. There is no evidence that any part of the NHS effectively constrained Advanz's Liothyronine Tablet prices.

4.160 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.[604] 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.

4.161 In *Genzyme*, the CAT observed that:

> '[I]n 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'.[605]

4.162 In this case, CCGs are responsible for funding prescriptions for Liothyronine Tablets out of their prescribing budgets. However, CCGs do not negotiate the prices of Liothyronine Tablets with pharmaceutical suppliers or purchase the medicines directly from them. Moreover, CCGs have no formal powers enabling them to limit the price they pay for pharmaceutical products. The NHSCC informed the CMA that it has separate bilateral relationships with NICE, the DHSC and NHS England, but none of these relates to drug pricing.[606]

4.163 Once a prescriber has written a prescription for a particular pharmaceutical product, the relevant CCG has no choice but to fund the medicine dispensed against that prescription.[607]

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[604] See section 1 of the NHS Act.
[605] *Genzyme* [2004] CAT 4, paragraphs 249-250.
[606] Document LIO3868, Note of call between the CMA and NHSCC dated 3 May 2017, paragraphs 10, 11, 13, and 37.
[607] See similarly *Genzyme* [2004] CAT 4, paragraphs 248-249. In the current case the responsible clinician is usually a GP, who retains prescribing independence even when a particular prescribing decision is being recommended by his or her CCG (since 2013 PCTs have been replaced by CCGs).

4.164 While Advanz was the sole supplier of Liothyronine Tablets, CCGs therefore had no choice but to pay for Advanz's Liothyronine Tablets.

4.165 Nonetheless, Advanz argues that '*it is clear that the NHS (via the CCGs) had the ability to influence prescribing practices, and that, as a matter of fact, did actively and effectively encourage switching from LIO to Levothyroxine*'.[608] Cinven also argues that the CMA has failed '*to take account of CCGs' ability to influence prescribing practices*'.[609]

4.166 The CMA rejects these arguments. As noted at paragraphs 3.76 to 3.79 above, the NHS consulted on proposals to recommend that Liothyronine Tablets no longer be routinely prescribed but concluded that they should still be prescribed for a small cohort of patients. The 2017 NHSCC consultation noted that:

> 'CCGs have been actively pursuing a reduction in Liothyronine prescribing in recent months. […] If prescribing is to be allowed to continue, there should be clear guidance in terms of the thyroid function test results and significant pressure on manufacturers to reduce the price to a reasonable level. At a lower cost, there would be less need to pursue deprescribing of a medication that some patients feel very strongly have had a positive effect on their quality of life.'[610]

4.167 The decision ultimately taken – not to recommend de-prescribing Liothyronine Tablets for all patients but to allow ongoing prescribing for '*individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist*' – represented an exception based on the clinical needs of a cohort of patients, despite the significant costs of continuing to prescribe a drug that was not priced at '*a reasonable level*'. Liothyronine Tablets were placed in the category of drugs '*which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation*'.[611]

4.168 The CMA concludes that this reflects the NHS's lack of countervailing buyer power in practice, as it demonstrates that even when faced with the high costs associated with Advanz's Liothyronine Tablets, it is difficult to switch to an alternative source of supply or to negotiate lower prices. The fact remains that

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[608] Document LIO6288, Advanz RSO, paragraphs 2.125-2.130.
[609] Document LIO6330, Cinven RSO, paragraphs 5.89-5.99.
[610] Document LIO7789.15, NHSCC: '*Items which should not be routinely prescribed in primary care: Consultation Report of Findings*', page 29 (emphasis added).
[611] Document PAD209, NHS: '*Items which should not routinely be prescribed in primary care: Guidance for CCGs, Version 2*', June 2019, pages 25-26 (emphasis added).

where Liothyronine Tablets were prescribed, CCGs were obliged to fund those prescriptions despite their feeling that the drug had been '*subject to excessive price inflation*' and its price was not at '*a reasonable level*'.[612]

iii. The absence of an effective constraint from the powers available to the DHSC

4.169 As explained at paragraphs 3.154 to 3.167 above, the Secretary of State has certain powers to monitor and intervene in drug pricing in specific circumstances, set out in sections 261 to 266 of the NHS Act and arrangements entered into with industry pursuant to the NHS Act. These powers are relevant to the assessment of countervailing buyer power, because they are exercisable by the Secretary of State, who would be acting to the benefit of the ultimate purchaser of Liothyronine Tablets (i.e. the NHS). The Secretary of State's role is discharged through the DHSC, and so this section will refer to the DHSC.

4.170 Advanz argues that '*At all times the DH/NHS held countervailing buyer power in its capacity as a monopsonist and a price regulator. It enjoyed extensive statutory and non-statutory competences to intervene on price and to take punitive action, the ability to leverage its statutory powers to obtain a price reduction without actually exercising them, and the power to ask Parliament to introduce legislative change to control price*'.[613] HgCapital also argues that '*the DH/NHS being the monopsony purchaser with statutory price control powers – had enormous countervailing buyer power at its disposal*'.[614] Cinven argues that '*the NHS had countervailing buyer power and the DoH had the ability to regulate the price of Liothyronine Tablets during the Relevant Period*'.[615]

4.171 For the reasons set out below, the CMA rejects these arguments. The CMA concludes that these powers – or the prospect of the DHSC using them, whether 'formally' or 'informally' – did not confer countervailing buyer power on the DHSC.

4.172 First, as explained in section 4.C.I above, the CAT, the Court of Appeal, the European Commission and the European Courts have consistently held, in

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[612] The CMA therefore rejects the Cinven Entities' argument that CCGs' and other NHS bodies' efforts to '*assess the cost effectiveness of medicines as part of exercising their functions*' demonstrates that the NHS had a choice in continuing to fund Liothyronine Tablets (document LIO6330, Cinven RSO, paragraphs 5.84-5.99); and Advanz's arguments that the ability of the NHS to initiate a consultation and make recommendations as a result amounts to the exercise of countervailing buyer power (document LIO6288, Advanz RSO, paragraphs 2.131-2.136).
[613] Document LIO7781, Advanz RSSO-2019, paragraph 1.6.5. See also document LIO6288, Advanz RSO, Schedule 2.
[614] Document LIO6258, HgCapital RSO, paragraph 164. See also paragraphs 165, 180 and 183.
[615] Document LIO6330, Cinven RSO, paragraph 5.3. See also paragraphs 2.4, 5.79, 5.90 and 5.102.

the pharmaceutical sector and in other sectors, that the prospect of 'regulatory' intervention does not negate the possibility of dominance.[616]

4.173 As a matter of principle, therefore, an argument that Advanz 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 and pricing behaviour. In refusing Pfizer permission to appeal the CAT's findings on dominance in *Phenytoin*, the Court of Appeal confirmed 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"*'.[617]

4.174 Secondly, as explained in section 4.C.I 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*',[618] 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*'.[619]

4.175 For example, 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,[620] '*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.[621]

4.176 The Parties do not suggest that the DHSC intervened in relation to Liothyronine Tablets during the Infringement Period, using its statutory powers

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[616] See, for example, *Hutchison 3G (UK) v Ofcom* [2005] CAT 39, paragraphs 98 to 99 and 138(b); *Hutchison 3G UK Limited v Ofcom* [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* [2009] CAT 14, paragraph 80; *Napp Pharmaceutical Holdings Limited v DGFT* [2002] CAT], paragraphs 153 to 155 and 165 to 168. Compare Case AT.39612 *Perindopril (Servier)*, footnote 3356 and the case cited. See also *Deutsche Telekom*, C-280/08P, EU:C:2010:603, paragraphs 84 and 92.
[617] Document PAD172, *Flynn Pharma Limited & Ors v CMA*, Order made by the Rt. Hon. Lord Justice Newey, dated 17 December 2018.
[618] *National Grid* [2009] CAT 14, paragraph 60.
[619] *Hutchison 3G (UK) v Ofcom* [2005] CAT 39, paragraphs 105(i), 110(c) and 126.
[620] The CAT expressly held that '*We agree with the CMA*' in relation to the relevance of the DHSC's powers: *Phenytoin CAT* [2018] CAT 11, paragraph 207.
[621] Document PAD172, *Flynn Pharma Limited & Ors v CMA*, Order made by the Rt. Hon. Lord Justice Newey dated 17 December 2018. See also *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 192 and 217; and *Phenytoin CAT* [2018] CAT 11, paragraphs 203 and 207.

or otherwise. The CMA assesses the scope of the DHSC's powers in Annex 5. Whatever their precise scope, the DHSC's powers would only undermine a finding of dominance if it could be shown that Advanz was in practice effectively constrained by the prospect of such intervention.[622]

4.177 Advanz's pricing behaviour in itself demonstrates that the prospect of regulatory 'intervention' by the DHSC did not effectively constrain its market power. 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 Advanz's pricing.[623]

4.178 There is some documentary evidence that Advanz apprehended, in a general sense, the possibility of DHSC 'intervention' in the price of Liothyronine Tablets. For example:

(a) When proposing price increases for products to meet a gap in performance versus AMCo's 2013 budget, AMCo staff noted: '*I have not proposed big price increases, wherever I had a fear that this may attract DH notice or other companies, may like to launch those products*'. Although Liothyronine Tablets were initially included as a candidate for price increases (categorised as '*Low*' risk),[624] staff later suggested substituting other drugs since '*Liothyronine may catch eyes of competitions* [sic]*, since its already a £7m+ product. Similarly Liothyronine may also catch eyes of DH, due to price increase*'.[625]

(b) A due diligence report prepared by Deloitte in relation to Cinven's acquisition of the Mercury Pharma group noted that: '*As Glacier [the code name for the group] is the exclusive or semi-exclusive supplier for much of this portfolio [generic drugs], price increases are possible, although the threat of a new generic competitor or intervention from DH means price increases need to be managed carefully*'.[626]

(c) In March 2015, Advanz staff noted that Liothyronine Tablets would soon be moving to Category C and commented that this change meant that '*Any big increase could be viewed seriously by DH and question us and we cant* [sic] *pass on the same to wholesaler. DH may also keep an eye on Pharma industry's de-branding strategy for price increases*'. Advanz staff described this '*Flip side*' of the switch to Category C as '*just some of the remote*

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[622] Compare the Court of Justice's finding in *Deutsche Telekom*, C-280/08P, EU:C:2010:603, paragraphs 80-85.
[623] Compare *Phenytoin CAT* [2018] CAT 11, paragraph 207.
[624] Document LIO0275, Email from [Advanz Commercial Servies Director] to [Advanz CEO] dated 27 May 2013.
[625] Document LIO0279, Email from [Advanz employee] to [Advanz Commercial Servies Director] dated 29 May 2013.
[626] Document LIO0771, Advanz's '*Project Glacier – final due diligence report (commercial) – Volume I (10 August 2012).pdf*', page 8.

thoughts which I have shared with you. Hope you will not view the flip side mentioned above is [sic] *a negative approach to price increase strategy*'.[627]

(d) When discussing the projected impact of the Costs Act, Advanz stated that: '*The Bill extended its focus on what it calls "High Priced Unbranded Medicines" where "Competition Fails". The Bill when passed would allow the* [Secretary of State] *to intervene under these circumstances. These are powers that industry believed he had previously that have now just been clarified in the Bill.* [Advanz] *will see no impact on its business pre the Bill being passed next year*'.[628]

4.179 However, this general apprehension did not prevent Advanz from continuing to increase the price of Liothyronine Tablets as part of its '*price increase strategy*'.[629]

4.180 Though Advanz stated that the reform to the DHSC's powers (discussed at paragraphs 3.161 to 3.167 above) only '*clarified*' existing powers, it was clear that Advanz expected '*no impact on its business*' before the Costs Act came into force. In fact, there is extensive contemporaneous documentary evidence showing that Advanz did not consider that it was subject to any meaningful prospect of price control or countervailing buyer power, and that its business strategy was to exploit its freedom to increase prices. Price increases would simply have to be '*managed carefully*' to avoid the risk that this would '*catch eyes of DH*' or '*attract DH notice*'. Advanz's strategy was to remain '*below the radar*' of the DHSC:[630]

> *'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*'[631]

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[627] Document LIO7789.9, Email from [Advanz Commercial Servies Director] to [Advanz CEO] dated 31 March 2015.
[628] Document LIO3774, Advanz's '*Courtney Due Diligence*', page 1.
[629] Compare the CAT's observation that '*It may well be that both Pfizer and Flynn were under the belief that the DH had intervened to reduce the price of phenytoin tablets, by some process, and clearly considered that the DH might seek to negotiate the price of phenytoin capsules if it so wished, although it is less clear whether they thought, at the time, that the DH had legal powers directly to control the price. That does not in itself indicate that the DH constrained their conduct.*' (*Phenytoin CAT* [2018] CAT 11, paragraph 229).
[630] See, for example, document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', slides 11-16 and speaking notes; document LIO0217, Advanz's '*Glacier Management Presentation.pdf*', slide 9: non-PPRS products '*have free pricing. The vast majority of these non-PPRS products … have no or limited competition thereby allowing sustainable price increases*'; document LIO0242, Advanz's '*Project Ampule Rating Agency Presentation_20121108_v03.pdf*', slides 14 and 21; document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', pages 39 and 58; document LIO0823, Email from [Advanz General Counsel and Secretary] to [Advanz Commercial Services Director] dated 9 August 2016; document LIO0824, Email from [Advanz Commercial Servies Director] to [Advanz CEO] and [Advanz General Counsel and Secretary] dated 9 August 2016.
[631] Document LIO6490.3, *'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012'*, pages 3, 6 and 8.

4.181 For example, while the due diligence presentation for the Mercury Pharma acquisition in August 2012 stated that '*price increases are possible, although the threat of […] intervention from DH means price increases need to be managed carefully*',[632] just a month later, speaking notes for [✂] (then Advanz CEO) state '*[o]n-patent drug cost control will be focus for DoH with limited resources […] on an individual drug basis where there in* [sic] *no/little competition allows drug producers to increase prices and margin – this is the key element for Mercury with its niche portfolio*'.[633] Similarly, while an email from May 2013 shows an Advanz employee expressing concerns to his manager that '*Liothyronine may also catch eyes of DH, due to price increase*',[634] this did not prevent Advanz from implementing a 23% price increase directly thereafter, from £48.28 to £59.49 per pack in July 2013, and a further 45% price increase three months after that, from £62.42 to £90.23.[635]

4.182 Further evidence on this point is discussed in section 5.B (*Advanz's business strategy*) below and Annex 6.2 (*'The Unfair Limb: Economic value – willingness to pay'*).

iv. Conclusion on countervailing buyer power

4.183 The CMA concludes that Advanz was not effectively constrained by countervailing buyer power on the part of its customers. In particular, any concerns Advanz may have had about the prospect of DHSC '*intervention*' in the price of Liothyronine Tablets did not represent a meaningful constraint on Advanz's pricing behaviour in practice, as is illustrated by its price increases. Rather, Advanz relied on its ability to exploit the freedom of pricing in the generics sector in order to achieve its core strategy.

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[632] Document LIO0771, Advanz's '*Project Glacier – final due diligence report (commercial) – Volume I (10 August 2012).pdf*', page 8.
[633] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', slide 15.
[634] Document LIO0279, Email from [Advanz employee] to [Advanz Commercial Servies Director] dated 29 May 2013.
[635] The CMA therefore rejects Cinven's argument that the contemporaneous documentary evidence shows that Advanz was subject to a meaningful constraint from its understanding of the DHSC's ability to intervene in its prices (document LIO6330, Cinven RSO, paragraphs 5.119-5.125). In any event, as explained above, the focus must be on Advanz's conduct in practice, which shows no meaningful constraint.

5. Abuse

A. Summary

5.1 The CMA concludes that Advanz abused its dominant position in the market for Liothyronine Tablets in the UK by imposing unfair selling prices during the Infringement Period (i.e. from at least 1 January 2009 to 31 July 2017), when prices were between £20.48 and £247.87 per pack.

5.2 In particular, in accordance with the legal test set out in the Court of Justice's judgment in *United Brands*,[636] the CMA finds that such prices were excessive and unfair and bore no reasonable relation to the economic value of Liothyronine Tablets.

5.3 This chapter is structured as follows:

(a) Section B explains the factual and commercial context for Advanz's abusive conduct.

(b) Section C sets out the relevant legal framework relating to excessive and unfair pricing.

(c) Section D sets out the CMA's assessment of Advanz's prices by reference to the first limb of the *United Brands* test (the '**Excessive Limb**'), concluding that the prices were excessive.

(d) Section E sets out the CMA's assessment of Advanz's prices by reference to the second limb of the *United Brands* test (the '**Unfair Limb**'), concluding that the prices were unfair.

(e) Section F sets out the CMA's conclusion that there was no objective justification for Advanz's pricing conduct.

(f) Section G sets out the CMA's conclusion that no exclusions applied to the Infringement and that the Infringement was capable of affecting trade within the UK.

[636] *United Brands*, 27/76, EU:C:1978:22, paragraphs 251–252.

B. Factual and commercial context of Advanz's abusive conduct

I. Summary

5.4 From 2007 and throughout the Infringement Period, Advanz developed and then implemented a strategy to exploit the absence of effective regulatory and competitive constraints on its market power in respect of Liothyronine Tablets in order to impose inflated selling prices on the NHS and patients. This strategy, which Advanz referred to as '*price optimisation*', was made possible by Advanz's market power, with the NHS and patients benefitting in no way. On the contrary, as a result of the strategy, many patients found that access to the medication they relied upon was threatened if not withdrawn entirely. Key documents evidencing Advanz's price optimisation strategy are included in Annex 8.[637]

5.5 Price optimisation, as devised by Advanz, relied on identifying drugs in the third phase of the drug lifecycle[638] with low volumes and high barriers to entry, meaning that competition was unlikely and prices were – contrary to the typical position for off-patent generic drugs – constrained only by the voluntary PPRS price control system and not by the usual competitive dynamics which off-patent drugs face (i.e. low barriers to entry and intense price competition). Advanz's strategy was then to withdraw these drugs from PPRS price controls and, once protected from competitive or regulatory constraint, to implement sustained and repeated price increases which in the case of Liothyronine Tablets lasted almost a decade. Advanz took advantage of a loophole in the existing regulatory scheme (under which the NHS relied on competition to keep prices low) and calculated that this loophole was unlikely to be closed.[639]

5.6 The strategy of price optimisation comprised four key stages:

(a) The acquisition or identification of products having characteristics suited to price optimisation, meaning products that were:

(i) In the PPRS (and so under pricing and profitability constraint at that time as a result of the PPRS price control).

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[637] The relevant pages of Annex 8 are identified in the footnotes using the format '**(A8/[page])**'.
[638] The first phase of the drug lifecycle involves research and development, the second phase concerns the recouping of the costs of development under exclusivity afforded by patents and other intellectual property rights. The third phase is genericisation when entry occurs and prices fall to reflect production costs. The three phases of the lifecycle are discussed at paragraphs 3.125ff above.
[639] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 8 (A8/47): '[✂].' The DHSC's policy was discussed at a meeting between the DHSC and the BGMA – it was recognised that overall the system provided cost savings and supply resilience, despite the existence of outliers: Document LIO0832, Note of meeting between the BGMA and DHSC dated 26 August 2016.

(ii) In the third stage of the drug lifecycle, but (crucially and unlike most off-patent generics) with no competition and strong barriers to entry (meaning that – once removed from the PPRS – the product would not be subject to any meaningful competitive constraints unlike typical off-patent generics).

(b) The removal of these products from PPRS price controls by de-branding.

(c) The implementation of sustained price increases.

(d) The reaping of strong margins,[640] with no or limited impact on costs or volumes.[641]

5.7 Price increases could be achieved without any risk, skill, or investment on the part of Advanz.

5.8 Advanz implemented this strategy in relation to Liothyronine Tablets over a period of almost 10 years from 2007 until entry by Morningside and Teva in 2017. During this time prices increased **6,021%** (from **£4.05** to **£247.87** per 28 tablets).

5.9 The strategy did nothing to benefit the NHS or patients: Advanz simply sold the same product at higher and higher prices to their detriment (in total 63 individual price increases were implemented). As a result, the NHS paid significantly more for Liothyronine Tablets than it would have absent the Infringement, reducing the money available for other healthcare services. Advanz's strategy also contributed to the NHS changing its prescribing guidance to restrict access to Liothyronine Tablets. This resulted in some patients being unable to access Liothyronine Tablets because the NHS would no longer prescribe them. Those patients suffered significant harm as a result, having to either obtain private prescriptions (at significant personal expense), source unlicensed liothyronine from overseas (and forego monitoring by their GP), or endure adverse effects on their health where they were not able to obtain Liothyronine Tablets.

5.10 Despite the obvious harm caused by its strategy, Advanz considered that it had a '*[s]uccessful business model*' driven by a strategy of '*price increases on products with limited competition and barriers to entry by new competitors*'.[642] The parent companies of Advanz – HgCapital and Cinven – were each aware of and played their part in implementing Advanz's strategy. Indeed, Advanz's

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[640] Document LIO0231, '*Project Glacier Lenders Presentation_NOTES.pdf*', page 26 (A8/81); document LIO3822, '*Project Navy Financial Due Diligence Report.pdf*', page 48.
[641] Document LIO3814, '*20150808 AMCo's Pricing Expertise.pptm*', pages 2-3 (A8/207-208).
[642] Document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 9.

strategy was an important factor in decisions made when the business was bought and sold.

5.11 Advanz's strategy evidences its intent to exploit its dominant position. While the CMA is not required to prove such intent on Advanz's part to establish that an abuse occurred, and although the existence of such intent is not sufficient in itself to establish an abuse,[643] the CMA regards Advanz's exploitative intent as highly relevant to its assessment of the facts in this case. Advanz's strategy is in particular relevant to the CMA's assessment under the first alternative of the Unfair Limb of the *United Brands* test (see paragraphs 5.257 to 5.259 below).

II. The four stages of Advanz's strategy

a. Stage 1: Identification of Liothyronine Tablets as being suitable for 'price optimisation'

i. Product within PPRS

5.12 In the early part of 2007, Advanz identified a potentially profitable loophole in the regulatory scheme for the pricing of pharmaceuticals in the UK and drew up a '*Branded Pharmaceuticals UK Business Plan*'. Advanz recognised that '*[t]he way in which the PPRS scheme works means that price increases cannot be made easily on branded products. In order to drive price increases there is a strategy to move to the generic name and increase prices*.' The business plan recognised that PPRS products (including Liothyronine Tablets specifically) '*can be moved from branded to generic resulting in their removal from the current PPRS scheme and hence from regulation. Prices on these products can be increased.*'[644]

ii. Product within third stage of drug lifecycle, with no competition and strong entry barriers

5.13 Candidate products for price optimisation needed to be in the third phase of the drug lifecycle (such that no significant R&D spend or risk would be incurred on Advanz's part), face limited or no competition, and benefit from strong barriers to entry. Liothyronine Tablets were identified as possessing such characteristics at the outset in 2007.[645]

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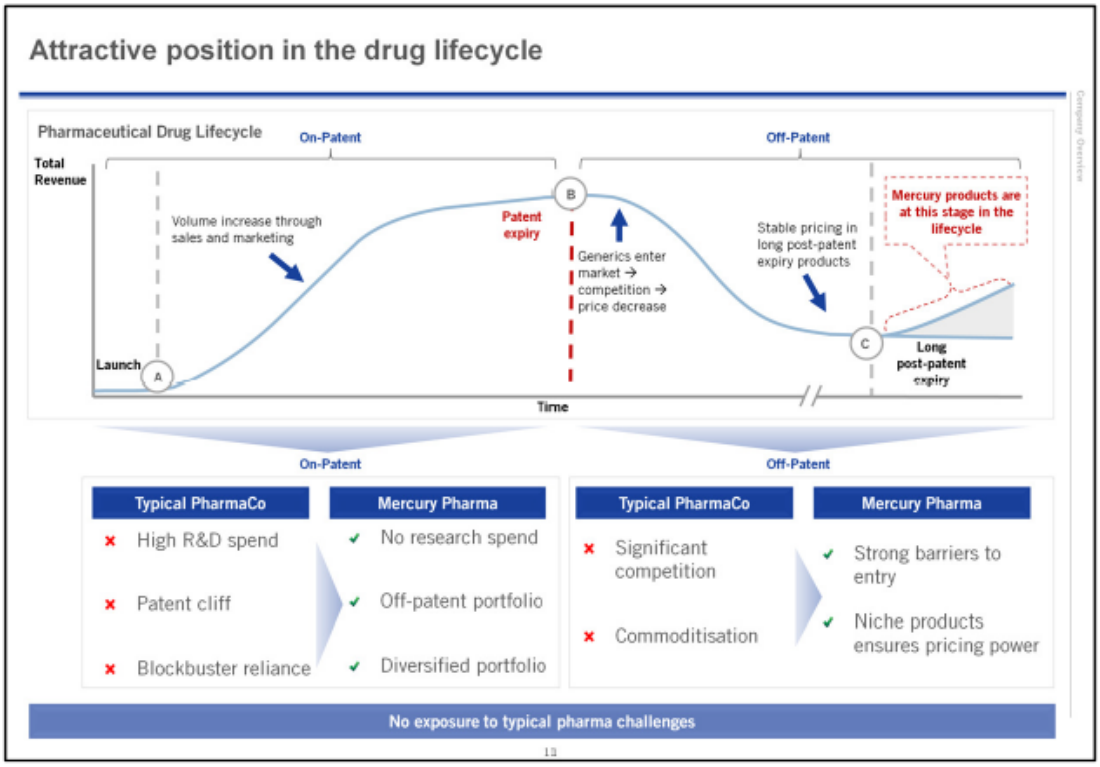
[643] See case law cited at paragraph 5.47 below.
[644] Document LIO0010, Advanz's 'UK Retail Brands Business Plan', page 3 (A8/4). See also Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', page 17 (A8/72).
[645] Document LIO0010, Advanz's 'UK Retail Brands Business Plan', page 3 (A8/4).

5.14 Advanz understood that the UK regulatory regime for pharmaceuticals was premised on the assumption that generic drugs in the third phase of their lifecycle (i.e. those drugs which were long off-patent – see paragraph 3.128 above) would typically be commoditised and face significant competition, such that price regulation was unnecessary. As the company's then CEO, [✂], explained to investors in 2012 immediately following Cinven's acquisition of the business from HgCapital, the UK's regime was focussed on controlling the cost of expensive 'on-patent' drugs. The regime was designed to maximise the limited resources available to the DHSC in establishing and administering regulatory controls over costs, and accordingly to manage the cost of off-patent drugs through encouraging competition. This system worked '*on an aggregate basis*' but on a drug-specific basis the system would not function to prevent drug producers from increasing their prices and margins. Moreover, Advanz calculated that it was unlikely that there would be any reform of the regulatory regime since the regime was – on aggregate – successful at controlling drug prices.[646]

5.15 In the same 2012 investor presentation, [Advanz CEO] set out Advanz's strategy in the context of this pricing regime. Advanz would continue to focus on certain unbranded 'niche' pharmaceutical products which did not follow the typical lifecycle because they were '*insulated*' from competition and other key risks. Little or no competition meant that Advanz benefitted from '*pricing/margin power*' and '*[s]trong entry barriers mean [the] position [is] sustainable*'. Figure 5.1 is an extract from an internal Advanz slide pack and the speaking notes below it show how Advanz expected its strategy to enable it to increase prices for its niche products above the levels that would typically be expected for old, off-patent drugs. Figure 5.2 sets out [Advanz CEO]'s speaking notes explaining that the UK regulatory regime would not constrain Advanz's price increases.

[646] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', page 16 (A8/71).

Figure 5.1: Diagram showing Advanz's strategy to focus on niche off-patent drugs



- Attractive position - niche off-patent products insulated from key pharma risks
  - No R&D spend or patent cliff
  - Little/no competition - pricing/margin power
  - Strong entry barriers mean position sustainable

Source: Advanz's presentation to investors.[647]

[647] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', page 12 (A8/67). In the speaking notes below the slide [✂] is a reference to [Advanz CEO].

Figure 5.2: Speaking notes setting out Advanz's strategy to exploit absence of regulation of niche off-patent drugs

- UK market well-penetrated by off-patent drugs, however disproportionate spend on on-patent drugs
- On-patent drug cost control will be focus for DoH with limited resources
- Off-patent drugs managed through encouraging competition

- Strong, established culture of prescribing un-branded (INN) drugs in the UK (medical school training, NHS culture etc.)
- NHS mechanism based upon encouraging competition to drive down drug prices
- System works on an aggregate basis (UK drug spend proportionately lower than most develop countries) and therefore no need/incentive to change
- However on an individual drug basis where there in no/little competition allows drug producers to increase prices and margin – this is the key element for Mercury with its niche portfolio

Source: Speaking note for Advanz's presentation to investors.[648]

5.16 In order to implement its strategy, Advanz acquired or identified products within its UK portfolio that were branded, had '*exclusive / semi-exclusive market positions*' (i.e. faced limited or no competition) and had '*limited sales potential*', meaning that it was '*harder for other suppliers to find it economically viable to enter the market*'.[649]

5.17 Advanz also viewed its acquisition of competing businesses by reference to the strategy. A presentation relating to Advanz's acquisition of Focus in 2014 identified seven products being acquired where Advanz '*believes there is no competition, no substitute and a high complexity in manufacturing. These products are unbranded generics and therefore there is no regulatory restriction to raising prices in the short term and no PPRS impact*'. Advanz calculated that it could achieve £3.6 million of price increases in respect of these products.[650]

5.18 Candidate products were also typically in the '*final stage of the product lifecycle*', with stable volumes and prices which were significantly below the original patented brand drug price.[651] Many were '*specialist*' products assessed by Advanz as '*less likely to be switched once prescribed*' due to the

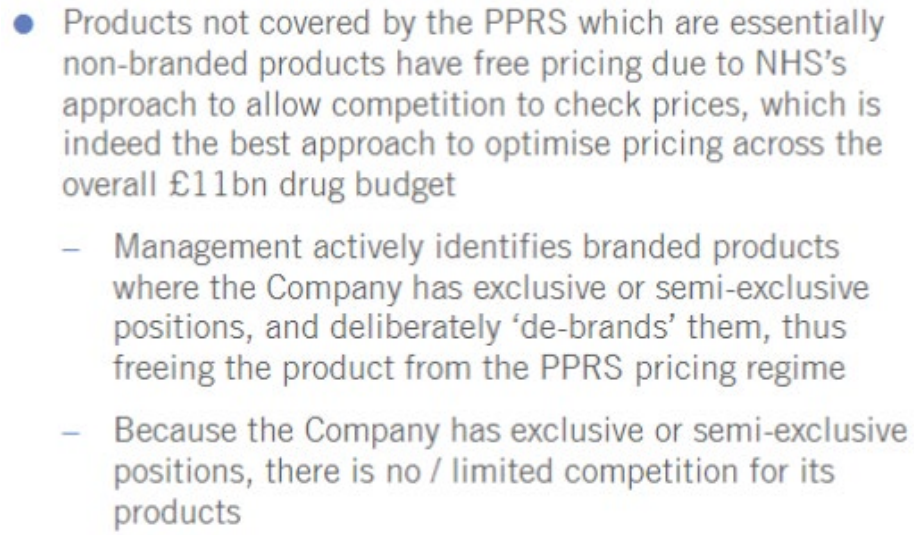
[648] Document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', page 16 (A8/71).
[649] Document LIO0242, Advanz's '*Project Ampule Rating Agency Presentation_20121108_v03.pdf*', slides 19, 21 and 27 (A8/128, 131 and 133).
[650] Document LIO0455, '*AMCo Sep14 - RAP_Final.pdf*', page 6 (A8/167).
[651] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum_vF.docx*', pages 40-41, 50 (A8/97-98 and 100); document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', page 55; document LIO0768, '*Project Armour CIM_v45.pdf*', page 46 (A8/173).

'*more complex nature of treatment*'.[652] The products often maintained a '*strong competitive position*' due to '*high technical barriers and regulatory complexity*'.[653] [✂].[654]

b. *Stage 2: Removal of Liothyronine Tablets from price controls by de-branding*

5.19 Products identified by Advanz as suitable for price optimisation were removed from the PPRS by de-branding.[655] The strategy continued following the replacement by HgCapital of Goldshield's management with new management led by a new chief executive, [✂],[656] and subsequently during Cinven's ownership of the business.[657] Figure 5.3, an extract of a presentation to ratings agencies from November 2012, sets out Advanz's reasoning for its de-branding strategy.

Figure 5.3: Extract of presentation explaining Advanz's systematic application of its de-branding strategy.



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[652] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum_vF.docx*', page 15 (A8/88); see also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 30 (A8/37), describing Liothyronine Tablets as a '*well-established medication*' with a '*niche indication*' and '*strong prescription history*'; document LIO0228, '*2012.08.24 Project Glacier Rating Agency Presentation.pdf*', page 29 (A8/62).
[653] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', pages 4 and 28 (A8/181 and 187); see also document LIO0740, '*Mercury Pharma Confidential Information Memorandum_vF.docx*', page 54 (A8/104); document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', pages 66-67 (A8/153-154); document LIO0768, '*Project Armour CIM_v45.pdf*', pages 55-56 (A8/175-176);.
[654] Document LIO0242, Advanz's '*Project Ampule Rating Agency Presentation_20121108_v03.pdf*', slide 32 (A8/135) (emphasis in original).
[655] Document LIO0010, '*UK Retail Brands Business Plan.doc*', page 3 (A8/4); see also document LIO0005, '*UK Monthly Report November 06.doc*', page 6.
[656] Document LIO0308, '*Project Glacier - 798108 - Final Report - 210512 (IMS).pdf*', pages 4 and 44 (A8/21 and 25).
[657] Document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', page 23 (A8/143).

Source: Presentation to Rating Agency, November 2012.[658]

c. Stage 3: Price increases

i. Gradual ratcheting up of prices to avoid regulatory scrutiny

5.20 Following de-branding, Advanz began to impose a series of significant price increases on candidate products, including Liothyronine Tablets. As set out in detail in Section 5.B.IV below, the price for Liothyronine Tablets rose more than 6,000% between its de-branding in 2007 and the end of Advanz's monopoly in 2017.

5.21 Rather than impose this increase overnight and draw immediate attention to its actions, Advanz steadily ratcheted up the price of Liothyronine Tablets over a number of years. This approach of gradual price increases was intended to avoid attracting scrutiny from the DHSC.

(a) In an email dated 27 May 2013, [Advanz Commercial Servies Director] explained to [Advanz CEO] that '*I have not proposed big price increases, wherever I had a fear this may attract DH notice or other companies may like to launch those products.*'[659]

(b) Similarly, an internal email between Advanz's staff dated 29 May 2013 warned: '*Liothyronine may also catch eyes of DH, due to price increase.*'[660]

5.22 Following discussions with HgCapital and Advanz management (including [Advanz CEO]), Cinven's internal recommendation to its investment committee summarised this aspect of Advanz's strategy:

(a) The DHSC's attention was not on the niche drugs in which Advanz specialised: '*[t]he focus [of the DHSC] 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*' (CMA's emphasis).[661]

(b) [✂].[662]

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[658] Document LIO0242, Advanz's '*Project Ampule Rating Agency Presentation_20121108_v03.pdf*', slide 27 (A8/133).
[659] Document LIO0275, Emails from [Advanz Commercial Servies Director] to [Advanz CEO] dated 27 May 2013.
[660] Document LIO0279, Email from [Advanz employee] to [Advanz Commercial Servies Director] dated 29 May 2013. See also document LIO0288, '*Price increase scenarios 30May 2013.xlsx*'.
[661] Document LIO6490.3, Cinven's *'Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012'*, page 8 (A8/47). See also the discussion in document LIO6537.23, Email from [Cinven Partner] to IC Members dated 30 July 2012.
[662] Document LIO6490.3, Cinven's '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', pages 3 and 8 (A8/42 and 47).

ii. Price increases driven by Advanz's market power

5.23 The sustained price increases were recognised by Advanz as being made possible through the lack of regulatory constraint, high demand inelasticity and high barriers to entry.[663] The evidence shows that Advanz developed a systematic approach to exploit circumstances in which '*competitive forces may not work to suppress prices*'.[664]

5.24 From its acquisition of Tertroxin in 1992 until the end of the Infringement Period, Advanz was the sole supplier of Liothyronine Tablets in the UK. Advanz was aware of its market strength and used it to raise prices.

(a) In a budget preparation document dated March 2011 emailed to [Advanz CEO], Liothyronine Tablets were listed as one of the products for which '*[p]rices have been increased on sole supply products which have been taken out of the PPRS scheme*'.[665]

(b) A memorandum to investors dated September 2012 explained that '*Mercury Pharma has a strong market position as the only supplier of Liothyronine tablets in the UK market* […] *Through its position as sole market provider in the UK, Mercury Pharma has strong pricing power. Over the last 3 years, Mercury Pharma has doubled the price of Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases, with volumes growing from FY2010 to FY2012 at a CAGR of 2%*'.[666]

(c) In a draft question and answer pack prepared for investors dated 12 November 2015, a slide on Liothyronine Tablets stated: '*No direct competitor* […] *Non-branded, therefore free pricing* […] *Volumes have been stable historically, with consistent price increases achieved*'.[667]

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[663] See Section 4.B.III.a.ii. above.
[664] Document LIO6490.3, Cinven's '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 6 (A8/45); document LIO0305, '*Project Glacier*', internal page 62 / pdf page 67 (A8/31), refers to Advanz's 'value maximising strategy' with regard to Liothyronine Tablets based on '*Strong pricing power as [Advanz] is the sole market provider in the UK*'.
[665] Document LIO0112, '*Budget 2011-2012_15_03_2011_version 2.docx*', page 5; attached to document LIO0111, Email from [Advanz employee] to [Advanz CEO] dated 18 March 2011.
[666] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62 (A8/112); see also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 30 (A8/37), and document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf*', page 47 (A8/160).
[667] Document LIO0601, '*Investor Q&A info pack - DRAFT 12Nov2015.pptx*', page 14 (A8/213).

d. Stage 4: Reaping strong margins, with no or limited impact on costs or volumes

5.25 The fourth stage of Advanz's strategy was to strengthen product margins. According to a financial due diligence report produced by EY, Advanz's '*[c]ontribution margin benefits from the continuous price increases*'.[668]

5.26 Advanz's internal and external documents demonstrate its assessment that '*genericisation, Pack size & Price increase* [sic]' could contribute significantly to its margins without significant increased costs or reduced volumes:[669]

(a) A presentation to investors in November 2012 stated that '*[b]etween FY 2010-12 […] stable historical volume growth reflects the market's acceptance of price increases*'.[670]

(b) A ratings agency presentation in September 2014 stated, under the heading of '*price optimisation*', that there were '*[c]ontinued price increases y-o-y [year-on-year] (not just one-offs). Below is the example of Liothyronine where volumes have remained stable over past 5 years while we were able to take four annual price increases*'.[671]

(c) Advanz explained to investors in December 2014 how through the application of its pricing strategy to Liothyronine Tablets, it had successfully '*leveraged the favourable market dynamics*' to deliver continued year-on-year price increases '*with stable volumes*' as set out in Figure 5.4 below.

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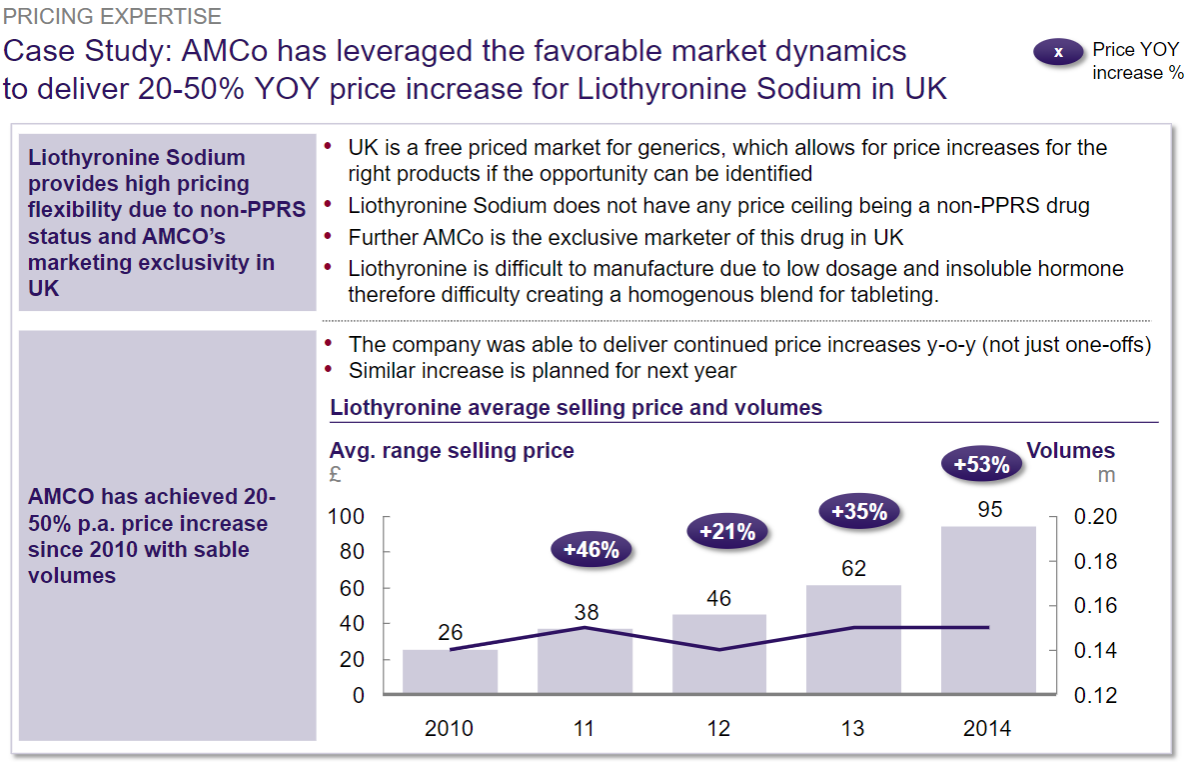
[668] Document LIO3822, '*Project Navy Financial Due Diligence Report.pdf*', page 48; see also document LIO0177, '*Project Glacier- Kick off - 130312_v2.pdf*', pages 13-14 (A8/15-16).
[669] Document LIO0029, '*Achieve 2 Million in Gross Margin in 2008-09 - 3 Price Changes.xls*', sheets 'Change of Price Summary', 'SUMMARY' and 'Liothyronine', attached to document LIO0028, Email from [Advanz employee] to [Goldshield Head of pharmaceuticals UK] dated 18 January 2008; see also document LIO0043, '*Proposed - Price Increase Model 2009-10.xls*', sheets '*VALUE SUMMARY*', and '*Liothyronine*', attached to document LIO0042, Email from [Goldshield Head of marketing brands and generics India] to [Goldshield Founder and Group Board Director] dated 28 November 2008; document LIO0180, Email from [Advanz CEO] to [Advanz Chief Strategy Officer], [Advanz Finance Director] and [Advanz Finance Director], dated 15 March 2012, stating that Liothyronine Tablets are '*easy for them [IMS Consulting Group] to forecast' as '[t]hey just need to apply some price increases to them*'.
[670] Document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf.pdf*', page 47 (A8/160).
[671] Document LIO0455, '*AMCo Sep14 - RAP_Final.pdf*', page 32 (A8/169). See also document LIO0794, '*20150802 Atoll Management Presentation vDRAFT.pdf*', page 24 (A8/204); and document LIO3087, '*Annex 18 - Amdipharm Mercury Management Presentation dated August 2015.PDF*', page 21.

Figure 5.4: Slide showing how Advanz applied its strategy in relation to Liothyronine Tablets



Source: Advanz's internal presentation, December 2014.[672]

(d) In 2015, an internal presentation prepared for inclusion in a management summary explained, again in the context of Liothyronine Tablets: '*Price increased, historical trends indicate there will be no impact on volumes, as no alternative product*'.[673]

(e) A 2016 email from [✂] (then Managing Director for Advanz's International Segment) responding to a query regarding a newspaper article which highlighted price increases for Liothyronine Tablets stated: '*Business as usual. We have seen a very small volume decline over the last 18 mths but it is very small (1-2%). So we characterise the market and volumes as flat!*'[674]

5.27 Advanz did not face effective competitive pressure in relation to its pricing of Liothyronine Tablets. As the company's internal documents show, although Advanz anticipated that entry by competitors would ultimately be triggered by its strategy and erode its prices, profits and market share (see paragraph 4.44

[672] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 58 (A8/197).
[673] Document LIO0542, '*20150722 Atoll MP Shell_JEFF_v14.pptx*' (A8/199), attached to document LIO0541, Email from [Advanz Director of Strategic Finance] to [Advanz Chief Financial Officer] dated 27 June 2015.
[674] Document LIO0687, Email from [Advanz Global Marketing Director] to [Vice President of Investor Relations and Communications, Advanz] dated 6 June 2016.

above), it nonetheless continued with its price increases, maximising short and medium term profit and causing significant immediate patient harm.

5.28 The potential for Advanz to face additional constraints from possible entrants during the Infringement Period was reduced as a result of its acquisition of Focus and Primegen, which were in the process of developing Liothyronine Tablet products at the time of their acquisition (see paragraphs 3.182 to 3.187 above).

5.29 While there is some limited evidence that Advanz apprehended, in a general sense, the possibility of DHSC intervention in the price of Liothyronine Tablets, there is extensive contemporaneous documentary evidence showing that Advanz did not consider that it was subject to any meaningful prospect of price control or countervailing buyer power, and that its strategy was to exploit this freedom to increase prices (see section 4.C.IV.b above and Annex 5).

III. Role of HgCapital and Cinven in Advanz's strategy

5.30 Advanz's private equity owners, HgCapital and Cinven, both understood and built on the commercial rationale of increasing prices where possible due, for example, to the '*inelasticity of demand*'[675] and the fact there was either '*no direct competitor*'[676] or that '*competitive forces may not work to suppress prices*'.[677] HgCapital was aware of Advanz's strategy for unbranded niche generics when it purchased the business in 2009 and drew attention to the strategy in its sales materials to Cinven.[678] Indeed, the price optimisation strategy was an important factor in Cinven's decision to invest in the business and one that Cinven intended to replicate with Amdipharm when it merged it with the Mercury Pharma group:

(a) The niche nature of Liothyronine Tablets was highlighted in an information memorandum prepared on behalf of the Mercury Pharma group and signed by [✂] (then CEO) and [✂] (then Chairman)[679] in September 2012 for the purposes of raising additional finance directly following the acquisition of the Mercury Pharma group by Cinven. The memorandum explained that '*Mercury Pharma has a strong market position as the only supplier of Liothyronine*

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[675] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62 (A8/112).
[676] Document LIO0601, '*Investor Q&A info pack - DRAFT 12Nov2015.pptx*', page 14 (A8/213).
[677] Document LIO6490.3, Cinven's '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 6 (A8/45).
[678] Document LIO0733, Hg's '*20090814 Trojan Final Commercial DD Report 1600 SENT.PDF*', a due diligence report prepared prior to the purchase notes at slide 21 that '*Trojan's [i.e. the Advanz business] success is based on identifying market niches with limited or no competition and leveraging favourable pricing regulation mechanisms in the UK.*') (A8/8), see also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', slides 13 and 30 (A8/35 and 37) which was prepared prior to the sale of the business to Cinven.
[679] The information memorandum was prepared on behalf of CCM Pharma UK Limited (subsequently renamed Amdipharm Mercury UK Limited), which was at the time the parent company of Mercury Pharma Group Limited: document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', pages 2 and 25.

tablets in the UK market […] Through its position as sole market provider in the UK, Mercury Pharma has strong pricing power. Over the last 3 years, Mercury Pharma has doubled the price of Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases, with volumes growing from FY2010 to FY2012 at a CAGR of 2%'.[680] The niche nature of Liothyronine Tablets was also noted in documentation prepared on behalf of the Mercury Pharma group immediately prior to its sale by HgCapital to Cinven. For example, a management presentation prepared for the purpose of providing information to potential purchasers in July 2012 described Liothyronine Tablets as a '*well-established medication*' with a '*niche indication*' and '*strong prescription history*'.[681]

(b) The final recommendation for Cinven to acquire the Mercury Pharma and Amdipharm groups explained that the investment rationale for the acquisition and combination of the Mercury Pharma and Amdipharm groups was to:

> 'Drive growth in the 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'.[682]

(c) That '*low risk value lever*' was the potential to exploit the free pricing regime for unbranded generic drugs in the UK by increasing the price of generic drugs, where Amdipharm faced little or no competition. As an earlier Cinven Partners investment recommendation explained:

> '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, <u>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</u>'.[683]

(d) This was a model that Mercury Pharma had already followed for some time. It was considered '*low risk*' because the markets for such niche generics were thought to fly under the radar of authorities (as Cinven's 2014 annual review

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[680] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62 (A8/112). See also document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf*', page 47 (A8/160).
[681] Document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 30 (A8/37).
[682] Document LIO6491.1, Cinven's '*Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012*', page 5 (A8/54).
[683] Document LIO6490.3, Cinven's '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 6 (A8/45) (emphasis added).

noted: '*Cinven identified niche generics as an attractive sub-sector for investment and international consolidation. In addition, the lower risk profile of older, low volume products make them less exposed to reimbursement pressures*'[684]). The final recommendation explained that:

> 'Amdipharm has not actively managed its portfolio in the UK in the way that Mercury has – for example, the majority of Amdipharm's products are still in PPRS rather than being sold as unbranded generics under free-pricing'.[685]

5.31 The business plan for Amdipharm was therefore to pursue:

> 'Price optimisation: de-branding products in strong market positions to optimise pricing (Amdipharm have taken a longer term view of price increases in the past, so this lever had a lot of stored potential […] It should be noted that this is the same strategy that [Advanz CEO] and the team have successfully executed at Mercury'.[686]

5.32 When the Cinven investment was announced, press coverage noted:

> '*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 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* [✂] *dubbed "little jewellery boxes", can still attract strong sales'*.[687]

IV. Implementation of Advanz's strategy: Advanz's prices

5.33 Advanz implemented its strategy of price increases over a period of 10 years from autumn 2007 until entry by Morningside and Teva in 2017. During this time prices increased 6,021% (from £4.05 to £247.87 per 28 tablets).

5.34 Immediately prior to the de-branding of Tertroxin in October 2007, the ASP for the drug was the equivalent of £4.05 per 28 tablet pack[688] and it was

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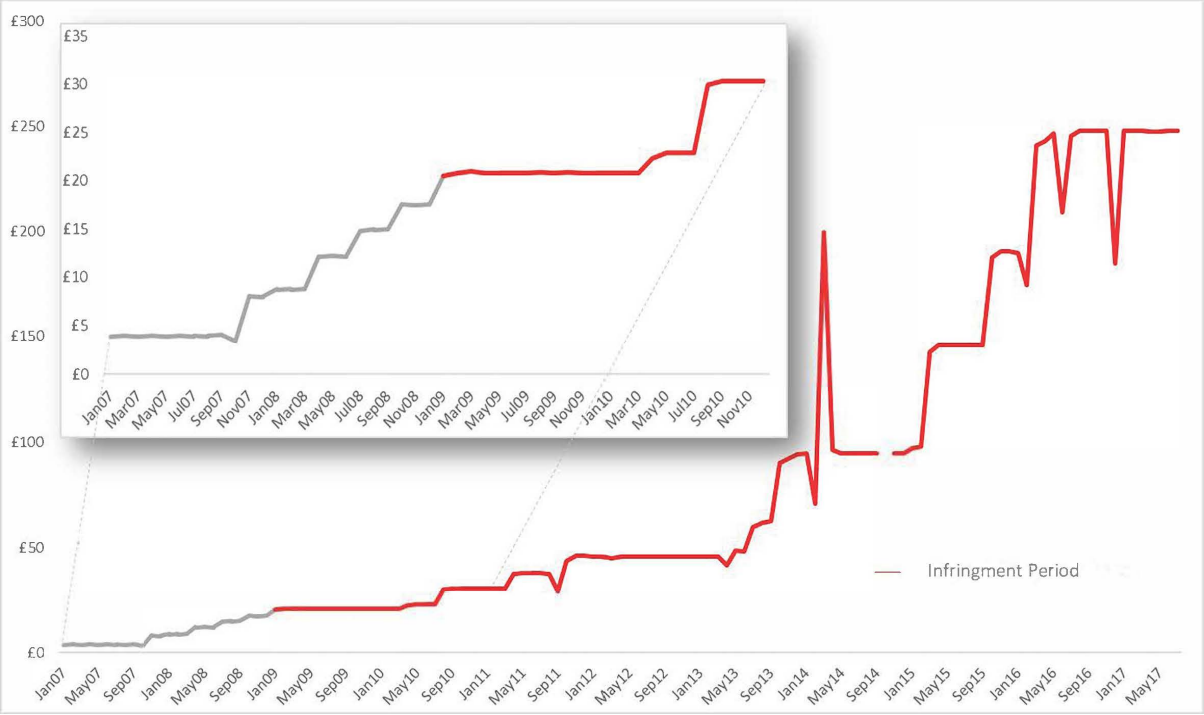
[684] Document PAD156, Cinven: '*Annual Review 2014*', page 78.
[685] Document LIO6491.1, Cinven's '*Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012*', page 31 (A8/56).
[686] Document LIO6491.1, Cinven's '*Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012*', page 36 (A8/58) (emphasis in the original).
[687] Document PAD067, FT: '*Cinven accelerates into UK healthcare*', 15 October 2012 (A8/114).
[688] As noted at paragraph 3.22 above, Advanz reduced the number of tablets per pack from 100 to 28.

Advanz's seventh most profitable product[689] in its portfolio of 62 drugs.[690] Having de-branded the drug, in October 2007 Advanz reduced the pack size from 100 to 28 and immediately increased its ASP to £8.05 per pack, in effect nearly doubling the price. A series of 63 individual price increases followed, across a number of corporate changes and transfers of ownership, so that in July 2017 Advanz's ASP had reached £247.87 per pack, amounting to a total increase of 6,021% compared to the September 2007 price equivalent of £4.05 per 28 tablets, as illustrated in Figure 5.5 below. During the Infringement Period, Advanz's direct costs ranged between £0.35 per pack in 2009 to an average of £3.23 per pack in 2017.[691]

Figure 5.5: Liothyronine Tablet ASPs (January 2007 to July 2017)[692]



Source: CMA analysis.

V. Significant adverse impact of Advanz's strategy on the NHS and patients

5.35 The implementation of Advanz's strategy has had a significant adverse impact on the NHS and patients, both directly in terms of the availability of the medication they rely on and through the broader impact on the health service.

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[689] Document LIO0010, Advanz's '*UK Retail Brands Business Plan.doc*', page 2 (A8/3).
[690] Document LIO0044, '*Consolidated PPA Rx data for 2003-07*', 'Rx data 2007' tab.
[691] The ASP for 2017 was slightly lower than this high point, at £247.77 per pack.
[692] As set out at paragraph 3.190 above, the outliers to the trend relate to particularly large orders in certain months. Document LIO2988.3, Advanz's '*Annex 3 - Liothyronine Tablets sold*'.

a. Direct impact on patients

5.36 The price increases implemented by Advanz eventually led to public health bodies reviewing prescription practices with a view to limiting access to Liothyronine Tablets, and to many CCGs implementing local policies to limit access. As a result, prescription volumes started to fall a few per cent towards the end of the Infringement Period and patients who depended on Liothyronine Tablets began to have difficulties accessing them. These availability issues and direct patient impact have increased after the end of the Infringement Period, as prices continue to be significantly inflated by the Infringement.

i. Efforts to limit prescribing of Liothyronine Tablets

5.37 In 2014, by which point the price of Liothyronine Tablets had risen by over 2,200% to around £95, they were identified by an NHS body as a treatment that represented '*poor value for money'.* In 2015, they were added to an NHS 'DROP-List' to encourage prescribers to review patients' treatment with a view to switching them away from Liothyronine Tablets.[693] Despite this, Advanz implemented a further substantial price increase, bringing its ASP above £247 in early 2016. Advanz's strategy attracted adverse press publicity in an article in the *Times* dated 5 June 2016 under the headline '*Huge price rise forces NHS to ditch life-changing drug*'. The article reported on the negative impact on patients' quality of life resulting from the deprescribing of Liothyronine Tablets. Internal emails prompted by the article reveal that Advanz's concern was the potential for this change in guidance to impact on its sales, although it established this would not affect its profits. When [Advanz Global Marketing Director] was asked in an internal email *'what do you think is meant by NHS encouraged docs to stop prescribing lio? Is it biz as usual for us for this product, or is there likely a big impact?*', he answered: '*Business as usual. We have seen a very small volume decline over the last 18 mths but it is very small(1-2%). So we characterise the market and volumes as flat!'*[694]

5.38 The link between Advanz's excessive Liothyronine Tablet prices and the constraints of the NHS's budget was again highlighted by the NHSCC in its 2017 consultation on medicines of low priority for NHS funding (by which time the price of Liothyronine Tablets had risen by over 6,000% to £247.87). In that consultation, the NHSCC explained that the '*growing cost [of prescriptions]*

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[693] Document PAD021, PrescQIPP Bulletin 117, July 2015; £95 was the price of Liothyronine Tablets during the second half of 2014 – the price at which PrescQIPP found Liothyronine Tablets to represent poor value money is implied by its identification of an overall annual spend on Liothyronine Tablets of £14,305,142.
[694] Document LIO0687, Email from [Advanz Global Marketing Director] to [Vice President of Investor Relations and Communications, Advanz] dated 6 June 2016.

coupled with finite resources means it is important that the NHS achieves the greatest value from the money that it spends' and made clear that '*[a]ny savings from implementing the proposals [to withdraw funding for drugs including Liothyronine Tablets] will be reinvested in improving patient care*'.[695]

5.39 In response to the 2017 NHSCC consultation, CCGs linked the high prices of Liothyronine Tablets to financial pressures they were experiencing, which in turn led to a need to ration the availability of Liothyronine Tablets: '*CCGs have been actively pursuing a reduction in Liothyronine prescribing in recent months* […] *At a lower cost, there would be less need to pursue deprescribing of a medication that some patients feel very strongly have had a positive effect on their quality of life*'.[696] In the final NHSCC guidance which followed this consultation, the NHSCC departed from the proposals in the consultation following responses explaining that '*liothyronine is an effective treatment which is invaluable to patient wellbeing, quality of life and condition management*' to conclude that '*deprescribing in "all" patients is not appropriate as there are recognised exceptions*'.[697]

ii. Impact of reduced prescribing on patients

5.40 The revised prescribing guidance published by PrescQIPP and subsequently by the NHSCC has meant that some patients who had previously been prescribed Liothyronine Tablets have had their treatment withdrawn or (in the case of newly diagnosed patients) have not been able to obtain a prescription for Liothyronine Tablets. In some instances, this impact on patients occurred after the end of the Infringement Period. The varied responses of individual CCGs mean that patients in different parts of the country may experience different availability of Liothyronine Tablets.[698]

5.41 The Chief Executive of Thyroid UK (Linda Mynott), who herself suffers from hypothyroidism and was first prescribed Liothyronine Tablets in 1999, had the

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[695] Document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', page 4.
[696] Document LIO7789.15, NHSCC: 'It*ems which should not be routinely prescribed in primary care: Consultation Report of Findings*', page 29. See also document PAD215, British Thyroid Foundation and others: '*T3 Prescribing Survey Report*'.
[697] Document PAD127, NHSCC guidance, page 8 and section 4.9. As noted at paragraphs 3.76 to 3.79 above, the NHSCC categorised Liothyronine Tablets as being among '*Items which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation.*'
[698] Evidence submitted to Parliament and the *Lancet Diabetes & Endocrinology* journal indicates that Liothyronine Tablet prescribing rates have fallen most dramatically in areas where levels of deprivation are greatest. Document PAD126, '*Liothyronine – Case Details with Clear Evidence that NHS England Guidance on Prescription of Liothyronine is not Being Followed by CCGs – Evidence in Response to a Request from the Lord O'Shaugnessy*', 19 October 2018, page 4; document PAD169, Taylor, P N, Razvi, S, Muller, I, et al.: '*Liothyronine cost and prescriptions in England*', Lancet Diabetes Endocrinol 2019; 7: 11–12.; and document PAD170, Taylor, P N, Razvi, S, Muller, I, et al.: '*Supplementary appendix',* Lancet Diabetes Endocrinol 2019; 7: 11–12.

medication withdrawn in December 2017. Her pharmacist informed her that the decision to withdraw the drug was '*due to the surge in the price of liothyronine in recent years*'. As a result, she has had to purchase (unlicensed) liothyronine overseas without a prescription at a cost of around £185 per year. She has explained that '*[h]aving my treatment stopped has also meant that I cannot be monitored in the same way as previously, because my GP will not continue to see me where I self medicate*'.[699] She is also aware of more than 250 other patients who have contacted Thyroid UK because funding for their Liothyronine Tablets was withdrawn or because they could not get it prescribed.

(a) Some of those patients who have had their medication withdrawn have not been able to find an alternative source of Liothyronine Tablets and have found that their symptoms returned. These patients have suffered significant harm to their quality of life.[700]

(b) Some patients have been able to obtain a private prescription for (licensed) Liothyronine Tablets and get it fulfilled in the UK paying £200 to £300 for a month's supply in 2018.[701]

(c) Others (like Ms Mynott herself) have been able to source (unlicensed) liothyronine outside the UK[702] or have turned to unlicensed NDT. These patients have also suffered financial harm as the cost to the patient is significantly greater than the NHS prescription charge.[703]

5.42 The CMA has received correspondence from members of the public which reflects the evidence of Ms Mynott. For example:

(a) One patient told the CMA: '*I pay £30 for 100 x 20 mcg tablets of Liothyronine* [in Germany]. *The equivalent amount of product in the UK would cost approximately £900*'.[704]

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[699] Document LIO11979, Linda Mary Mynott's witness statement, paragraph 27.
[700] Document LIO11979, Linda Mary Mynott's witness statement, paragraphs 28 and 32–33.
[701] Document LIO11979, Linda Mary Mynott's witness statement, paragraph 31.
[702] See document LIO5535, Email from [name withheld] to Ronan Flanagan (CMA) dated 6 December 2017; document LIO7848, Email from [name withheld] to Paul Dean (CMA) dated 20 April 2019; document LIO5921, Email to the CMA from [name withheld]; document LIO5358, Email to the CMA from [name withheld]; document LIO7777, Letter from Julia Lopez MP (Hornchurch and Upminster) to Andrea Coscelli (CMA) dated 2 January 2019; document PAD178, UK Parliament: '*Motion to Regret moved by Lord Hunt of Kings Heath on 20 June 2018*', Volume 791, Column 2066 (text only); see also document LIO7789.12, NHS Brighton and Sussex University Hospitals: '*Information for patients currently treated with T3 (liothyronine)*'.
[703] By the end of the Infringement Period, the NHS prescription charge in England was £8.60.
[704] Document LIO5535, Email from [name withheld] dated 6 December 2017.

(b) Another patient has said: '*I have autoimmune problems and I am having to purchase meds and now I have to forkout on the state pension for the thyroid hormones t3*'.[705]

(c) A third patient has said: '*I* […] *have chosen to purchase my annual supply in France, for now. My annual cost of the drug equates what it would cost the NHS for just about one month!*'[706]

(d) The father of a patient told his MP that his daughter '*is faced with a monthly bill of approx. £600 to restore her life to a tolerable level.*'[707]

5.43 Case studies of the harm suffered by patients who have had Liothyronine Tablets withdrawn were submitted in evidence to Parliament in a 2018 report. In a debate in the House of Lords prior to submission of the report, Lord Hunt of Kings Heath observed that '[s]*ome clinicians are helping patients by giving them private prescriptions, but these are expensive. The Brighton and Sussex University Hospitals NHS Trust is informing patients that their only option is to obtain the drug privately.*' He referred to another patient *'who is looking for a price to purchase T3 privately. She contacted Pharmacy2U and asked for a price for 56 T3 tablets. From four suppliers, only one could supply and that price was £774. That was for 56 tablets, one a day.*'[708]

b. Cost to NHS and indirect impact on patients

5.44 The NHS budget is finite and legitimate demands for healthcare inevitably exceed available funding. Accordingly, financial resources need to be prioritised. During much of the Infringement Period, the NHS has sought to achieve significant savings.[709] In 2006, the last full year prior to the de-branding of Liothyronine Tablets, the NHS's annual spend on Liothyronine Tablets was approximately £604,000. By contrast, during the Infringement Period, the NHS's annual spend on Liothyronine Tablets increased year on year, and by 2016 it had reached over £30 million (see paragraph 5.365 below). In total, the CMA has calculated that the Infringement has resulted in the NHS spending *at least* £92,368,282 more than it would otherwise have spent (see paragraph 7.134 below).

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[705] Document LIO5921, Email to the CMA from [name withheld].
[706] Document LIO5358, Email to the CMA from [name withheld].
[707] Document LIO7777, Letter from Julia Lopez MP (Hornchurch & Upminster) to Andrea Coscelli dated 2 January 2019.
[708] Document PAD178, UK Parliament: *'Motion to Regret moved by Lord Hunt of Kings Heath on 20 June 2018'*, Volume 791, Column 2066 (text only), page 4.
[709] In this respect, 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. See document PAD074, NHS: '*Efficiency*', page 2.

5.45 As a result of the increased prices, CCGs have had to commit extra money to continue to fund the supply of Liothyronine Tablets to patients.[710] The former Chief Executive of the NHSCC (Julie Wood) has explained in detail to the CMA the cost implications of Advanz's prices for Liothyronine Tablets on CCG budgets:

> 'the financial impact of the significant price increases of liothyronine will have had effects on patient care, as CCGs will have sought to offset the additional price by changing their other commissioning priorities in order to achieve financial balance or to hit financial control totals. I believe that the impact of having to offset the additional price will have resulted in funds being unavailable for services or increases in thresholds for the other treatments funded by CCGs. It also means there is less available financial resource to invest in new technologies, including new drugs and improvements in patient care.'[711]

C. Legal framework

I. Overview

5.46 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.

5.47 The concept of abuse is an objective one relating to the behaviour of an undertaking in a dominant position. The existence of anti-competitive intent on the part of the dominant undertaking is not a requirement for a finding of abuse.[712] However, evidence of such intent, while not sufficient in itself, constitutes a fact that may be taken into account in order to determine that a dominant position has been abused.[713]

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[710] The potential harm to patients denied funds diverted to purchasing drugs sold at excessively high prices was also one of the relevant factors taken into account by the CAT in denying interim relief to Flynn in the *Phenytoin* proceedings: '*The over-riding consideration is that, taking all the circumstances into account, the harm to the public from allowing the continuation of higher prices for this product outweighs the harm to Flynn that this may cause. A relevant factor in this finding is that it is not only the pecuniary effect of high prices on the resources of the NHS that is in issue, although that is serious enough, but the consequent effect on the health and well-being of affected patients and hence to public health overall and the public interest.*': *Phenytoin CAT* [2017] CAT 1, paragraph 105.
[711] Document LIO12042, Julie Lizbeth Wood's witness statement, paragraph 30.
[712] *Tomra Systems ASA and Others v Commission*, C-549/10 P, EU:C:2012:221, paragraph 21. See also *Hoffmann-La Roche*, 85/76, EU:C:1979:36, paragraph 91.
[713] *Generics (UK) Ltd and Others v CMA*, C-307/18, EU:C:2020:52, paragraph 162. See also *Tomra Systems ASA and Others v Commission*, C-549/10 P, EU:C:2012:221, paragraphs 20–21 and 24.

5.48 Section 18(2)(a) of the Act states that directly or indirectly imposing unfair selling prices constitutes an abuse.[714]

5.49 The '*seminal*'[715] judgment on unfair pricing is *United Brands*[716] 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 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.'

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[714] Section 18(2) of the Act; Article 102(a) TFEU; and *United Brands*, 27/76, EU:C:1978:22, paragraph 248.
[715] See *Phenytoin CoA* [2020] EWCA Civ 339, 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 CAT* [2018] CAT 11, paragraph 285.
[716] *United Brands*, 27/76, EU:C:1978:22.

5.50 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.[717] Competition authorities have a '*margin of manoeuvre*' or '*discretion*' in deciding which methodology to use.[718]

5.51 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.[719] 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).[720]

5.52 This two limb test has been consistently applied by the European Commission,[721] competition authorities of Member States of the EU,[722] the Court of Justice,[723] the High Court,[724] the CAT,[725] and the Court of Appeal[726] (most recently in its *Phenytoin* judgment dated 10 March 2020).[727]

5.53 While the competition authority bears the legal burden of proof and must take a rigorous reasoned approach to the legal and factual questions,[728] it is not required to apply an approach or methodology that is so complex and time-

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[717] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 84–86, 97(iii)–(iv) and 251.
[718] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(iii), 107, 120–121, 246 and 251.
[719] *United Brands*, 27/76, EU:C:1978:22, paragraph 251.
[720] *United Brands*, 27/76, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 7; *Attheraces Limited v the British Horseracing Board Limited* [2005] EWHC 3015 (Ch), paragraph 294; and Case COMP/A.36.568/D3 *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, paragraphs 102, 149–150 and 215.
[721] *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, paragraphs 98–103 and 145–152.
[722] 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.
[723] For the most recent example see *Autortiesību un komunicēšanās konsultāciju aģentūra / Latvijas Autoru apvienība v Konkurences padome* ('***Latvian Copyright***'), C-177/16, EU:C:2017:689, paragraph 36.
[724] *Ineos Vinyls Ltd v Huntsman Petrochemicals (UK) Ltd* [2006] EWHC 1241 (Ch), paragraphs 217–218.
[725] *Albion Water and Another v Water Services Regulation Authority and Others ('**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*, 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.
[726] *Attheraces Limited v British Horse Racing Board Limited* ('***Attheraces CoA***') [2007] EWCA Civ 38, paragraphs 114–119.
[727] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v)–(viii).
[728] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 243 and 246.

consuming that the relevant authority has neither the time nor the resources to deal with cases of alleged unfair pricing.[729]

II. Limb one of the United Brands test: is the price excessive?

5.54 The first limb of the *United Brands* test asks '*whether the difference between the costs actually incurred and the price actually charged is excessive*'.[730] 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.[731] Then the authority should determine whether the margin is '*excessive*'.[732] 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').[733]

5.55 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.[734]

5.56 In each of *Ineos Vinyls Ltd v Huntsman Petrochemicals (UK) Ltd*,[735] *Attheraces CoA*,[736] *Albion Water I*[737] and *Albion Water II*,[738] a price/cost 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

5.57 The measurement of '*the costs actually incurred*'[739] in, or '*reasonably attributable*'[740] to, supplying the product in question will include:

(a) The costs directly incurred in supplying the product or service;[741] and

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[729] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 244.
[730] *United Brands,* 27/76, EU:C:1978:22, paragraph 252; *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraph 36, *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 97(v) and 249.
[731] *Phenytoin CoA*, [2020] EWCA Civ 339, paragraph 97(v).
[732] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).
[733] *Phenytoin CoA*, [2020] EWCA Civ 339, paragraphs 97(v) and 252.
[734] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 254; see also *ibid* paragraphs 120–125, 185 and 249–250.
[735] *Ineos Vinyls Ltd v Huntsman Petrochemicals (UK) Ltd* [2006] EWHC 1241 (Ch), paragraphs 217.
[736] *Attheraces CoA* [2007] EWCA Civ 38, paragraphs 116 and 209.
[737] *Albion Water I* [2006] CAT 23, paragraph 314.
[738] *Albion Water II* [2008] CAT 31, paragraphs 20 and 194.
[739] *United Brands,* 27/76, EU:C:1978:22, paragraph 252. See also *Albion Water II* [2008] CAT 31, paragraph 20.
[740] *Albion Water II* [2008] CAT 31, paragraph 198.
[741] *Albion Water I* [2006] CAT 23, paragraph 314; *Albion Water II* [2008] CAT 31, paragraph 89.

(b) An appropriate apportionment of the indirect costs that are reasonably attributable to the product or service.[742]

5.58 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*'[743] 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.'[744]

5.59 The 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*'.[745]

5.60 Further, it is well-established that any costs must be reasonably and efficiently incurred.[746] As the CAT explained in *Albion Water II*: '*Community jurisprudence only permits the inclusion of efficiently incurred costs*'.[747]

ii. Reasonable rate of return

5.61 The judgment in *United Brands* only refers to the costs of production, without further definition.[748]

5.62 As the European Commission recognised in *Scandlines*,[749] it is legitimate that a company may want to cover its cost of capital. Similarly, the CAT

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[742] *United Brands,* 27/76, EU:C:1978:22, paragraph 254.
[743] *Albion Water II* [2008] CAT 31, paragraph 88.
[744] *Albion Water II* [2008] CAT 31, paragraph 93.
[745] *United Brands*, 27/76, EU:C:1978:22, paragraph 254. See also *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, paragraph 117.
[746] *Ministère Public v Tournier*, 395/87, EU:C:1989:319, paragraph 42.
[747] *Albion Water II* [2008] CAT 31, paragraph 88.
[748] *United Brands*, 27/76, EU:C:1978:22, paragraphs 251 and 254. See also *Albion Water II* [2008] CAT 31, paragraph 89.
[749] *Scandlines Sverige AB v Port of Helsingborg*, Commission decision of 23 July 2004, paragraph 224.

recognised in *Albion Water II*[750] 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.

5.63 It is not necessary to adopt any particular approach to the determination of the '*plus*' part of the Cost Plus calculation.[751] The identification of a reasonable rate of return is not a matter of '*precise mathematics*'.[752] Rather, it is a question of judgement and appreciation on which experts may well take differing views.[753] In exercising that judgement, where relevant, regard may be had to the interests of patients and the NHS.[754]

b. Differential

5.64 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.[755]

5.65 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 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'.[756]

5.66 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*'.[757]

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[750] *Albion Water II* [2008] CAT 31, paragraph 89.
[751] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 253.
[752] *Genzyme Limited v OFT* ('***Genzyme Remedy***') [2005] CAT 32, paragraph 279.
[753] *Genzyme Remedy* [2005] CAT 32, paragraph 255.
[754] *Genzyme Remedy* [2005] CAT 32, paragraph 256.
[755] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(v).
[756] *Albion Water II* [2008] CAT 31, paragraph 199.
[757] *Albion Water II* [2008] CAT 31, paragraphs 193–194.

III. Limb two of the United Brands test: is the price unfair?

5.67 An excessive price may be unfair either:

(a) '*in itself*'; or

(b) '*when compared to competing products*'.[758]

5.68 This is an alternative rather than a cumulative test.[759] Accordingly, it is sufficient to demonstrate that one of the alternatives of the Unfair Limb is satisfied to establish an infringement.[760]

5.69 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.[761] There is no fixed list of categories of evidence relevant to unfairness.[762]

5.70 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*[763] *by the undertakings*'.[764] As to that duty:

(a) The law does not pre-determine 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.[765]

(b) The authority has a margin of manoeuvre or discretion as to how it performs its duty of fair evaluation including with regard to the depth and intensity of the inquiry but there is no general duty to perform a '*full*' investigation in all cases.[766] 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

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[758] *United Brands*, 27/76, EU:C:1978:22, paragraph 252. See confirmation of this test in *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraph 36.
[759] *Isabella Scippacercola and Ioannis Terezakis v Commission*, C-159/08 P, 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* [2020] EWCA Civ 339, paragraph 259.
[760] *Phenytoin CAT* [2018] CAT 11, paragraph 366.
[761] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(vii).
[762] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(vi).
[763] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 114 and 116: '*There is an important evidential burden upon an undertaking being investigated*.'
[764] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 259–260. 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*.'
[765] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 112, 114 and 116.
[766] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 113, 116 and 270.

competition authority to make its own investigations, but it is not under a legal duty to do so.[767] 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.[768]

a. Assessing whether a price is unfair in itself

5.71 The authority has a considerable margin of appreciation when assessing whether an excessive price is also unfair.[769]

5.72 A price which '*significantly exceeds*' the economic value of the product supplied '*will be prima facie excessive and unfair*'.[770] However, other factors are relevant to that determination.

5.73 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*'.[771]

5.74 In this respect, the CAT found that factors establishing a dominant position may be relevant to assessing whether an excessive price is unfair:

> '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.'[772]

5.75 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*

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[767] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 270 and 273.
[768] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 270.
[769] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 135 and *Albion Water II* [2008] CAT 31, paragraphs 216, 261 and 263.
[770] *Attheraces CoA* [2007] EWCA Civ 38, paragraph 204. See also *Albion Water II* [2008] CAT 31, paragraph 265.
[771] *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 *Post Danmark*, C-23/14, EU:C:2015:651, paragraph 30.
[772] *Albion Water II* [2008] CAT 31, paragraph 213.

whatsoever'.[773] 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*'.[774]

5.76 In *Albion Water II*, the CAT recognised the importance of taking end customers' interests into account and looking beyond the immediate interests of competitors,[775] 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*'.[776]

5.77 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.[777] 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.[778]

5.78 All other factors taken into account by the CMA in the 2016 infringement decision in *Phenytoin* are 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 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…'[779]

b. Assessing whether a price is unfair when compared to competing products

5.79 Alternatively, an excessive price can be unfair when compared to competing products.[780]

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[773] *Albion Water II* [2008] CAT 31, paragraph 268. See also Opinion of AG Jacobs in *Ministère Public v Tournier*, 395/87, EU:C:1989:215, paragraph 43.
[774] *Albion Water II* [2008] CAT 31, paragraph 268.
[775] *Albion Water II* [2008] CAT 31, paragraph 271.
[776] *Albion Water II* [2008] CAT 31, paragraph 218. See also *Attheraces CoA* [2007] EWCA Civ 38, paragraph 215.
[777] See, to that effect, *Attheraces CoA* [2007] EWCA Civ 38, paragraph 215 and *Phenytoin CAT* [2018] CAT 11, paragraphs 404 and 346. See also AT.40394 *Aspen*, Commission decision of 10 February 2021, paragraph 163.
[778] AT.40394 *Aspen*, Commission decision of 10 February 2021, paragraph 163.
[779] *Phenytoin CAT* [2018] CAT 11, paragraph 369.
[780] *United Brands*, 27/76, EU:C:1978:22, paragraph 252.

5.80 Comparators do not have to be identical[781] or in the same relevant market as the product at issue.[782] 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.[783] Comparisons must be made on a consistent basis.[784]

5.81 A comparator cannot be considered meaningful simply on the basis that the customer is paying the price imposed.[785] Comparisons should not be drawn with other products, the price of which may also have been inflated by the exercise of substantial market power.[786]

5.82 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 our view assist that that price is based on a comparison with other prices which are not cost-justified either.'[787]

5.83 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*'.[788]

c. Economic value

5.84 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*'.[789]

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[781] *SABAM v Weareone.World, Wecandance*, C-372/19, EU:C:2020:959, paragraph 32 and *Albion Water II* [2008] CAT 31, paragraph 252.
[782] *SABAM v Weareone.World, Wecandance*, C-372/19, EU:C:2020:959, paragraph 32 and *Phenytoin CAT* [2018] CAT 11, paragraph 373.
[783] See, for example, *Albion Water II* [2008] CAT 31, paragraphs 252–253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin CAT* [2018] CAT 11, paragraph 373.
[784] See, for example, *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraphs 38, 44-46 and 51 and *Albion Water II* [2008] CAT 31, paragraphs 252–253; *Scandlines*, paragraphs 169 and 175; and *Phenytoin CAT* [2018] CAT 11, paragraph 373.
[785] See, for example, *Albion Water I* [2006] CAT 23, paragraphs 754–756.
[786] 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 49–50.
[787] *Albion Water I* [2006] CAT 23, paragraph 757.
[788] *Albion Water II* [2008] CAT 31, paragraph 257.
[789] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 171.

5.85 The Court of Appeal explained 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*.'[790] 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*'.[791] Competition authorities are not required to adopt any particular approach to the determination of economic value.[792]

5.86 Determining the '*economic value*' of a product involves a considerable margin of appreciation[793] with appropriate weight being given to factors on both the supply and demand side.[794]

5.87 The economic value of a product may exceed Cost Plus as a result of non-cost related factors including,[795] where applicable, '*additional benefits not reflected in the costs of supply*'[796] or any '*particular enhanced value from the customer's perspective*'.[797]

5.88 This was, for instance, the case in *Scandlines*[798] and *Attheraces*[799] 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.

5.89 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.[800]

5.90 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

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[790] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.
[791] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172 (emphasis in original).
[792] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 253.
[793] *Albion Water I* [2006] CAT 23, paragraph 310 and *Albion Water II* [2008] CAT 31, paragraphs 216 and 263. See also *Phenytoin CAT* [2018] CAT 11, paragraphs 407 and 425.
[794] *Albion Water II* [2008] CAT 31, paragraph 225. See also *Phenytoin CAT* [2018] CAT 11, paragraph 411.
[795] *Albion Water II* [2008] CAT 31, paragraph 222; and *Scandlines*, paragraph 226. See also *Attheraces CoA* [2007] EWCA Civ 38, paragraph 218.
[796] *Albion Water II* [2008] CAT 31, paragraph 7.
[797] *Albion Water II* [2008] CAT 31, paragraph 222.
[798] *Scandlines*, paragraph 241.
[799] *Attheraces CoA* [2007] EWCA Civ 38, paragraph 218.
[800] *Albion Water II* [2008] CAT 31, paragraph 226.

service in question is either '*not more, or not significantly more, than*' the production costs.[801]

5.91 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.[802] The European Commission reached the same conclusion in *Deutsche Post*.[803] 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*'.[804]

5.92 Economic value is not simply whatever price a product or service will fetch or '*the market will reasonably bear*'.[805] That was confirmed by the Court of Appeal in *Attheraces*[806] and *Phenytoin*:

> '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.'[807]

5.93 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).'*[808]

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[801] *Albion Water II* [2008] CAT 31, paragraphs 225 and 249.
[802] *Albion Water II* [2008] CAT 31, paragraph 249.
[803] COMP/C-1/36.915 *Deutsche Post AG - Interception of cross-border mail* ('***Deutsche Post***'), paragraph 162.
[804] *Albion Water II* [2008] CAT 31, paragraph 225. See also paragraph 264.
[805] *Attheraces CoA* [2007] EWCA Civ 38, paragraphs 210–211. 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.
[806] *Attheraces CoA* [2007] EWCA Civ 38, paragraph 205.
[807] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 154–155.
[808] Opinion of AG Pitruzzella in *SABAM v Weareone.World*, C-372/19, EU:C:2020:598, paragraph 25.

5.94 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.[809] 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*'.[810]

5.95 However, the Court of Appeal has subsequently explained that, '*even if there is dependency there might still be some economic value but not necessarily reflecting the full price demanded*'.[811]

5.96 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.[812]

IV. Other methodologies

5.97 Methods other than the *United Brands* test that have been used by EU and domestic courts for determining whether a price is unfair[813] include prices charged by (i) the dominant firm at a different point in time;[814] (ii) non-dominant firms;[815] and (iii) the dominant firm or other firms in different geographical markets.[816]

5.98 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,

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[809] *Hoffmann-La Roche*, 85/76, EU:C:1979:36, paragraph 41.
[810] Opinion of AG Jacobs in *Ministère Public v Tournier*, 395/87, EU:C:1989:215, paragraph 65.
[811] *Phenytoin CoA [2020]* EWCA Civ 339, paragraph 167.
[812] *Phenytoin CoA [2020]* EWCA Civ 339, paragraphs 155 and 172.
[813] *United Brands*, 27/76, EU:C:1978:22, paragraph 253, and *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraph 37. See also *Napp* [2002] CAT 1, paragraph 391.
[814] *British Leyland v Commission*, C-226/84, EU:C:1986:421, paragraphs 27–30.
[815] *Bodson v SA Pompes funèbres des régions libérées*, 30/87, EU:C:1988:225, paragraph 31; *Napp* [2002] CAT 1, paragraph 392.
[816] *Ministère Public v Tournier*, 395/87, EU:C:1989:319, paragraph 38; *Lucazeau*, 110/88, 241/88 and 242/88, EU:C:1989:326, paragraph 25; *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraph 38.

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.[817]

5.99 There is, however, no rule of law requiring competition authorities to use more than one test or method to assess an unfair pricing abuse.[818]

V. Burden and standard of proof

5.100 The burden of proving an infringement of the Chapter II prohibition lies with the CMA.[819] However, this burden does not preclude the CMA from relying, where appropriate, on inferences or evidential presumptions.[820]

5.101 The standard of proof that the CMA is required to meet is the civil standard of a balance of probabilities,[821] nothing more and nothing less. [822]

D. Limb one of the *United Brands* test: Excessive Limb

I. Summary

5.102 The CMA concludes that throughout the Infringement Period, from at least 1 January 2009 to 31 July 2017, the prices charged by Advanz for Liothyronine Tablets were excessive within the meaning of the Excessive Limb of the *United Brands* test (see section 5.C.II above).[823] This is because when Advanz's average selling prices (ASPs) for Liothyronine Tablets (set out in section 5.B.IV above) are compared to any reasonable measure of the costs of supplying Liothyronine Tablets, including a reasonable rate of return (Cost Plus – see section 5.D.II below), the Differential is material at all times throughout the Infringement Period (see section 5.D.III below).

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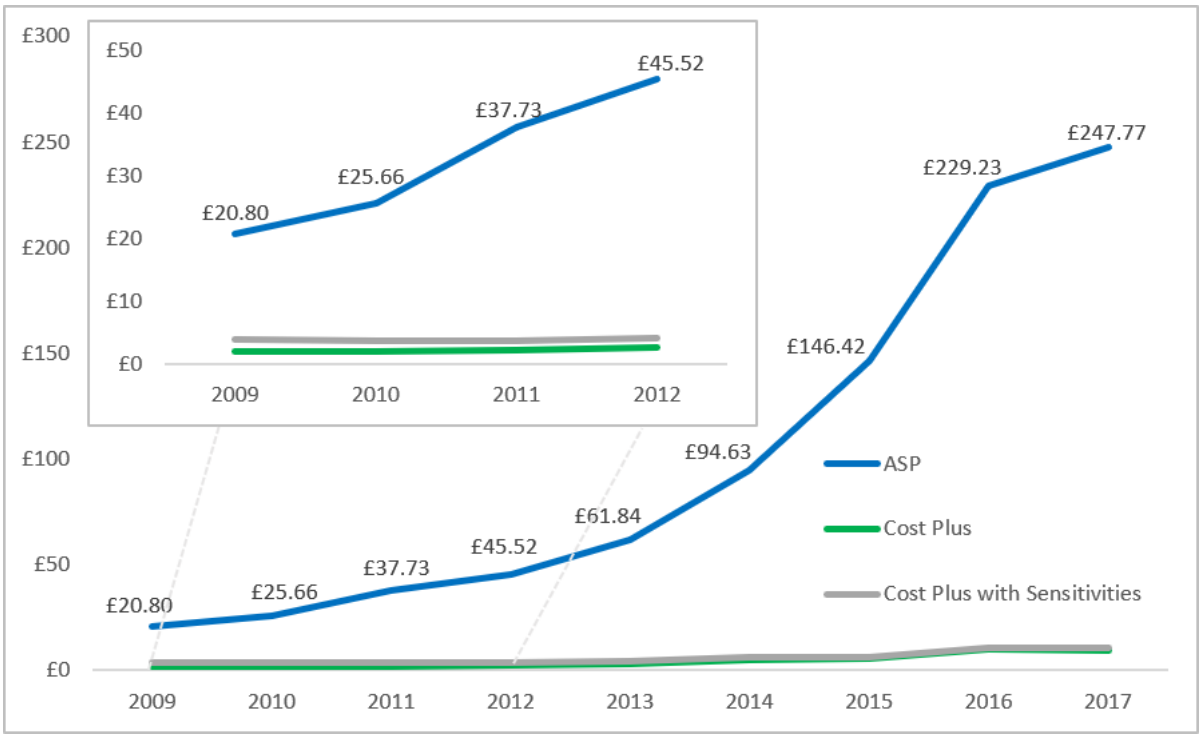
[817] *Ministère Public v Tournier*, 395/87, EU:C:1989:319, paragraph 38; *Lucazeau*, 110/88, 241/88 and 242/88, EU:C:1989:326, paragraph 25; *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraphs 38 and 57.
[818] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(iv).
[819] *Napp* [2002] CAT 1 paragraphs 95 and 100. See also *JJB Sports plc v OFT* [2004] CAT 17 paragraphs 164 and 928 to 931; and *Tesco Stores Limited and Others v OFT* [2012] CAT 31 paragraph 88.
[820] *Napp* [2002] CAT 1, paragraph 100. See on the CMA's duty to fairly evaluate all the evidence before it *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 110 to 117 and paragraph 5.70 above.
[821] See *AH Willis and Sons Limited v OFT* [2011] CAT 13, paragraphs 46 and 47. *Tesco Stores Limited and Others v OFT* [2012] CAT 31, paragraph 88.
[822] *Re S-B (Children)* [2009] UKSC 17 [34]. See also *Re B (Children)* [2008] UKHL 35, paragraph 72. The CAT has expressly accepted the Supreme Court's reasoning in *North Midland Construction plc v OFT* [2011] CAT 14, paragraphs 15 to 16.
[823] Not all prices above Cost Plus are excessive. *Albion Water II* [2008] CAT 31, paragraph 199 establishes that a material difference between price and cost must be shown (paragraph 5.65 above).

5.103 The Differential rose significantly during the Infringement Period from around 900% in 2009 to reach about 2,450% by 2017 (annual ASPs increased from £20.80 in 2009 to £247.77 in 2017, against a Cost Plus which increased from £2.08 in 2009 to £9.78 in 2017), and 2,500% at other points in the Infringement Period (2015).[824, 825]

5.104 Even when a number of sensitivities (covering alternative approaches to the allocation of common costs, the valuation and amortisation of product rights and the rate of return) are applied, the Differential was at all times above 300%, rising to almost 2,000% by 2017. Figure 5.6 below sets out a comparison of Advanz's ASPs for Liothyronine Tablets with Cost Plus and Cost Plus with sensitivities. This Differential translates into actual levels of return that were orders of magnitude higher than those which could reasonably be expected in the UK generics market, considering the stable, low risk, non-innovative nature of the product and the underlying market structure. To put this in perspective, an investor who placed £100 with Advanz at the start of the Infringement Period in 2009, with the specific aim of supporting the supply of Liothyronine Tablets, would have received a return of £11,804 by the end of the Infringement Period in 2017.[826]

[824] The ASP and Cost Plus for 2017 covers the part year 1 January to 31 July 2017.
[825] £20.80 is the lowest annual ASP; the lowest monthly ASP was £20.48 in January 2009. Cost Plus is calculated as an annual cost figure, so the CMA has calculated the Differential against the annual average ASP for each year.
[826] See paragraph 5.193 below.

Figure 5.6: Advanz's ASPs over time compared with Cost Plus and Cost Plus with sensitivities (£s)



Note: ASPs are annual averages; the 2017 figure is the average to July 2017.
Source: CMA analysis.

5.105 Taking account of its prioritisation principles,[827] the CMA decided to focus its Investigation only on prices of £20.48 per pack (the price in January 2009) and above.[828] The CMA has not reached a conclusion on the exact level (above Cost Plus but below £20.48 per pack) at which Advanz's prices became excessive and unfair as a matter of law. Therefore, although it is possible that prices somewhere above Cost Plus but below £20.48 per pack may have also been excessive and unfair, the CMA has limited itself to finding that Advanz's prices were excessive and unfair when they reached at least £20.48 per pack. This means that the lowest price which is covered by the CMA's infringement finding exceeds Cost Plus by 900% for the year 2009.[829]

II. Costs plus a reasonable rate of return (Cost Plus)

a. Cost Plus assessment

5.106 The total costs involved in the supply of Liothyronine Tablets are split into three categories:

[827] Prioritisation principles for the CMA (CMA 6) of April 2014.
[828] Cost Plus already includes a reasonable rate of return. However, as set out in paragraphs 5.65 ff above, not every price above Cost Plus would have been excessive and unfair.
[829] See paragraph 5.184 below.

(a) Direct costs;

(b) Indirect costs; and

(c) Reasonable rate of return.

i. Advanz's direct costs

5.107 Direct costs are those costs that are directly attributable to the supply of Liothyronine Tablets in the UK. Advanz provided information in respect of the following direct costs throughout the Infringement Period:[830]

(a) The cost of purchasing Liothyronine Tablets from [✂] (its CMO – see paragraph 3.170 above);

(b) Fees paid to [✂] in respect of technical expert support in the manufacture of Liothyronine Tablets;

(c) Dual sourcing costs;

(d) Stock write-off costs;[831]

(e) Batch specific variation costs (BSVs – see paragraph 3.97 above).

5.108 The CMA has treated the direct costs incurred by Advanz as specific to Liothyronine Tablets and assumed that they were reasonably and efficiently incurred.

5.109 Advanz's direct costs in supplying Liothyronine Tablets ranged from £0.35 to £4.01 during the Infringement Period.[832] Direct costs remained broadly stable with the exception of 2016 and 2017, when relatively high one-off costs were incurred for BSVs.[833]

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[830] Direct costs of production were provided in document LIO4426, '*Annex 1 to Concordia's response to the CMA's s.26 notice dated 6 September 2017*'. These direct cost figures did not include one-off costs associated with dual sourcing and stock write-offs.
[831] Dual sourcing and stock write-off costs were provided as part of the Advanz RSO (document LIO6288). See document LIO6284.60, '*FTI Report Evidence Item-17 -* [✂] *Data_01032018.xlsx*'; document LIO6284.61, '*FTI Report Evidence Item-18 - Piramal POs*'; and document LIO6284.72, '*FTI Report Evidence Item-29 - Stock write off - Liothyronine tabs - 2010-2017*'.
[832] Product Rights are directly attributable to the manufacture and supply of Liothyronine Tablets. As Product Rights are recognised as an asset within Advanz's capital base, the CMA's Cost Plus recognises the associated costs in two parts: (i) any related amortisation charges are recognised as a 'direct cost'; and (ii) a reasonable rate of return is given on the asset value of Product Rights. The CMA's approach to the valuation of the Product Rights assets and the appropriate rate of return is set out in more detail under 'Reasonable rate of return' (the 'Plus').
[833] See Table 5.1 below.

5.110 The CMA and the Parties agree on the treatment of all components of direct costs, except for the treatment of BSV costs. Annex 3 provides more detail on the respective components of direct costs.

5.111 With respect to BSV costs, in response to the 2019 SSO, Advanz reviewed its financial data for the period 2014 to 2017 and identified approximately [✂] of costs which it said related to 'additional stability testing' for BSVs.[834] Advanz states that these costs related to the additional validation and testing required to ensure that each batch of Liothyronine Tablets produced is safe and meets the MHRA guidelines.

5.112 As explained in more detail in Annex 3, Advanz accounted for BSV costs within the 'Technical, regulatory and specific' cost category, which are group level indirect costs that relate to Advanz's portfolio of drugs, including Liothyronine Tablets. Advanz allocates a proportion of these common costs to Liothyronine Tablets and treats them as an 'indirect cost'.[835]

5.113 The CMA's review of the information provided by Advanz found that:

(a) Only [✂] of the [✂] BSV costs identified by Advanz were relevant to Liothyronine Tablets during the Infringement Period;[836] and

(b) The majority of relevant BSV costs were incurred in 2016 and 2017; no BSV activity took place in 2009, 2010 or 2012 and BSV costs in all other years were much lower.

5.114 Although Advanz accounted for BSV costs in the 'Technical, regulatory and specific' cost category, the identified costs of [✂] related to activity that was directly attributable to Liothyronine Tablets. The CMA therefore concludes that it is more appropriate to treat those BSV costs as a 'direct cost', in the year the costs were incurred. Although Advanz only provided BSV cost information for the period 2014 to 2017, the CMA understands that BSV activity also took place in 2011 and 2013. The CMA's Cost Plus therefore recognises the actual

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[834] Document LIO7790.5, '*FTI Report Evidence Item-47 - BSV costs 2014 - 2017.ods*'.
[835] See paragraphs 3.26 ff of Annex 3.
[836] The CMA asked for supporting evidence from Advanz to verify the nature and timing of the costs incurred. Advanz was only able to provide evidence to support approximately [✂] of the [✂] (see document LIO7832, Advanz's response to question 1 of the CMA's s.26 notice dated 29 July 2019; document LIO7833, '*Confidential Annex 1 -- Update to Evidence Item 47 - 20 August 2019*'; document LIO7834, '*Confidential Annex 2 -- Invoices - BSV and additional dual sourcing - 1. BSV costs - POs and invoices*'; document LIO7835, '*Confidential Annex 2 -- Invoices - BSV and additional dual sourcing - 2. Additional dual sourcing - POs and invoices*'). Of those verifiable costs, the CMA identified a further approximately [✂] of costs that should be excluded from the analysis, as these costs related to services provided after the Infringement Period (see document LIO7851, '*RE_ Case 50395_ CMA request for information*'; document LIO7853, '*RE_ Case 50395_ CMA request for information*'; document LIO7854, '*Amdipharm Liothyronine invoice details CMA Sep 2019*'). As a result, only [✂] of the [✂] has been included as direct costs in the Cost Plus assessment.

BSV costs incurred during the period from 2014 to 2017 and includes an estimate of BSV costs in the years 2011 and 2013.[837]

ii. Advanz's indirect costs

5.115 In addition to the direct cost of individual drugs, Advanz also incurs costs that are not directly related to the supply of individual products or product groups. These costs are 'indirect costs', which in this case are common costs, i.e. those incurred in the supply of more than one product. Depreciation of group fixed assets is also treated as an 'indirect cost', as these assets are shared across all drugs in Advanz's portfolio.[838] To determine an appropriate amount of common costs for a particular product, a portion of total attributable common costs is allocated to each of the products that a company supplies.

5.116 Advanz's indirect costs in supplying Liothyronine Tablets ranged from £0.54 to £1.17[839] during the Infringement Period.

5.117 Advanz provided the CMA with information on the total common costs incurred at a group level between 2014 and 2017.[840]

5.118 The CMA has used the 2014 to 2017 indirect cost data provided by Advanz to calculate an average for that period. It has then applied the average 2014 to 2017 costs over the remainder of the Infringement Period. This assumes that indirect costs pre-2014 were consistent with indirect costs between 2014 and 2017. In the CMA's judgement, this is a reasonable approach, given the issues with Advanz's pre-2014 cost data (described in Annex 3).[841]

5.119 As explained in paragraph 5.115 above, common costs need to be allocated between all the products supplied by Advanz in order to determine the share that it is appropriate to include in the Cost Plus assessment for Liothyronine Tablets. There are three broad types of cost drivers that can be used separately or in combination. These are: (i) output-based cost drivers; (ii) input-based cost drivers; and (iii) value-based cost drivers.[842]

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[837] In response to the 2020 SSO, the Parties argued that the BSV costs should also be recognised in the period 2009–13. Advanz submitted that it had undertaken BSV activity in 2011 and 2013 but was unable to provide an estimate of the costs. The CMA has applied an average of the costs incurred during the period 2014–2017 to the two years for which no cost information was provided by Advanz, i.e. 2011 and 2013. See Annex 3, paragraph 3.35.
[838] See paragraph 5.138 below.
[839] This includes a depreciation charge – see explanation at paragraph 5.138 below. See Table 5.1 below.
[840] Document LIO6284.82, '*FTI Report Evidence Item-40 - My Model*', 'Indirect costs' tab.
[841] For example, Advanz told the CMA that its management accounts in the pre-2014 period were less comprehensive than from 2014 onwards (document LIO1901.1, Note of call between the CMA and Advanz on 19 January 2017, page 2), and therefore it was only able to identify costs unrelated to Liothyronine Tables in the 2014 to 2017 data.
[842] A cost driver is a measure of an activity which either causes a particular cost or which might be considered to be closely correlated to the cost. See for further details paragraphs 3.36 ff of Annex 3.

5.120 The CMA concludes that using an output-based cost driver – the volume of packs sold – is the most appropriate method to allocate common costs to Liothyronine Tablets in this case because:

(a) It is a transparent, practical, and verifiable method since data on the number of packs sold are readily available.

(b) Using volumes (number of packs sold) to allocate common costs ensures that the cost allocation is objective. Undertaking the cost allocation exercise across a company's whole portfolio (i.e. calculating the proportion of Liothyronine Tablet sales volumes relative to all of Advanz's sales) ensures that total common costs are recovered and no more.

5.121 The CMA recognises, however, that there is no single valid approach to common cost allocation and that alternative methods (for example, an input-based cost driver such as an activity-based costing approach) may also be appropriate, where the information required is both available and reliable.

5.122 In response to the 2017 SO, Advanz provided an activity-based costing model, using the 2014 to 2017 indirect cost data, to allocate its common costs to Liothyronine Tablets.[843, 844] Advanz does not however use activity-based costing as part of its normal course of business. Given the limitations of Advanz's cost data, the choice of allocation and percentage drivers used in its model were based on management assumptions that were not supported by sufficiently robust and reliable data. As a result, the CMA considers that Advanz's activity-based costing assessment was neither sufficiently objective nor transparent.

5.123 Therefore, in this case, the CMA concludes that activity-based costing is not a suitable and reliable way of allocating common costs to Liothyronine Tablets.

5.124 Nonetheless, as a cross-check, on a precautionary basis, the CMA has carried out a sensitivity assessment using an adjusted version of Advanz's activity-based costing model (see paragraphs 5.166 to 5.169 below and Annex 3). The result of this does not alter the CMA's overall finding that prices of Liothyronine Tablets during the Infringement Period were excessive (see Annex 3, paragraphs 3.172 to 3.186).

5.125 The CMA has also considered whether allocating costs using value-based cost drivers, such as revenue, would be appropriate. However, if sales revenues were used, a greater proportion of common costs would be

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[843] Document LIO6361.3, First FTI Report, paragraph 8.20.
[844] Activity-based costing is a costing method that allocates common costs on the basis of the causal links between the costs incurred by the business and the activities driving those costs.

allocated to higher priced products. This could lead to circular outcomes when assessing whether prices are excessive because a potentially excessive price might appear justified simply by virtue of the fact that it is high. Therefore, the CMA has rejected allocating indirect costs using revenue.[845]

iii. Reasonable rate of return (the 'Plus')

5.126 As set out in paragraph 5.62 above, when establishing the '*costs actually incurred*' it will normally be necessary to allocate a reasonable rate of return to cover the cost of capital i.e. the 'Plus' element of Cost Plus.[846] The reasonable rate of return reflects the opportunity cost to investors of providing capital to Advanz to purchase assets and fund working capital requirements.

5.127 In order to determine a reasonable rate of return in this case, the CMA has followed the well-established return on capital employed ('**ROCE**') model. Where capital employed can be reliably measured, ROCE is generally accepted as the most objective way of calculating a reasonable rate of return and is therefore preferable to other methods.[847] In this case, the relevant data are available to measure both the capital employed and the cost of that capital (the weighted average cost of capital ('**WACC**')), which are the two inputs required to calculate the reasonable rate of return:

(a) Capital employed (or capital base): this is the amount of capital that Advanz had to deploy to operate in the UK Liothyronine Tablets market during the Infringement Period. This includes both tangible and intangible assets and

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[845] This is consistent with the CAT's approach in *Genzyme Remedy*. See *Genzyme Remedy* [2005] CAT 32, paragraph 268, where the CAT agreed with the OFT's rejection of Healthcare at Home's submission that certain costs should be allocated solely according to turnover as such an approach would allocate an unduly high proportion of overheads to the drug under investigation, because of the high cost of the drug. See also *Phenytoin CAT* [2018] CAT 11, paragraphs 351–352 where the CAT concluded that the CMA's allocation of common costs based on volume was reasonable and *Socrates v Law Society* [2017] CAT 10, paragraph 83.

[846] As well as incurring direct and indirect costs, firms also incur capital costs in acquiring the necessary fixed assets and working capital. Assets include items such as buildings, machinery and intellectual property, while working capital is required to cover the day-to-day operational financing requirements of a business (e.g. stock, debtors, creditors). Where an asset has a finite useful economic life, the costs of purchasing the asset are spread over the period during which it is used, via an annual depreciation or amortisation charge. Amortisation is the term for decreasing the recorded value of an asset over time to reflect its reduced worth. In the context of tangible assets, amortisation is referred to as depreciation. The depreciation or amortisation charge reflects the cost associated with acquiring the asset, with the main difference to the direct and indirect costs referred to above being that the timing of the recording of cost is spread over the life of the asset, rather than being recorded at the point the cost was incurred. The charge will therefore be included in direct or indirect costs, depending on whether the assets are directly attributed to the supply of Liothyronine Tablets in the UK. 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 European Commission in *Scandlines*, paragraph 224 and by the CAT in *Albion Water II* [2008] CAT 31, paragraph 89. In *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 253, the Court of Appeal acknowledged that it is not necessary to adopt any particular approach to the determination of the '*plus*' part of the Cost Plus calculation.

[847] The ROCE model has practical, real-world applications and is used extensively by businesses, investors, financial analysts and regulators to assess the appropriate rate of return. Businesses use the ROCE approach to appraise investment projects; financial analysts use it to measure risk and returns investors expect when investing in companies; and UK regulators use the ROCE to determine an appropriate rate of return when setting prices in regulated industries such as gas, electricity, and water.

working capital (deducting any amortisation or depreciation already charged).[848]

(b) Cost of capital (or WACC): this is the average percentage return that debt and equity investors expect in return for providing funds to a company they have invested in.

5.128 The reasonable rate of return is calculated by multiplying capital employed by cost of capital.

5.129 In the remainder of this section, the CMA describes its approach to the valuation of capital employed and to determining an appropriate rate of return for investors.

- *Advanz's capital base / capital employed*

5.130 As explained in paragraph 5.127 (a), capital employed includes fixed assets (both tangible and intangible assets) and working capital.

5.131 As not all of Advanz's assets are attributable to the supply of Liothyronine Tablets, the first step in determining the value of capital employed is to identify the assets used in their supply. The CMA reviewed the categories of fixed assets under which Advanz has recorded its assets and concludes that the following categories ought to be included:

(a) Land and buildings;

(b) Plant and machinery;

(c) Office equipment;

(d) Motor vehicles;

(e) Software; and

(f) Assets associated with the costs of obtaining the manufacturing know-how and the MA required for the supply of Liothyronine Tablets (**'Product Rights'**).

5.132 Advanz referred to each of these asset categories as being '*attributable to Liothyronine*'.[849] The CMA has seen no evidence to indicate that these assets

[848] Capital employed is the total value of fixed assets used in the supply of Liothyronine Tablets plus the working capital required to cover the day-to-day operational financing requirements of the business.
[849] Document LIO4426, '*Annex 1 to Concordia's response to the CMA's s.26 notice dated 6 September 2017*'.

are not used in the supply of Liothyronine Tablets and has therefore treated them as attributable to Liothyronine Tablets.[850]

5.133 Of the fixed asset categories identified, the most material asset to the supply of Liothyronine Tablets in the UK is the intangible asset relating to Product Rights. Paragraphs 5.139 to 5.146 explain the CMA's approach to valuing Product Rights; and paragraphs 5.148 to 5.149 and paragraphs 5.150 to 5.155 set out its approach to the valuation of fixed assets and working capital respectively.

5.134 The CMA does not include the following three asset categories in its assessment of capital employed for the following reasons:

(a) Goodwill – this relates to the difference between the purchase price and the total value of identifiable assets of the company at the time of purchase. The 'goodwill' asset is not required for the supply of Liothyronine Tablets in the UK.

(b) Customer/distributor/supplier relationships – Advanz did not provide any reliable evidence that it had incurred one-off costs when it established its supplier relationship with its CMO for Liothyronine Tablets. Given the lack of independent and reliable evidence, the CMA does not recognise such an asset in Advanz's capital base. Although no relevant costs were incurred during the Infringement Period, on a cautious basis, the CMA still allocates some costs that relate to Advanz's supplier relationship with its CMO as 'indirect costs' in its Cost Plus.

(c) Patents and trademarks – Advanz has recorded nil values for the assets within this category. This is consistent with the fact that Liothyronine Tablets are a generic drug and not under patent and Advanz has not carried out any research or development in respect of Liothyronine Tablets during the Infringement Period.[851]

- *The CMA's approach to asset valuation of fixed assets*

5.135 The value of capital employed should reflect the economic cost of the resources involved, which is the cost of resources used at a price at which

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[850] There is one exception relating to land and buildings. Advanz provided evidence identifying the value of land which is in India and which is not used in the supply of Liothyronine Tablets: document LIO2988.1, '*Annex 1 – Asset level breakdown (freehold land and buildings)*'. The CMA therefore included land and buildings in the asset categories listed in paragraph 5.131 above, with the exception of the land in India which is not used in the supply of Liothyronine Tablets.
[851] See Annex 3, paragraph 3.77.

they would be traded in a competitive market. Approaches to valuing the economic cost of an asset may be determined by reference to:

(a) Accounting values such the 'gross book values' which is the acquisition cost (i.e. the costs actually incurred in purchasing or developing a specific asset) or the 'historical cost' in accounting terms. The 'net book value' is another accounting value which is the historical cost less any amortisation or depreciation charged; or

(b) the 'value to the business' approach, which estimates the loss the entity would suffer if it were deprived of the asset involved. This may be determined by reference to:

(i) Entry value (replacement cost);

(ii) Exit value (selling price less the costs of selling the asset or 'net realisable value'); or

(iii) Value in use (discounted present value of the cash flows expected from continuing use and ultimate sale by the present owner).[852, 853]

5.136 Accounting values such as acquisition cost may differ from the economic cost of an asset, particularly if the asset was purchased some time ago. In the circumstances of this case, as explained in 5.140, the CMA considers that the acquisition cost is unlikely to provide an appropriate measure of the economic cost for the Product Rights intangible asset that is required to supply Liothyronine Tablets in the UK.

5.137 The CMA has therefore used the 'value to the business' approach to value Advanz's fixed assets. In most cases, the asset's value in its most profitable use (in other words, when the asset is used in its current operations to generate revenue, i.e. its 'recoverable amount') will exceed its replacement cost. In such circumstances, the entity will, if deprived of the asset, replace it, and use the new asset in its operations to generate revenues. Based on accounting standards, the asset value is the lower of the replacement cost and recoverable amount. This follows from the long-established principle of prudence in financial reporting to use the lower asset value to ensure that assets are not overstated and provide a true reflection of the economic value of an asset. In most cases, the value of the asset will therefore be its

[852] The basis for valuing assets for the purposes of determining the ROCE is set out in Edwards, J, Kay, J A, and Mayer, C (1987), '*The Economic Analysis of Accounting Profitability*'.
[853] The exit value and value in use measures are referred to as the 'recoverable amount'.

replacement cost. Further detail on the CMA's approach to asset valuation is set out in paragraphs 3.78 to 3.91 of Annex 3.

5.138 Another factor to consider when valuing capital assets is the reduction in the value of the asset that may result from the depreciation of an asset. Depreciation and amortisation are the costs associated with spreading the costs of capital assets over their useful economic lives. This can affect the value of a capital asset. The costs associated with amortisation and depreciation (amortisation and depreciation charge) are included in the CMA's Cost Plus assessment as direct and indirect costs, described in paragraphs 5.107ff and 5.115ff above. Annex 3 provides more detail on the amortisation and depreciation profiles used for the fixed asset categories set out in paragraph 5.131 above.[854]

- *The CMA's approach to asset valuation: Product Rights*

5.139 Product Rights form an important part of Advanz's capital base. As set out in paragraph 5.135 above, there are two alternative approaches to determining the economic cost of Product Rights:

(a) The actual acquisition cost is the amount actually paid by Advanz to acquire the Product Rights for Liothyronine Tablets (a proportion of the £1 million paid by Advanz to acquire the MA for Liothyronine Tablets in 1992); or

(b) The value to the business approach, which is the lower of replacement cost and recoverable amount.

5.140 The CMA considers that the actual acquisition cost is unlikely to be an appropriate measure in this case as it is unlikely to reflect the economic cost of Product Rights during the Infringement Period. This is because:

(a) The MHRA has told the CMA that regulatory requirements have increased in complexity since the marketing authorisation (MA) for Liothyronine Tablets was awarded in 1992 (see paragraph 3.98 above). The stricter regulatory requirements associated with the award of an MA mean that a potential entrant during the Infringement Period would have likely had to pay more to obtain an MA for Liothyronine Tablets than Advanz paid to acquire the MA in 1992.

[854] See Annex 3, paragraphs 3.151-3.155.

(b) It is not straightforward to establish the relevant acquisition costs of Liothyronine Tablets as the £1 million acquisition cost related to a portfolio of 22 drugs acquired by Advanz.

5.141 The CMA therefore uses the 'value to the business' approach, and more specifically 'replacement cost' as the approach to determine the value of Advanz's Product Rights in this case because:

(a) As explained in paragraph 5.137, in most cases the replacement cost is likely to be lower than the recoverable amount. In this case, due to the substantial economic profits made on Liothyronine Tablets, the replacement cost is lower than the recoverable amount.

(b) In any event, replacement cost is more appropriate for the purposes of determining the value of an asset in an excessive pricing case more generally, as using the recoverable amount to value Product Rights would be circular: the recoverable amount is likely to be inflated as a result of the pricing conduct under investigation.

5.142 The CMA calculates the replacement cost of Product Rights by assessing the entry costs of firms that have successfully entered the UK market for Liothyronine Tablets. This provides an objective and independent proxy for the value of Product Rights.

5.143 There have been two successful new entrants in the Liothyronine Tablets market since the end of the Infringement Period, namely Morningside and Teva. Morningside incurred costs of [<£500,000] to enter the UK market for Liothyronine Tablets. Teva estimates that its costs ranged between [✂] and [<£1 million].

5.144 The CMA's replacement cost valuation therefore ranges from [<£500,000] to [<£1 million].

5.145 Taking a conservative approach, the CMA has used the upper end of Teva's entry cost estimate range ([<£1 million]) as the value of Product Rights for the purposes of its Cost Plus assessment and does not depreciate Product Rights during the Infringement Period. The CMA has not only chosen the higher of the cost estimates provided by the two entrants but also adopted the upper end of the higher cost estimate, i.e. Teva's upper end estimate of [<£1 million].

5.146 The Parties propose alternative valuations derived from reports authored by EY (the '**EY Report**') and Globalview Advisors.[855] The CMA rejects the Parties' proposed valuations as both the EY and Globalview valuations are based on prices charged during the Infringement Period and are therefore likely to be inflated by the pricing conduct under investigation.

5.147 More detail on the CMA's approach to valuing Product Rights and reasons for rejecting the approach set out in the Globalview and EY Reports is provided in Annex 3.

- *The CMA's approach to asset valuation: fixed assets other than Product Rights*

5.148 Advanz also employs fixed assets and has categorised them as explained in paragraph 5.131 above. These relate to those fixed assets employed by the corporate group as a whole, a proportion of which is notionally attributable to Liothyronine Tablets.[856]

5.149 The CMA concludes that it is reasonable to use net book values as a proxy for the efficient cost of these assets to Advanz.[857] The CMA considers that it is reasonable to allocate the value of fixed assets that are attributable to Liothyronine Tablets on the basis of volume (number of packs sold).

- *The CMA's approach to asset valuation: working capital*

5.150 As set out in paragraph (a) above, the capital base ('capital employed') of a company (which is used to calculate a reasonable rate of return) includes both tangible and intangible assets as well as working capital. Working capital is the amount of capital employed in financing short-term assets, net of the capital provided by short-term liabilities. Working capital is typically calculated by taking the value of trade receivables (sales which have been executed but the cash has not yet been received) and inventory, less the value of trade payables. As explained in paragraph 5.153, the majority of Advanz's working capital balance consists of receivables, and capital tied up in the receivables balance is likely to be exposed to less risk than the business as a whole.

5.151 The CMA requested data from Advanz on the value of trade payables, trade receivables and inventory for Liothyronine Tablets. Advanz was unable to

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[855] Document LIO4937, '*EY Report*', Exhibit 15; Document LIO1724, '*Mercury PPA Report.pdf*', page 29.
[856] This category includes assets described by Advanz as '*land and buildings, plant and machinery, office equipment, motor vehicles and software*'. For completeness, Advanz reported nil values for the following categories in respect of Liothyronine Tablets: customer/distributor relationship, patents and trademarks, IP R&D. See document LIO4426, '*Annex 1 to Concordia's response to the CMA's s.26 notice dated 6 September 2017*'.
[857] Net book value is unlikely to differ materially to value to the business for these assets.

provide data specific to Liothyronine Tablets in respect of trade receivables and trade payables.[858]

5.152 Advanz did, however, provide data which could be used to estimate the share of receivables and payables that related to Liothyronine Tablet sales.[859] The CMA used this information to calculate the actual working capital balance associated with Liothyronine Tablets.

5.153 The majority of Advanz's working capital balance consists of receivables. Using Advanz's actual receivables balance is very favourable to Advanz. This is because the receivables balance resulting from a product sold at an excessive price does not represent an efficient level of capital employed in the business, since the high price inflates the level of receivables proportionately. Given the substantial upward trend in prices during the Infringement Period, any distorting impact of using actual receivables is bound to increase towards the end of the Infringement Period.

5.154 The CMA therefore concludes that Advanz's actual receivables balance represents a significant overestimate of a receivables balance associated with producing Liothyronine Tablets efficiently (see Annex 3, paragraphs 3.143 to 3.149).

5.155 However, it is not necessary to attempt to restate the working capital estimates to an efficient level, given that doing so would not change the CMA's overall conclusion that Advanz's prices were excessive during the Infringement Period.[860]

- *The CMA's approach to cost of capital*

5.156 As set out in paragraph 5.127, the second input to the reasonable rate of return requires the CMA to establish the cost of capital, i.e. the average percentage return that debt and equity investors expect in return for providing

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[858] Document LIO1726, '*Liothyronine Data (2)*' states in note number 7 that '*Product specific receivables data for Liothyronine is not available' and in note number 8 that 'Product specific payables data for Liothyronine is not available*'.
[859] Document LIO6284.82, '*FTI Report Evidence Item-40 - My Model*', 'Working capital - Tables' tab.
[860] Given the substantial upward trend in prices during the Infringement Period, the distorting impact of using actual receivables is greatest towards the end of the Infringement Period. As the difference between prices charged and costs incurred in the later part of the Infringement Period was very high, including Advanz's actual working capital in the assessment as part of Advanz's capital base does not affect the outcome of the CMA's assessment. Alternative approaches include linking the working capital to the estimated Cost Plus, i.e. assuming prices are set at Cost Plus or taking the price point at which prices first become excessive and using that price to derive the working capital allowance. Such approaches may be appropriate in other cases. As explained in paragraph 5.161, if Advanz's working capital levels are estimated by reference to the 2009 ASP rather than than by reference to the actual prices charged, Advanz's Cost Plus is significantly lower in the latter part of the Infringement Period, and consequently, the Differential in those years is even higher.

funds to a company they have invested in (the weighted average cost of capital or WACC).

5.157 The CMA considered WACC estimates from the Parties' internal documents. These ranged from [✂] to [✂]:

(a) While Advanz did not provide formal estimates of the cost of capital it uses as a business, it did state that a rate of [✂] was applied from at least 2010 onwards for internal project appraisals.[861]

(b) Globalview Advisors used a post-tax WACC of [✂] when valuing the intangible assets of Mercury Pharma Limited following the acquisition by Cinven in May 2013.[862]

(c) A Goldman Sachs presentation dated 4 September 2015 provided analysis of the potential financial impact of acquiring AMCo from Cinven.[863] The report estimated a range of different post-tax WACCs, with [✂].[864]

(d) EY estimated Advanz's post-tax WACC to be in the range of [✂] to [✂] and selected a value of [✂] for preparing its purchase price allocation report in September 2016.[865]

5.158 As explained in more detail in Annex 4, the CMA concludes that the cost of capital estimates from the Parties' internal documents are not suitable for an assessment of efficient capital costs. All of them were created in order to provide an assessment at a specific point in time and for a particular purpose. That makes them unsuitable for the purpose of estimating a WACC for the whole Infringement Period. They are also unsuitable for the following reasons:

(a) Advanz's [✂] cost of capital estimate represents a 'hurdle rate' that is likely to reflect a rate of return that management would hope to generate but that would not necessarily be achieved. Management might use this higher hurdle rate for project appraisal as a way of overcoming optimism bias.

(b) The cost of capital estimates used by Globalview Advisors and EY include a *'small company premium'* and a *'specific company premium'*.[866] This approach is not appropriate as there is no basis for it in the Capital Asset Pricing Model ('**CAPM**'), which is the model used by both reports.[867] Further, the Globalview Advisors and EY Report provide post-tax WACC estimates but

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[861] Document LIO2589, Advanz's response to question 1 of the CMA's s.26 notice dated 27 February 2017.
[862] Document LIO1724, '*Mercury PPA Report.pdf*', page 29.
[863] Document LIO1923, *'Document 2.pdf *Project Harmony – presentation'*.
[864] Document LIO1923, '*Document 2.pdf *Project Harmony – presentation*', page 27–29.
[865] Document LIO4937, '*EY Report*', Exhibit 15.
[866] Document LIO1724, '*Mercury PPA Report.pdf*.', page 28; document LIO4937, '*EY Report*', pages 52-53.
[867] See Brealey, RA (1991), '*Principles of Corporate Finance'*, chapter 8.

the CMA considers that a pre-tax WACC is more appropriate for the purposes of an economic cost assessment.

(c) Goldman Sachs' WACC estimates are also presented as post-tax. While they do not suffer from the same methodological issues as the Globalview Advisors or EY Report assessments with respect to the inclusion of premia outside the CAPM, the CMA observes that, after adjusting the analysis to make it comparable with the CMA's pre-tax WACC, Goldman Sachs' WACC estimates fall towards the lower end of the CMA's WACC estimate range. Therefore, on a cautious basis, the CMA does not use them to assess efficient capital cost.

5.159 Given the wide range of WACC estimates evidenced from the Parties' internal documents and the inappropriateness of using those estimates for the purposes of an economic cost assessment for the reasons outlined above, the CMA has instead used market data to estimate a reasonable rate of return for Advanz that takes into account any potential changes in the cost of debt and equity over the course of the Infringement Period. The CMA concludes that in this case, it is appropriate to apply a 10% WACC on capital employed as a reasonable rate of return for its Cost Plus assessment. More detail on how the CMA arrived at a 10% WACC estimate is set out in Annex 4.

iv. Results of Cost Plus analysis

5.160 Using the approach outlined above, Table 5.1 and Figure 5.7 below set out the costs per pack in the Cost Plus analysis for each year of the Infringement Period.

Table 5.1: Cost Plus for Liothyronine Tablets 2009-2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Simple Average
Direct costs per unit	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Indirect/common costs per unit	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Amortisation charge	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Depreciation charge	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on intangibles	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on tangibles	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Return on working capital	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Total Costs	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78	4.94

Source: CMA Cost Plus assessment – 'Cost stacks post reps' tab.

Figure 5.7: Cost Plus stack (total costs) for Liothyronine Tablets 2009-2017 in £s

[✂]

Source: CMA Cost Plus assessment – 'Charts' tab.

5.161 As can be seen from Table 5.1 and Figure 5.7 above, the return on working capital inflates the Cost Plus numbers towards the end of the Infringement Period considerably. This is because, as described above, the prices charged increase substantially throughout the Infringement Period, which in turn inflates the receivables balance in working capital. To illustrate this inflation: if the return on working capital were to be calculated by reference to the 2009 ASP throughout the Infringement Period rather than by reference to the price reflecting Advanz's ongoing conduct, total costs for the last three years of the period would have been as follows: £3.04 for 2015, rather than £5.63 when using the 2015 ASP; £5.61 for 2016, rather than £9.87 when using the 2016 ASP; and £5.05 for 2017, rather than £9.78 when using the 2017 ASP.[868] Consequently, the Differential in each of those years would be significantly higher, increasing from: 2,501% to 4,723% in 2015; 2,222% to 3,987% in 2016; and 2,434% to 4,809% in 2017.

5.162 Based on the assessment set out above, Advanz's Cost Plus ranged from £2.08 per pack of Liothyronine Tablets to £9.87 per pack during the Infringement Period, with a simple average of £4.94.

b. Sensitivities to Cost Plus

5.163 The CMA's approach to assessing the value of Product Rights (the most material asset), the approach to common cost allocation and the appropriate return on capital are the main areas of judgement within the CMA's Cost Plus assessment and the main areas of difference between the CMA and the Parties with respect to the calculation of Cost Plus. The CMA has applied a

[868] CMA Cost Plus assessment – 'Cost stacks post reps' tab

series of sensitivities to the data used in its Cost Plus analysis to assess the effect of using alternative methods as set out below. These sensitivities function as cross-checks to the results of the CMA's Cost Plus analysis above.

5.164 The cumulative application of these sensitivities results in a Cost Plus with a sensitivities range between £4.88 and £12.08 over the Infringement Period (see Table 5.2 below). This compares with a Cost Plus range of between £2.08 and £9.87 over the Infringement Period.

5.165 Sensitivities have been applied in relation to:

(a) The allocation of common costs, by using an adjusted version of Advanz's activity-based costing model;

(b) An *ex ante replacement cost* valuation of Product Rights to factor in a possible risk of failure, as a cross-check to the CMA's replacement cost valuation based on Teva's upper end cost estimate of [<£1 million]; and

(c) The application of a 15% WACC, to allow for a further five percentage points of return on capital in addition to the 10% WACC used in the Cost Plus assessment.

i. Allocation of common costs: activity-based costing

5.166 In the CMA's Cost Plus analysis, common costs are allocated using an output-based cost driver, i.e. using volume (the number of packs sold) as the cost driver. As explained at paragraph 5.120 above, the CMA considers that a volume-based approach provides an objective, transparent, practical and verifiable method by which to allocate common costs and is the most appropriate method in the circumstances of this case.

5.167 The CMA recognises, however, that there is no single valid approach to cost allocation and that alternative methods may be appropriate where suitable information is available.

5.168 As set out at paragraph 5.122 above, Advanz provided an activity-based costing model in response to the 2017 SO.[869] In order to test the impact of using activity-based costing rather than a purely volume-based allocation, the CMA has applied an adjusted version of Advanz's model to the results of its Cost Plus calculation. Details of its sensitivity assessment are set out in Annex 3.

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[869] Document LIO6361.3, First FTI Report, section 8.

5.169 Applying the activity-based costing method to allocate common costs increases Cost Plus, on average, by £0.67 per pack.[870]

ii. Product Rights valuation

5.170 In response to the 2017 SO, each of HgCapital and Cinven submitted that the use of Teva's entry costs understated the *ex ante* replacement costs of the Product Rights.[871] They submitted that there was a material risk of failure in obtaining the Product Rights and that Teva simply happened to be successful in obtaining the Product Rights the first time.[872]

5.171 While the CMA considers that its methodology in valuing the Product Rights for the purpose of its Cost Plus assessment is appropriate,[873] in response to the Parties' representations to the 2017 SO, the CMA also provides for a sensitivity on the Product Rights valuation to factor in a possible risk of failure (that is the risk that a potential entrant requires more than one attempt) and to reflect uncertainty around the level of investment required to obtain the Product Rights, leading to an upper end valuation of £2.1 million. As set out in paragraphs 3.189 to 3.194 of Annex 3, the CMA's Product Rights sensitivity is very favourable to the Parties.

5.172 To put the Product Rights sensitivity valuation into context, the outcome of the sensitivity assessment [✂] Teva's entry cost and [✂] than Morningside's entry costs. Given that the sensitivity valuation is an order of magnitude higher than the actual costs incurred by actual entrants, it is unlikely to represent the efficient cost of Product Rights.[874] Application of the Product Rights valuation sensitivity increases Cost Plus, on average, by £1.18 per pack.

iii. Reasonable rate of return on capital: WACC

5.173 As explained further in Annex 4, estimating an appropriate WACC is an area of judgement. As a cross-check, the CMA has applied a sensitivity using a 15% WACC, allowing for an additional five percentage points of return on capital above what the CMA has concluded is the appropriate WACC. The

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[870] See CMA's Cost Plus model 'Cumulative sensitivities'.
[871] Document LIO6331, First Cinven CRA Report, paragraph 88; document LIO6259, First HgCapital CRA Report, paragraph 100.
[872] Document LIO6331, First Cinven CRA Report, paragraphs 89–90; document LIO6259, First HgCapital CRA Report, paragraphs 102–104. Both CRA reports applied their 10–15% risk of failure estimate to [✂], reflecting the upper end of the range of entrants' cost estimates, rather than applying 10–15% to Teva's [✂] figure.
[873] See paragraph 5.141.
[874] See Annex 3, paragraphs 3.215-3.218.

CMA considers it appropriate to use the same WACC estimate for the duration of the Infringement Period.

5.174 In carrying out this sensitivity assessment, the CMA has not applied the 15% WACC to working capital because it does not carry the same risk as other capital employed to supply Liothyronine Tablets, as it relates to the amount of capital employed in financing short term assets, net of the capital provided by short term liabilities.[875] As explained in Annex 3, the CMA's approach to determining the level of working capital is very favourable to Advanz as it is based on Advanz's actual working capital despite the fact that the receivables balances resulting from a product being sold at an excessive price do not represent an efficient level of capital employed in the business: the high price inflates the level of receivables proportionately.

5.175 Applying the higher WACC of 15% to Advanz's tangible and intangible fixed assets increases Cost Plus, on average, by £0.56.

iv. Results of Cost Plus with sensitivities

5.176 The combined result of applying sensitivities to Cost Plus with regard to (i) common cost allocation, (ii) the approach to Product Rights valuation and (iii) a reasonable rate of return (i.e. WACC), which cumulatively are very favourable to the Parties, is set out in Table 5.2 below.

Table 5.2: Cost Plus with sensitivities for Liothyronine Tablets 2009-2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017	Simple Average
Cost Plus	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78	4.94
Activity-based costing	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Product Rights sensitivity[876]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
15% WACC	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]	[✂]
Cost Plus with sensitivities	4.94	4.88	6.00	5.02	6.34	7.49	7.51	12.08	11.88	7.35

Source: CMA Cost Plus assessment – 'Cumulative sensitivities' tab.

[875] The CMA continues to apply a 10% WACC to working capital.
[876] Here, the CMA uses the higher of the outturn costs from the two Product Right sensitivities (£2.1 million with no amortisation and £2.1 million amortised over 20 years), which is the scenario where the £2.1 million Product Rights are amortised over 20 years from 2009.

c. Summary of the CMA's Cost Plus assessment

5.177 The overall results of the CMA's costs analysis under the Excessive Limb are set out in Table 5.3 below.

Table 5.3: ASPs for Liothyronine Tablets compared with Cost Plus and Cost Plus with sensitivities 2009-2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017*	Simple average
ASP	20.80	25.66	37.73	45.52	61.84	94.63	146.42	229.23	247.77	
Cost Plus	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78	4.94
Cost Plus with sensitivities	4.94	4.88	6.00	5.02	6.34	7.49	7.51	12.08	11.88	7.35
Note: ASPs are annual averages; the 2017 figure is the average to July 2017.										

Source: CMA Cost Plus assessment – 'Cost stacks post reps' tab.

III. Advanz's prices were materially above Cost Plus

5.178 The CMA concludes that Advanz's prices were at all times materially above Cost Plus during the Infringement Period.[877] This conclusion is based on both (i) the material Differential above Cost Plus; and (ii) the level of profits extracted by Advanz during the Infringement Period from the supply of Liothyronine Tablets, which were far higher than any reasonable level of profit expected for an off-patent generic pharmaceutical drug.

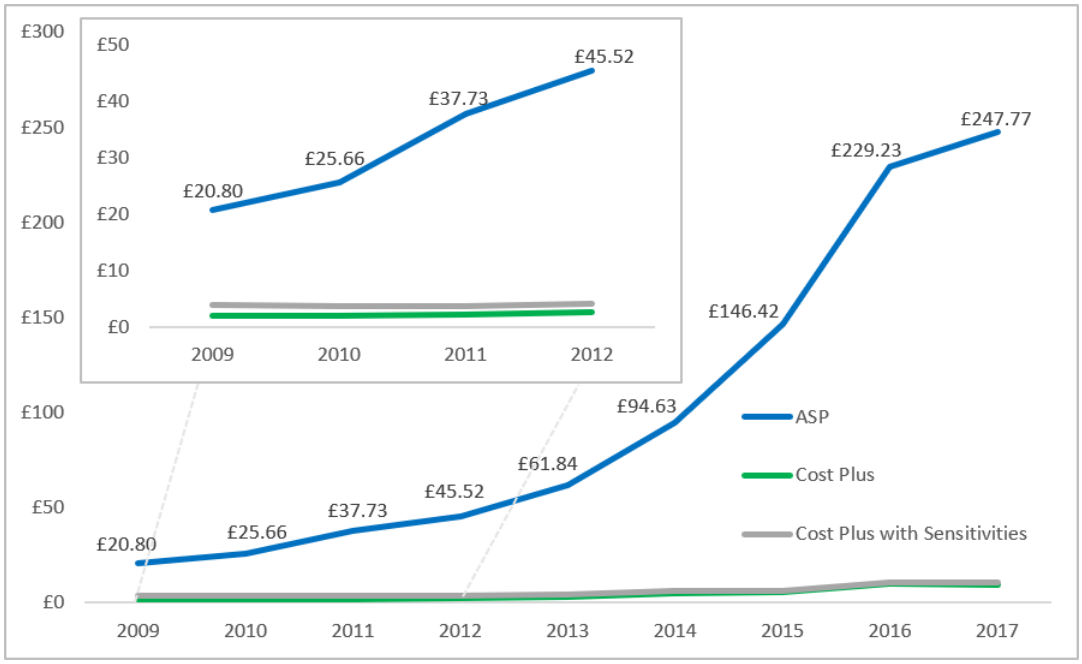
a. The scale of the Differential

5.179 The CMA concludes that the Differential between Advanz's prices and its Cost Plus was material throughout the Infringement Period. The same finding holds true when Advanz's prices are compared with Cost Plus with sensitivities.

5.180 A comparison of Advanz's prices against Cost Plus and Cost Plus with sensitivities is set out in Figure 5.8 below. The inset focuses on the time period between 2009 and 2012 so that greater clarity for that period is provided against the scale of the graph required to capture the overall Infringement Period.

[877] The relevant legal test has been described as 'materiality' in *Albion Water II* [2008] CAT 31, paragraph 199 and 'appreciability' in *Latvian Copyright*, C-177/16, EU:C:2017:689, paragraphs 55 ff.

Figure 5.8: Advanz's ASPs over time compared with Cost Plus and Cost Plus with sensitivities



Note: Data for 2017 cover only January to July.
Source: CMA analysis.

5.181 As set out in paragraph 5.66 above, the assessment of whether a differential is excessive '*involves a proper degree of discretionary judgment by the decision-maker*'.[878] Using its judgement, the CMA concludes that the price differences set out above, both when comparing Advanz's prices with Cost Plus and Cost Plus with sensitivities, are, in the words of the *Albion Water II* judgment, '*sufficiently large to be deemed excessive*' by any reasonable measure and therefore material.[879] This conclusion is based on the sheer scale of the Differential, which increased persistently over the course of the more than 8.5 year Infringement Period[880] and the level of profitability of Liothyronine Tablets over that Infringement Period.

5.182 In exercising its judgement, the CMA has also had regard to the reasons for the large Differential (namely Advanz's systematic price optimisation strategy) as well as differentials that were found to be excessive in earlier cases: *Deutsche Post* (25%);[881] *Albion Water II* (at least 46.8%);[882] and *Napp* (in excess of 80% gross profit margin on sales).[883] These further support the CMA's conclusion that Advanz's prices during the Infringement Period were excessive.

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[878] *Albion Water II* [2008] CAT 31, paragraphs 193–194.
[879] *Albion Water II* [2008] CAT 31, paragraph 199.
[880] Eight years and seven months.
[881] Case COMP/C-1/36915 *Deutsche Post*, paragraphs 166–167.
[882] *Albion Water II* [2008] CAT 31, paragraph 199.
[883] *Napp* [2002] CAT 1, paragraphs 393–405.

i. Scale of Differential above Cost Plus

5.183 The Differential is calculated by deducting Cost Plus from the ASP. Any excess above Cost Plus reflects the economic profits extracted by Advanz. In other words, the prices charged and profits earned above Cost Plus are the excess returns that Advanz's investors received over and above the 10% return allowed for in the CMA's Cost Plus assessment. At their lowest level, the prices charged by Advanz during the Infringement Period (ASP of £20.80 per pack) led to excess economic profits for Advanz of over 900% above Cost Plus.[884]

5.184 Table 5.4 below sets out the Differential per pack in pounds and percentage terms, when prices are compared to Cost Plus. The table also sets out the total revenue differential for each year during the Infringement Period. This is calculated by multiplying the Differential per pack by the number of packs sold in each year.

Table 5.4: Differential above Cost Plus for Liothyronine Tablets 2009-2017

	2009	2010	2011	2012	2013	2014	2015	2016	2017*
Liothyronine Tablets ASP (£)	20.80	25.66	37.73	45.52	61.84	94.63	146.42	229.23	247.77
Cost Plus (£)	2.08	2.10	3.12	2.75	3.99	5.11	5.63	9.87	9.78
Differential (£)	18.72	23.56	34.61	42.77	57.85	89.52	140.79	219.36	237.99
Differential (%)	900%	1119%	1110%	1554%	1449%	1751%	2501%	2222%	2434%
Revenue differential (£m)	2.66	3.33	5.25	6.13	8.79	13.24	21.08	33.89	17.82
Note: Data for 2017 cover only January to July.									

Source: CMA Cost Plus assessment – 'Differentials' tab.

5.185 In 2009 (the first year of the Infringement Period), the Differential based on a comparison between prices charged by Advanz and Cost Plus is £18.72 (900%) per pack, rising to £237.99 (2,434%) per pack in 2017.[885] The figures show that Advanz increased its profits in each full year of the Infringement Period.[886]

5.186 Multiplying the Differential (as defined, the differential between prices charged and Cost Plus) by the number of packs of Liothyronine Tablets sold each year

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[884] £20.80 is the lowest annual ASP; the lowest monthly ASP was £20.48 in January 2009. Cost Plus is calculated as an annual cost figure, so the CMA has calculated the Differential against the annual average ASP for each year.
[885] CMA Cost Plus assessment – 'Differentials' tab.
[886] The profits in Cost Plus also increased in each full year of the Infringement Period, owing to the approach of using actual receivables in working capital. See the returns allowed for in Cost Plus at Table 5.1 and Figure 5.7 above.

provides a total revenue differential of £2.66 million in 2009 (the first year of the Infringement Period) and £33.89 million in 2016 (the last full year of the Infringement Period). The absolute size of the total revenue differential is £112 million over Cost Plus – this is 1,894% higher than the total Cost Plus for all packs sold during the Infringement Period.[887]

ii. Scale of Differential above Cost Plus with sensitivities

5.187 Even when comparing prices charged for Liothyronine Tablets with Cost Plus with sensitivities, the Differential amounts to £15.86 (321%) per pack in 2009 rising to £235.89 (1,985%) per pack in 2017.[888] The figures again show that Advanz increased its profits in each full year of the Infringement Period.

Table 5.5: Differential above Cost Plus with sensitivities

	2009	2010	2011	2012	2013	2014	2015	2016	2017*
Liothyronine Tablets ASP (£)	20.80	25.66	37.73	45.52	61.84	94.63	146.42	229.23	247.77
Cost Plus with sensitivities (£)	4.94	4.88	6.00	5.02	6.34	7.49	7.51	12.08	11.88
Differential (£)	15.86	20.79	31.72	40.50	55.51	87.14	138.91	217.15	235.89
Differential (%)	321%	426%	529%	807%	876%	1163%	1851%	1797%	1985%
Revenue differential (£m)	2.25	2.94	4.81	5.81	8.44	12.89	20.80	33.55	17.66
Note: Data for 2017 cover only January to July.									

Source: CMA Cost Plus assessment – 'Differentials' tab.

5.188 Multiplying the Differential (amended to reflect the difference between prices charged and Cost Plus with sensitivities) by the number of packs of Liothyronine Tablets sold each year leads to a total revenue differential of £2.25 million in 2009 and £33.55 million in 2016. The absolute size of this total revenue differential across the Infringement Period as a whole amounts to £109 million over Cost Plus including sensitivities – this is 1,216% higher than the total Cost Plus including sensitivities for all packs sold during the Infringement Period.

b. The profitability of Liothyronine Tablets during the Infringement Period

5.189 The CMA has compared the actual returns Advanz made on Liothyronine Tablets during the Infringement Period with the CMA's estimate of a reasonable rate of return in this market, i.e. its WACC of 10%. This analysis

[887] CMA Cost Plus assessment – 'Differentials' tab.
[888] CMA Cost Plus assessment – 'Differentials' tab.

shows that Advanz's actual returns were orders of magnitude higher than the CMA's WACC of 10% and significantly higher than a reasonable return that any investor would expect from an investment in Liothyronine Tablets. The profitability measures used in the analysis are:

(a) Earnings before Interest and Tax (EBIT) – this is a measure of Advanz's profitability that takes into account all direct and indirect costs including depreciation and amortisation. It assesses Advanz's profits relative to its revenues; and

(b) Return on Capital Employed (ROCE) – this measure is the ratio of Advanz's EBIT profits relative to the capital investment required to operate in this market. The ROCE metric enables direct comparison with the CMA's cost of capital benchmark (WACC), which reflects the market-based return required to adequately compensate investors for investing in the UK generics market. It establishes a rate of return that takes into account the risks associated with operating in markets like Liothyronine Tablets. Unlike EBIT or other Return on Sales (ROS) profitability measures, it allows for direct comparison with market-based returns.

5.190 Both measures of profitability rely only on the actual prices charged and the actual costs incurred.

Table 5.6: Advanz's EBIT and ROCE returns on Liothyronine Tablets during the Infringement Period

	2009	2010	2011	2012	2013	2014	2015	2016	2017*
Revenues (£)	2.95m	3.62m	5.73m	6.53m	9.40m	14.00m	21.92m	35.42m	18.55m
EBIT (£)	2.82m	3.49m	5.46m	6.36m	9.07m	13.61m	21.63m	34.71m	18.26m
EBIT (%)	95%	96%	95%	97%	97%	97%	99%	98%	98%
Advanz's ROCE (%)	287%	357%	559%	651%	928%	1395%	2213%	3547%	1866%

Notes:
a) EBIT is the revenue less the sum of direct costs, indirect costs, amortisation, and depreciation based on the CMA's Cost Plus.
b) The Infringement Period ended in July 2017; the EBIT profit, and the resulting ROCE margin therefore reflects only part-year profits earned in that year.
c) In calculating Advanz's actual ROCE, the CMA recognises the costs associated with working capital as a finance cost, i.e. Advanz's ROCE is equal to EBIT less working capital costs (which is financed at 10%)÷Advanz's capital employed (based on the CMA's Cost Plus valuation of Product Rights and fixed assets).
d) Advanz's ROCE is to be compared with the CMA's WACC of 10% which is the return that investors would expect to achieve from investing in the UK generics market. For the part-year in 2017, to enable comparison of the actual return with the required return benchmark, Advanz's actual ROCE should be compared the pro-rated required rate of return of 5.8%.

Source: CMA Cost Plus assessment – 'Differentials' tab.

5.191 EBIT margins remained very high throughout the Infringement Period, ranging between 95% and 99% (EBIT margins are bounded at 100%).

5.192 Advanz's ROCE also remained very high throughout the Infringement Period and the actual levels of return that investors received during the Infringement Period were orders of magnitude higher than any reasonable rate of return that any investor could reasonably expect to make in the UK generics market.

5.193 To illustrate the level of actual returns earned by Advanz, it is useful to consider the example of an investor wishing to invest £100 in the UK generics market. Under normal competitive conditions, the investor would likely expect a return of £10 a year on its initial investment, that is, a 10% return – which is the CMA's estimate of Advanz's WACC – on the £100 investment.[889] However, if the investor had placed its capital of £100 with Advanz at the start of the Infringement Period, with the specific aim of supporting the supply of Liothyronine Tablets, that investor would have made a return of £287 in the first year of the Infringement Period. In the following year, the £100 would have yielded a return of £357; and £559 in the year after that. The return on the investment would increase year on year until reaching its peak in 2016 when the investor's £100 would have yielded a return of £3,547 in that year. In total, an investor would have earned £11,804 by the end of the Infringement Period from the £100 invested in 2009.[890]

5.194 This is far higher than the level of return that could reasonably be expected for an investment in a generic, white-pill, off-patent pharmaceutical product in which: (i) the cost of production remained largely stable in absolute terms; (ii) the likelihood of incurring ancillary costs, for example, to improve customer services, was low as purchases were guaranteed from a single, publicly-funded customer; (iii) revenues were predictable as the demand for the product was stable, even in the context of increasing prices; (iv) the level of investment required to sell or market the product was low, as there was no immediate threat of entry from competitors; and (v) the level of capital investment would have remained stable throughout, with no additional investment required to innovate or improve the product given the nature of the product and its users and the underlying market structure.

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[889] See paragraphs 5.126–5.129 for more detail on the CMA's assessment on the required rate of return.
[890] The ROCE margins also remain very high even when the Product Rights valuation is based on the CMA's inflated ex ante replacement cost estimate of £2.1m (amortised over 20 years). The ROCE margins are between 125% and 2580%. Advanz's actual returns are significantly higher than the CMA's benchmark WACC of 10% or the sensitised benchmark WACC of 15%.

IV. Additional representations in relation to Cost Plus

a. Portfolio pricing

5.195 The CMA's Cost Plus analysis assesses the costs of Liothyronine Tablets on an individual product basis. Advanz argues that the '*CMA's product-specific approach to Cost Plus in this case is completely divorced from market reality in the pharmaceutical sector since [Advanz], and the industry more broadly, allocate costs and set prices not on a single product basis but on a portfolio basis*'.[891] It has provided evidence that it claims shows that '*the profitability of [Advanz]'s UK medicine portfolio as a whole was within the well-established PPRS guidelines*'.[892] Cinven also argues that it is common in the pharmaceuticals sector to approach costs, prices and profits on a portfolio basis. It observed that this is implicit in the approach under the PPRS.[893]

5.196 The CMA concludes that it is not appropriate to assess the excessiveness of Advanz's prices on a portfolio basis. The argument fails to take into account the fact that undertakings have a special responsibility for each product in respect of which they have a dominant position (here, Liothyronine 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*'.[894]

b. Allocation of fixed costs in a multi-firm scenario

5.197 The Parties have also argued that if, in a competitive market, there were multiple suppliers of Liothyronine Tablets, the unit costs per supplier would be higher because firms would need to recover fixed costs over lower volumes. Accordingly, the Parties submit that an adjustment to reflect multiple suppliers should be included in the CMA's calculation of Cost Plus,[895] and have each

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[891] Document LIO6288, Advanz RSO, paragraph 6.77.
[892] Document LIO6361.5, [✂] witness statement, paragraphs 62–77.
[893] Document LIO6330, Cinven RSO, paragraph 10.68.
[894] *Napp* [2002] CAT 1, paragraph 413.
[895] Document LIO6361.1, First Compass Lexecon Report, paragraphs 5.28(b) and 5.44; document LIO6331, First Cinven CRA Report, paragraph 111; document LIO6259, First HgCapital CRA Report, paragraph 79.

calculated what they consider to be appropriate costs under such hypothetical conditions.[896]

5.198 The CMA concludes that in accordance with *United Brands* and following the Court of Appeal's judgment in *Phenytoin*, a 'multi-firm' adjustment to Cost Plus is neither necessary nor appropriate. The Court of Appeal has confirmed that '*the first step in the analysis for the excessive limb [of the United Brands test] 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 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 done, there is no reason, based on the applicable authorities, why the authority should not use that methodology to ascertain an appropriate counterfactual for the excessive limb of the analysis. In other cases, it may be necessary to determine the excessive limb by other methods*.'[897]

5.199 The Court of Appeal in *Phenytoin* also confirmed that there is no obligation to arrive at a hypothetical benchmark (in the sense of an artificial construct) in every case and the first step in the analysis for the Excessive Limb is likely in most cases to be an assessment of the costs actually incurred by the dominant undertaking, including a reasonable rate of return.[898] The Court stated that the CMA was not required in considering the Excessive Limb as a matter of law to seek *'"to establish a benchmark price (or range) that would have pertained in circumstances of normal and sufficiently effective competition using the evidence more widely available". Such an approach might be appropriate in some cases, but has not been specifically endorsed by the CJEU in either United Brands or Latvian Copyright (…).'*[899]

5.200 In this case, a Cost Plus assessment based on the *costs actually incurred* by Advanz as the monopolist supplier of Liothyronine Tablets in the UK during the Infringement Period (as opposed to notional costs in a hypothetical multi-

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[896] Document LIO6361.1, First Compass Lexecon Report, paragraphs 5.44 to 5.68; Document LIO6331, First Cinven CRA Report, section 4.2.4; Document LIO6259, First HgCapital CRA Report, section 4.1.1.
[897] CoA in *Phenytoin*, paragraph 252 (emphasis added). Along similar lines, the CoA stated: '*As was pointed out in argument the overarching description of an abuse in United Brands at paragraph [249] is by reference to a comparison with "trading benefits" realised in conditions of normal and sufficiently effective (i.e. workable) competition. This necessarily comparative exercise does not exclude a benchmark premised upon the undertaking's own cost base or an assessment of what an appropriate ROS or ROCE would be for that undertaking.'* - CoA in *Phenytoin*, paragraph 122.
[898] CoA in *Phenytoin*, paragraphs 121 and 252. Green LJ also noted that in *'paragraph [249] [of United Brands] the Court says only that it is "advisable" to ascertain whether the undertaking had exploited its dominance in a way which it could not have "… if there had been normal and sufficiently effective competition", these being the words said to create the requirement for a hypothetical benchmark price. There is no specific reference to price in the paragraph and in any event the expression "advisable" is inconsistent with the Court intending to provide anything more than guidance as to best practice. It would have used more directive language had it intended to lay down a fixed rule*.' (CoA in *Phenytoin*, Green LJ, paragraph 123).
[899] CoA in *Phenytoin*, paragraph 248.

player market which did not exist during the Infringement Period), including a reasonable rate of return (in accordance with the risk profile of the investment), can be carried out.

5.201 It is also an appropriate benchmark for the CMA to rely on in the Excessive Limb in the specific circumstances of this case. In particular, this case does not involve the supply of intangible goods such as IP rights or any other scenario where a cost-price comparison '*might be artificial'*[900] and make '*little sense'*.[901] A Cost Plus assessment based on a single-player market further constitutes an appropriate basis for calculating the level of excess above costs during the Infringement Period: throughout the period, Advanz was, in fact, the sole supplier of Liothyronine Tablets.

5.202 The multi-firm adjustment proposed by the Parties is further addressed as part of the CMA's assessment of the Unfair Limb at paragraphs 5.355 to 5.359 below (Multi-Firm Prices assessment).

c. Alternative comparators proposed by the Parties

5.203 The Parties have proposed a number of additional comparators, which they argue the CMA should take into account in its analysis. The Parties' representations are not all consistent as to where in the analysis the comparators should be applied. However, they include representations that they should be applied in the CMA's assessment under the Excessive Limb of the *United Brands* test.

5.204 Comparators proposed in this context include Post Entry Prices, Entry Plan Prices, Forecast Prices, and prices derived from Cournot modelling. All of these, according to the Parties, establish what the price of Liothyronine

[900] See Court of Appeal in *Phenytoin*, paragraph 78.
[901] See, e.g., AG Wahl in his Opinion in *Latvian Copyright*, C-177/16, EU:C:2017:286.

Tablets may have looked like in conditions of normal and sufficiently effective competition.[902, 903, 904]

5.205 Under the *United Brands* test, in order to establish whether prices charged were excessive within the meaning of the Excessive Limb in circumstances where (like in this case) Cost Plus can be calculated and does not provide an inappropriate counterfactual, it is sufficient for the authority to carry out a Cost Plus calculation, without the need to establish an additional benchmark price or a range of prices.[905] Accordingly, having carried out a Cost Plus assessment, the CMA does not consider it necessary or appropriate to assess any of the additional comparators proposed by the Parties as part of the Excessive Limb of the *United Brands* test.

5.206 However, the CMA has given due consideration to these comparators in section 5.E.IV below.

E. Limb two of the *United Brands* test: Unfair Limb

I. Summary

5.207 The CMA concludes that the prices charged by Advanz for Liothyronine Tablets during the Infringement Period were unfair by reference to the Unfair Limb of the *United Brands* test. In particular, the CMA concludes that:

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[902] See document LIO6259, First HgCapital CRA Report, paragraph 4: '*[T]he SO's analysis, placing reliance on a single "point estimate" cost benchmark, should in any case have been tested against other evidence available on levels of price consistent with competition in the Liothyronine market, and indeed with alternative assumptions on costs that better reflect the market conditions during the Hg period and the specific features of the Goldshield investment. (…) In particular, the competitive price expectations of potential entrants; the actual prevailing prices at which multiple potential rivals started to make serious efforts to enter, and modelled prices in a Cournot setting are all far above the proposed benchmark set out in the SO (…) These alternative benchmarks (…) constitute useful competitive-market benchmarks that should be taken into consideration.*' See also document LIO6258, HgCapital RSO, paragraphs 72 and 73: '*The actual prices charged in a market with three independent competitors provide useful information that the CMA has completely failed to take into consideration in its assessment.*'

[903] Similarly, Cinven argues that comparators other than Cost Plus were relevant to at least three stages of the assessment, including the Excessive Limb (both in order to establish the relevant competitive benchmark price and the significant and persistent 'excessiveness' of prices charged). See document LIO6330, Cinven RSO, paragraph 7.18: '*Such benchmarks are relevant to at least three stages of the assessment:*
(a) First, establishing the relevant competitive benchmark price, which the prices in question must be shown to exceed,
(b) Second, determining whether the difference between the price and the relevant competitive benchmark can reasonably be deemed "excessive", i.e. stage one of the United Brands test [and]
(c) Third, assessing whether an excessive price can also be considered unfair.'

[904] Advanz's RSO emphasises the importance of alternative methodologies or comparators for the Excessive Limb. See document LIO6288, Advanz's RSO, paragraph 6.75: '*(…) there is not a single methodology to examine if pricing is excessive under Limb 1: it can be examined under a Cost Plus analysis, and/or by reference to other methodologies that may be more appropriate taking into account the "specific features" of the case.*'

[905] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 254; see also *ibid* paragraphs 120–125, 185 and 249–250.

(a) There are no demand-side factors which would add (or materially add) to the economic value of Advanz's Liothyronine Tablets (section 5.E.II);

(b) Advanz's prices were unfair in themselves (section 5.E.III); and

(c) There is no reason to consider that Advanz's prices were fair when compared to competing products. In coming to this conclusion, the CMA has evaluated comparators advanced by the Parties and finds that:

(i) While Post-Entry Prices may constitute a *prima facie* valid comparator, in this case the prevailing Post-Entry Prices continue to be significantly inflated by Advanz's abusive exercise of market power during the Infringement Period, and so do not indicate that Advanz's pricing was fair (section 5.E.IV.a); and

(ii) The Parties have not provided evidence which shows that there is any other *prima facie* valid comparator or argument (section 5.E.IV.b).[906]

II. Economic value

5.208 The CMA concludes that there are no demand-side factors which would add (or materially add) to the economic value of Liothyronine Tablets. This means that the economic value of Liothyronine Tablets is captured in the Cost Plus assessment set out in section 5.D.II above. In reaching this conclusion, the CMA finds that:

(a) The price that an unbranded generic medicine can command in the third phase of the drug lifecycle is unrelated to its therapeutic value and is instead primarily driven by the degree of competition faced by suppliers.

(b) In any event, the therapeutic value of Liothyronine Tablets is likely to be no higher than that of Levothyroxine Tablets, which were priced significantly below the Cost Plus of Liothyronine Tablets during the Infringement Period.

(c) The DHSC was not readily willing to pay a premium for Advanz's Liothyronine Tablets above their Cost Plus. The DHSC neither actively approved Advanz's excessive prices nor passively accepted them. Instead, the prices paid reflect Advanz's ability to exercise market power and the lack of any alternative available to the DHSC other than to pay Advanz's prices.

5.209 As set out in paragraph 5.204 above, the Parties have also raised a number of other comparators and arguments as being potentially relevant to assessing the economic value of Liothyronine Tablets, specifically: (i) Post-Entry Prices; (ii) Forecast Prices; (iii) prices derived from Cournot modelling;

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[906] *United Brands*, 27/76, EU:C:1978:22, paragraph 252.

(iv) Entry Plan Prices; and (v) Multi-Firm Prices. For the reasons set out in section 5.E.IV below the CMA concludes that these do not provide evidence of additional economic value beyond that already reflected in Cost Plus.

a. No additional non-cost related factors

i. Liothyronine Tablets' characteristics would not be expected to create enhanced value from the customer's perspective

5.210 Given that Liothyronine Tablets are a very old, unbranded generic drug in the third stage of the drug lifecycle, and given the limited relevance of therapeutic value to the determination of prices during that stage, the CMA does not consider that Liothyronine Tablets can be regarded as offering any '*particular enhanced value from the customer's perspective*'.[907] Accordingly, the characteristics of the product would not be expected to add to the economic value of Advanz's Liothyronine Tablets.

5.211 Once a drug becomes generic (i.e. relevant patent protections have expired), the expectation is that the cost of the innovation that led to its creation has been recouped during the period of any patent protection and any innovation rewarded.[908] As explained at paragraph 5.14 above, the UK pharmaceuticals pricing regime is based on the assumption that generic drugs in the third phase of their lifecycle will become commoditised and that competition between suppliers of these homogenous products will drive prices down toward costs of production. Prices are not determined by the use to which the product is put:

(a) Suppliers of the same drug primarily compete based on price: one supplier's drug will offer no added value versus a rival's homogenous product.[909] This means that effective competition will typically reduce generic drug selling prices and keep them low, as pharmacies seek to purchase at the lowest cost. Ultimately, these lower prices are expected to flow through to the DHSC, to the benefit of patients and the NHS.

(b) The therapeutic value of the drug does not feature in the pricing negotiations between pharmacies and suppliers. Even essential drugs which generate significant (at times life-saving) patient benefits generally become relatively

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[907] *Albion Water II* [2008] CAT 31, paragraph 222.
[908] For a description of the three phases of the drug lifecycle, see paragraphs 3.125ff above. See also document PAD143, EC: '*Pharmaceutical Sector Inquiry Final Report*', July 2009, sections 1.2 and 1.3. See also document PAD213, European Commission: '*Communication from the Commission: Executive Summary of the Pharmaceutical Sector Inquiry Report 2009*', pages 7–9, section 2.1.
[909] See paragraph 5.293 below.

inexpensive in the third phase, with prices close to the costs of production, provided that competition is effective (see paragraphs 5.292 to 5.298 below).

(c) Taken together, this means that the primary driver of price is the degree of competition faced by the suppliers, rather than the therapeutic value of a product.

5.212 Liothyronine Tablets were first marketed in the 1950s and were in the third phase of the drug lifecycle during the entirety of the Infringement Period. In 2007, prior to de-branding, Liothyronine Tablets were sold at the (profitable) ASP of no more than £4.05 per pack.[910] By this point any innovation that had led to their first marketing around 50 years earlier had long since been recouped and any patents had expired at the latest during the 1970s. They were not the subject of any more recent innovation in the decades which followed, including during the Infringement Period.[911] Advanz itself has acknowledged that '*LIO is neither a new breakthrough drug nor an innovative drug*'.[912] Given the product's age and the lack of innovation or meaningful investment, Advanz's Liothyronine Tablets would not be expected to offer any enhanced value from the customer's perspective.

5.213 The fact that Advanz was able to implement and sustain a series of substantial price increases for Liothyronine Tablets which brought ASPs significantly above the costs of production, despite their age and non-innovative character, reflects Advanz's market power and the successful implementation of its price optimisation strategy which is described in Section 5.B.II above (see also further the discussion in section 5.E.II.b: '*Customers were not readily willing to pay a premium*').

ii. Therapeutic value to patients

5.214 Notwithstanding the findings above concerning the limited relevance of therapeutic considerations to the price of a drug in the third phase of the lifecycle, the CMA has also considered whether, in theory at least, the patient benefit, or therapeutic value of a drug may be an example of '*additional benefits*' or '*enhanced value*' which might lead to a product being able to command a pricing premium.[913]

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[910] Despite the absence of competition, pre-debranding, prices remained closer to Advanz's costs of production due to the operation of the PPRS.
[911] To the extent it was appropriate to account for any investments contributing to improvements in Liothyronine Tablets, these have been covered in the CMA's Cost Plus assessment – see section 5.D above.
[912] Document LIO6288, Advanz RSO, paragraph 2.112.
[913] As set out at paragraph 5.87 above, the economic value of a product may be higher than its Cost Plus if there are '*additional benefits not reflected in the costs of supply*' (*Albion Water II* [2008] CAT 31, paragraph 7) or any

5.215 In assessing therapeutic value, it may be instructive to look at the prices being charged in relevant comparator markets which are effectively competitive.[914] The CMA considers that Levothyroxine Tablets are the most appropriate comparator for these purposes, given that they treat the same primary condition as Liothyronine Tablets and they are in the same (tablet) format. It concludes that, while Liothyronine Tablets clearly benefit a significant number of patients (including those with severe or acute conditions, as well as patients who do not respond to Levothyroxine Tablets), their therapeutic value is likely to be no higher than that of Levothyroxine Tablets, which were priced significantly below the Cost Plus of Liothyronine Tablets for the entire Infringement Period.[915] Accordingly, the CMA concludes that the prices of Levothyroxine Tablets support a finding that the economic value of Liothyronine Tablets is captured in the Cost Plus assessment set out in section 5.D above.

5.216 Liothyronine Tablets and Levothyroxine Tablets both treat the same primary condition, relieving the symptoms associated with hypothyroidism.[916] There are, however, certain differences between the two drugs, with each having some advantages over the other.

5.217 In the case of Levothyroxine Tablets:

(a) The drug is the primary choice for treating patients who suffer from hypothyroidism and is in fact suitable for treating a far larger number of people than Liothyronine Tablets.[917]

(b) There appears to be no doubt about the efficacy of Levothyroxine Tablets; however some doubt exists among experts as to the efficacy of Liothyronine Tablets (see paragraph 3.49 above).[918]

(c) Achieving an appropriate dosage of Levothyroxine Tablets appears to be easier than for Liothyronine Tablets. As set out at paragraph 3.48 above, Levothyroxine has a longer half-life than liothyronine, which means it is more stable and Levothyroxine Tablets are more appropriate for once-daily dosing.

5.218 By contrast:

'*particular enhanced value from the customer's perspective*' of that product (*Albion Water II* [2008] CAT 31, paragraph 222).
[914] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 172.
[915] See Table 3.5 and Table 5.1 above.
[916] See paragraphs 3.19-3.20 above. Symptoms typically include weight gain, tiredness, sluggishness and depression.
[917] See paragraph 3.38 above.
[918] The CMA notes that the NHSCC nevertheless decided that Liothyronine Tablets should continue to be prescribed for specific patients (see paragraphs 3.76 to 3.79 above).

(a) Liothyronine Tablets appear to be more suitable than Levothyroxine Tablets for treating severe hypothyroidism, thyroid cancer and myxoedema coma (although it is more common for liothyronine injections to be used for myxoedema coma (see paragraph 3.30 above)).

(b) It appears that there is a relatively small cohort of hypothyroid patients for whom Levothyroxine Tablets are ineffective (see the clinical evidence set out in chapter 3 above). For these patients, Liothyronine Tablets offer a treatment which achieves broadly equivalent therapeutic outcomes to those which Levothyroxine Tablets offer to the vast majority of hypothyroid patients.

5.219 Given that: (i) Liothyronine Tablets and Levothyroxine Tablets treat the same primary condition and, when effective, relieve the same symptoms; and (ii) to the extent that there are differences between the drugs, each has certain advantages *vis-à-vis* the other (and notably, Levothyroxine Tablets appear not to suffer from doubts as to their efficacy and are suitable for treating a far larger number of patients than Liothyronine Tablets), the therapeutic value of Liothyronine Tablets is likely to be no higher than that of Levothyroxine Tablets and, if anything, less. The NHSCC has recognised that the price of Liothyronine Tablets '*has risen significantly and there is limited evidence for efficacy above Levothyroxine*'.[919] This is consistent with Levothyroxine Tablets being for many years the first line treatment for hypothyroidism, reflecting the fact that they are the preferred treatment for patients where a choice is possible.

5.220 Despite this, the ASPs of Levothyroxine Tablets (prior to the suspension of Teva's MA in 2012) were just [✂] to [✂] per pack,[920] whereas the ASPs of Liothyronine Tablets were between £20.80 and £247.87 per pack during the Infringement Period (see paragraph 5.322 below). The prices per pack of Levothyroxine Tablets are significantly lower than the CMA's Cost Plus figures for Liothyronine Tablets and therefore support a conclusion that the economic value of Liothyronine Tablets is not more, or not significantly more, than Cost Plus.

5.221 Cinven submits that second line treatments, reserved for a smaller sub-set of patients, are frequently significantly more expensive than the relevant first line

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[919] Document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', paragraph 4.9.

[920] Based on the prices of 50 mcg and 100 mcg strengths of Levothyroxine Tablet prior to 2012. In 2012, Teva's MA was suspended and so there were only two suppliers. There were only two suppliers of 25 mcg Levothyroxine Tablets until 2016. See section 3.F.II above. Following Teva re-commencing supply of all three strengths in late 2016, prices started to decline but had not stabilised by the end of the Infringement Period. In any event, the highest price of 50mcg or 100mcg tablets during the Infringement Period was £1.07 in 2015, which was also significantly below Cost Plus.

treatment.[921] It does not follow that any particular second line treatment should have a higher economic value than the first line treatment. In referring to Levothyroxine Tablets, the CMA does not suggest that all medicines which treat the same condition should be priced at an equivalent level. One treatment may have a different price (either higher or lower) compared to another treatment for a variety of reasons. For example, a treatment may be cheaper or more expensive to produce, it may or may not benefit from patent protection, it may exist within a more or less mature and competitive market. The true reason underlying any price differential is by its nature highly fact-specific.

5.222 In *Phenytoin* the CAT indicated that it considered that the inherent effectiveness of a drug might lend it economic value (i.e. consumers might reasonably pay a premium for the product because it was effective).[922] The CMA considers that this may well be true for new, innovative products but not for older, generic products. It is not the case that treatments with a greater 'therapeutic value' compared to other treatments (e.g. because they possess a stronger beneficial effect or more longer-lasting beneficial effect or have fewer negative side effects) necessarily command a pricing premium over other treatments. Rather, customers of such medicines will ordinarily drive competition between suppliers and drive prices close to their costs of production, regardless of their clinical benefit, with decisions on treatment already determined by the relevant clinician. As Oxera[923] state (see paragraph 5.293 below), suppliers have observed that where there is more competition, price is the main determinant of the sales they achieve, and they are unable to use brand value or product quality to differentiate themselves. In this third stage of the lifecycle, the ability to inflate prices significantly above costs rests on an absence of effective competition, rather than on customer or clinician views of the therapeutic benefits of a given drug.

5.223 Even if it were the case that drugs with greater therapeutic value could have a higher economic value, in this case Liothyronine Tablets do not provide a significantly different (or superior) therapeutic value compared to Levothyroxine Tablets: the therapeutic benefit of the two products (relief of the symptoms of hypothyroidism) is broadly equivalent and where a choice exists, patients are prescribed Levothyroxine Tablets. If anything, the lack of any doubt about the effectiveness of Levothyroxine Tablets suggests their therapeutic value should be higher than that of Liothyronine Tablets. Accordingly, the CMA infers that there is no reason to attach an additional

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[921] Document LIO12052, Cinven RSSO-2020, paragraphs 7.30-7.33.
[922] *Phenytoin CAT* [2018] CAT 11, paragraph 412.
[923] Oxera Consulting LLP ('**Oxera**').

'premium' above Cost Plus to reflect the 'therapeutic value' of Liothyronine Tablets for those patients who are prescribed Liothyronine Tablets because Levothyroxine Tablets are ineffective for them. While this cohort of patients does benefit from being prescribed Liothyronine Tablets, the benefit that they receive is very similar to the benefit received by patients prescribed Levothyroxine Tablets – for which no equivalent premium is paid – where Levothyroxine Tablets are effective. This indicates that the reason for the 'premium' which Advanz charged during the Infringement period is explained by dependency of the NHS on purchasing from Advanz alone.

5.224 HgCapital also argues that the CMA is wrong to find that '*Liothyronine and Levothyroxine should have the same economic value*' and that the CMA errs by '*[n]ot attributing any economic value*' to the contribution that Liothyronine Tablets makes to the treatment of the cohort of patients for whom Levothyroxine Tablets are ineffective.[924] HgCapital mischaracterises the CMA's position. The CMA does not find that the economic value of Liothyronine Tablets and Levothyroxine Tablets are the same. Indeed, the CMA has found that the economic value of Liothyronine Tablets is not more than (or not significantly more than) its Cost Plus, which at £2.08 to £9.87 per pack during the Infringement Period, is significantly higher than the selling price of Levothyroxine Tablets (and by implication their economic value). As explained in paragraph 5.219, the CMA finds that there is no reason to attribute any *additional* economic value over and above Cost Plus to Liothyronine Tablets based on the therapeutic value it provides to the cohort of patients for whom Levothyroxine tablets are ineffective, because (i) Levothyroxine Tablets remain the preferred treatment for the significant majority of patients and they provide a broadly equivalent benefit when effective; and (ii) the cohort prescribed Liothyronine Tablets is effectively captive and it is their dependency that explains the 'premium' charged rather than any superiority of Liothyronine Tablets over Levothyroxine Tablets (see further the discussion in the following section: '*Customers were not readily willing to pay a premium*').

5.225 Moreover, even if the CMA were to attribute additional economic value (to reflect patient benefit) over and above Cost Plus, given the very high disparity between Cost Plus and Advanz's prices during the Infringement Period, any reasonable adjustment would not change the CMA's analysis (set out in section 5.E.III.a below), that there was a substantial disparity between Advanz's prices and the economic value of Liothyronine Tablets. For

[924] LIO7798 HgCapital RSSO-2019, paragraphs 219 to 223. Similarly, Cinven suggests that the CMA has found that the economic value of Liothyronine Tablets is equal to or less than the economic value of Levothyroxine Tablets (LIO7791 Cinven RSSO-2019, paragraph 9.44).

example, even if an amount equal to the entire price of Levothyroxine Tablets at the relevant time were added over and above the Cost Plus per pack of Liothyronine Tablets (which would clearly significantly overstate any potential additional therapeutic value), this would not change the outcome of the CMA's analysis in this regard.

5.226 HgCapital argues that the CMA should assess therapeutic value by reference to the 'quality adjusted life year' ('**QALY**').[925] Cinven argues that Levothyroxine Oral Solution is a more relevant comparator for assessing the therapeutic value of Liothyronine Tablets than Levothyroxine Tablets.[926] The CMA does not accept these representations, which are addressed in Annex 6.

b. Customers were not readily willing to pay a premium

5.227 The CMA concludes that the ultimate purchasers of Liothyronine Tablets, primarily the DHSC/NHS but also private patients, were not '*readily willing to pay a premium*' for Liothyronine Tablets.[927] Instead, the CMA concludes that the level of prices paid for Liothyronine Tablets were reflective of Advanz's substantial market power.

i. There is no evidence that the DHSC/NHS or private patients were readily willing to pay a premium for Liothyronine Tablets

5.228 Prices paid do not define economic value in an abuse case. It is well-established, and recently confirmed by the Court of Appeal in *Phenytoin*, that the simple fact that customers pay the prices charged by a dominant undertaking does not indicate that those prices reflect the economic value of the product.[928] As explained in paragraph 5.92 above, economic value is not simply whatever price a product or service will fetch or '*the market will reasonably bear*'.[929] Accordingly, the fact that the ultimate customers of Liothyronine Tablets, i.e. the NHS via CCGs and certain private patients, paid the price demanded by Advanz is not in itself evidence of the economic value of that product.

5.229 In fact, there is no evidence to support the contention that the DHSC/NHS (or private patients) were readily willing to pay a premium over Cost Plus for

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[925] Document LIO7798, HgCapital RSSO-2019, paragraph 215.
[926] Document LIO12052, Cinven RSSO-2020, paragraphs 7.31.
[927] See paragraph 5.89 above.
[928] *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 154–155.
[929] *Attheraces CoA* [2007] EWCA Civ 38, paragraphs 205, 210–211. See also *Albion Water II* [2008] CAT 31, paragraph 226, and *Phenytoin CoA* [2020] EWCA Civ 339, paragraphs 154–155.

Liothyronine Tablets or perceived the economic value of Liothyronine Tablets to have increased during the Infringement Period.

5.230 The Parties nonetheless argue that this could be inferred from three pieces of evidence:

(a) Advanz claims that the fact that the NHSCC guidance issued following its consultation in 2017 did not recommend the complete de-prescribing of Liothyronine Tablets was '*clear evidence that the DH/NHS was genuinely willing to pay the price for LIO*'.[930]

(b) Cinven refers to Morningside contacting the DHSC in 2018 regarding its launch of a branded Liothyronine Tablets product and proposing a list price of £168, and argues that there was '*no indication that the DoH perceived this price as too high or that the DoH would be unwilling to pay such a price*'.[931]

(c) Advanz argues that an increase in the NHS Reimbursement Price in April 2019 suggested that '*there is value to the DH/NHS in the price for LIO being increased*'.[932]

5.231 None of these arguments provides any evidence that Advanz's customers were readily willing to pay a premium for Liothyronine Tablets. Where this evidence is relevant at all, it shows that the opposite was true.

- *The 2017 NHSCC guidance*

5.232 The 2017 NHSCC consultation in fact demonstrates that Advanz's prices rose beyond a level which CCGs could sustain and CCGs resorted to attempting to change prescribing patterns in order to mitigate the impact of Advanz's high prices. The consultation took place in the context of clear evidence that CCGs did not consider that Liothyronine Tablets were priced at a reasonable level:

> 'CCGs have been actively pursuing a reduction in Liothyronine prescribing in recent months. […] If prescribing is to be allowed to continue, there should be clear guidance in terms of the thyroid function test results and significant pressure on manufacturers to reduce the price to a reasonable level. At a lower cost, there would be less need to pursue deprescribing of a medication that

[930] Document LIO6288, Advanz RSO, paragraph 6.164. See also document LIO12052, Cinven RSSO-2020, paragraph 7.41; and document LIO6288, Advanz RSO, paragraphs 6.157-6.158.
[931] Document LIO7791, Cinven RSSO-2019, paragraphs 9.64-9.65. See also paragraphs 6.40-6.42 and document LIO12052, Cinven RSSO-2020, paragraph 7.44.
[932] Document LIO7781, Advanz RSSO-2019, paragraphs 8.121 and 8.139.

some patients feel very strongly have had a positive effect on their quality of life.'[933]

5.233 The consultation included Liothyronine Tablets in the category of '*[i]tems which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation*'.[934]

5.234 The NHSCC's consultation followed Liothyronine Tablets' earlier addition to the PrescQIPP DROP-list to encourage GPs to review all patients for suitability for switching to Levothyroxine Tablets (see paragraphs 3.73 to 3.75 above). PrescQIPP's February 2016 bulletin explained that '*Liothyronine features on the DROP-List as an item which is poor value for money and has limited clinical value*'.[935] The document went on to note that '*[s]witching to levothyroxine could release significant savings nationally*'.[936]

5.235 As explained in paragraphs 3.76 to 3.79 above, following the NHSCC's consultation it published guidance for CCGs in November 2017 which sought to reduce prescribing of the drug. Under this guidance, Liothyronine Tablets were retained in the category of drugs '*which are clinically effective but where more cost-effective products are available, including products that have been subject to excessive price inflation*'.[937] However, the guidance departed from the initial recommendation, recognising that Liothyronine Tablets are necessary for some patients. It stated that Liothyronine Tablets should be de-prescribed aside from for '*individuals who, in exceptional circumstances, have an on-going need for liothyronine as confirmed by a consultant NHS endocrinologist*'. The guidance also recommended that new prescriptions should only be initiated by a consultant endocrinologist in the NHS, and not by primary care practitioners (GPs).

5.236 As explained above, there is no particular therapeutic superiority of Liothyronine Tablets over Levothyroxine Tablets. There is, however, a small sub-set of patients who are unresponsive to Levothyroxine Tablets and who derive a therapeutic value from Liothyronine Tablets which is broadly

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[933] Document LIO7789.15, NHSCC: '*Items which should not be routinely prescribed in primary care: Consultation Report of Findings*', page 29 (emphasis added).
[934] Document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', paragraph 4.9.
[935] Document PAD083, PrescQIPP Bulletin 121, February 2016, page 1.
[936] Document PAD083, PrescQIPP Bulletin 121, February 2016, page 1.
[937] Document PAD022, NHSCC: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', page 16 (emphasis added) (the description of Liothyronine Tablets as a drug where there has been excessive price inflation remains in the revised version of this document: Document PAD209, NHS: '*Items which should not routinely be prescribed in primary care: Guidance for CCGs, Version 2*', June 2019, pages 25-26). See also document PAD022, NHS: '*Items which should not routinely be prescribed in primary care: A Consultation on guidance for CCGs*', pages 4, 8, 19–20 and 27–30.

equivalent to the therapeutic value of Levothyroxine Tablets. These patients are in effect dependent on Liothyronine Tablets as they cannot switch to another treatment. But this is different from patients or the NHS being willing to pay a premium. The case of Liothyronine Tablets is very different from a case such as *Scandlines*, where ferry operators chose to operate from Helsingborg because of advantages conferred by that port's geographic location and this may have created additional economic value for those customers. Moreover, in that case a pricing premium may have served to ration a capacity-constrained resource (the port). [✂][938]

5.237 Though Liothyronine Tablets uniquely meet the clinical needs of those patients who are unresponsive to Levothyroxine Tablets, the NHSCC guidance makes clear that the decision not to recommend de-prescribing them for this cohort of patients (only) was taken despite the '*excessive price inflation*' of the drug, which meant its use should otherwise be minimised – not because of any recognition that that price reflected its economic value. This was therefore explicitly not a decision that reflected '*the economic value that the DH/NHS ascribe to LIO at the prevailing price*', as Advanz claimed.[939] Instead it reflected the fact that CCGs had no option but to continue funding the drug at a price that was negatively affecting their ability to provide care, because of the dependency of this cohort of patients. CCGs continued to have no choice but to pay Advanz's prices where Liothyronine Tablets were prescribed.

5.238 The fact that Liothyronine Tablets were added to the DROP-list in 2015 and subject to the NHSCC consultation in 2017 does not indicate that Advanz's customers were readily willing to pay its prices at every point prior to those dates.[940] Instead, it indicates that this was the point at which it became recognised that the prices demanded by Advanz for the product represented poor value for money.

5.239 Where CCGs were no longer willing to fund Liothyronine Tablets for particular patients, Advanz's prices also reached a level beyond that which individual patients could bear, even where they considered themselves unable to switch to Levothyroxine Tablets (see section 5.B.V.a.ii above). The accounts of such patients show that they considered themselves to have little choice but to seek alternative sources of liothyronine (generally unlicensed liothyronine) where their CCGs decided that they were not willing to pay an excessively

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[938] [✂]. See document LIO6435.1, Morningside's response to question 2 of the CMA's s.26 notice dated 11 May 2018.
[939] Document LIO6288, Advanz RSO, paragraph 6.152.
[940] Document LIO7791, Cinven RSSO-2019, paragraph 9.62. The CMA notes that PrescQIPP's decision to add Liothyronine Tablets to the DROP-List was based on 2014 expenditure and therefore 2014 prices.

high price for (licensed) Liothyronine Tablets. It is clear that at least some patients were not willing to pay such high prices for Liothyronine Tablets when procuring them at their own cost, despite their medical need for them. For example, one patient told the CMA that she was not willing to pay '*£1800 for 6 mths supply of liothyronine*'. Rather, she obtained '*the same amount from Germany for £61*'.[941]

- *The 2018 exchange between Morningside and the DHSC*

5.240 The 2018 exchange between Morningside and the DHSC is not informative of the price that the DHSC was readily willing to pay for Liothyronine Tablets during the Infringement Period. It related to a proposed regulated list price for a branded form of the drug under the statutory scheme which provides for a maximum price set by the DHSC[942] – a different scenario from unregulated generic drug prices. In any event, the DHSC made no comment on the acceptability or otherwise of that proposed list price – [✂].[943] The DHSC did not set or approve a price; and Morningside's prices for the version it ultimately launched have fallen considerably [✂], as has the NHS Reimbursement Price.

- *The April 2019 Drug Tariff adjustment*

5.241 As explained at paragraph 3.143 above, the adjustment to the April 2019 Drug Tariff arose as a result of a need to ensure community pharmacy margins were maintained, and applied across the board to Category M drugs. It was not specific to Liothyronine Tablets and did not reflect any assessment or approval of the price of Liothyronine Tablets. Accordingly, it is irrelevant to the economic value of Liothyronine Tablets or the price that the DHSC/NHS is readily willing to pay for them.

ii. Prices paid in fact reflected Advanz's substantial market power

5.242 In contrast to the absence of evidence that Advanz's customers were readily willing to pay a premium for its Liothyronine Tablets, there is a wealth of evidence demonstrating that prices simply reflected Advanz's substantial market power.

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[941] Document LIO7848, Email from [name withheld] to Paul Dean (CMA) dated 20 April 2019.
[942] See the Branded Health Service Medicines (Costs) Regulations 2018.
[943] Document LIO7343, note of call between CMA and DHSC dated 29 August 2018. Document LIO9059, email from CMA to Clifford Chance dated 19 March 2019, provides corrections to figures provided. [✂] document LIO6486.1, Morningside's response to the CMA's s.26 notice dated 30 May 2018.

5.243 Contemporaneous documents discussed in detail in section 5.B above and in Annex 6.2 show that Advanz was aware that the DHSC's policy was to rely on competition to control off-patent, unbranded generic drug prices and not to scrutinise those prices individually, and that Advanz's strategy was to use its market power to exploit this lack of scrutiny and increase prices where competition failed to be effective.[944] For example, in 2014 Advanz stated that it '*benefits from significant pricing power for products with limited or no competition and important clinical need*' and noted that its price increases led to '*no volume impact given the importance of the drugs*'.[945] This lack of competition and DHSC/NHS scrutiny, and the clinical importance of the niche generic drugs Advanz focused on, meant it was able to exploit its market power to increase prices:

> 'NHS cost control focus unlikely to be concentrated on small volume niche segments which would have minimal impact … Price control for drugs with few (1-3) competitors poses a risk of no supply if players exit'.[946]

5.244 Advanz emphasised these points to investors specifically in relation to Liothyronine Tablets, for example in 2012:

> '[Advanz] has a strong market position as the only supplier of Liothyronine tablets in the UK market. … Through its position as sole market provider in the UK, [Advanz] has strong pricing power. Over the last 3 years, [Advanz] has doubled the price of

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[944] See, for example, document LIO0231, Advanz's '*Project Glacier Lenders Presentation_NOTES.pdf*', slides 11,16 and 17: '*Mercury's attractive portfolio (niche, exclusive/semi-exclusive) leads to strong pricing power and ability to extract signifiacnt [sic] margins from the NHS reimbursement mechanism*'; '*On-patent drug cost control will be focus for DoH with limited resources*'; '*System works on an aggregate basis … However on an individual drug basis where there in [sic] no/little competition allows drug producers to increase prices and margin – this is the key element for Mercury with its niche portfolio*'; '*Non-PPRS products not subject to formal price control – limited competitive pressures mean Mercury can drive price increases*'. Elsewhere Advanz noted that '*non-PPRS*' drugs face '*no regulatory price ceiling*' (document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', pages 7 and 52-53). See also document LIO0455, '*AMCo Sep14 - RAP_Final.pdf*', page 6; and document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 13: '*The system is designed to be self-regulating … the Company's unique portfolio of niche products with exclusive / semi-exclusive market positions shields it from the downward pricing spiral mechanism and provides room for continued price increases*'. See further document LIO0232, Mercury Pharma materials presentation, September 2012, slide 10. Document LIO0242, Advanz's '*Project Ampule Rating Agency Presentation_20121108_v03.pdf* slides 14 and 21: Advanz's '*Portfolio comprises low-cost, off-patent products which are not the main focus of healthcare cost reduction initiatives*'. Increasing the prices of such drugs was therefore '*a low risk value lever*' (document LIO6491.1, '*Final recommendations to the Investment Committee*', 30 July 2012, slide 5). When implementing individual price increases, Advanz staff noted their desire not to '*attract DH notice*' or '*catch eyes of DH*' (document LIO0275, Emails from [Advanz Commercial Servies Director] to [Advanz CEO] dated 27 May 2013; document LIO0279, Email from [Advanz employee] to [Advanz Commercial Servies Director] dated 29 May 2013).

[945] Document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', page 23.

[946] Document LIO0493, Advanz's '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 8.

Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases'.[947]

iii. Acquiescence

5.245 Advanz also argues that there can have been no abuse of a dominant position in this case as it did not act unilaterally, but rather the prices of Liothyronine Tablets were the outcome of agreement between Advanz and the DHSC/NHS.[948] The CMA addresses Advanz's argument that this evidence establishes that its conduct was not unilateral in nature in Annex 6.2. As explained in detail there, the DHSC/NHS did not '*acquiesce*' to Advanz's prices. For the avoidance of doubt, Advanz's argument on DHSC/NHS '*acquiescence*' provides no insight into the economic value the DHSC/NHS attached to Liothyronine Tablets or its ready willingness to pay Advanz's prices: it is not the case that the DHSC/NHS considered Advanz's price increases to reflect any enhanced value in the product, that it 'approved' Advanz's prices as reflective of the economic value of Liothyronine Tablets, or that it made an informed decision not to intervene in those prices for that (or any other) reason. The CMA therefore rejects Advanz's argument that '*The DH's/NHS's willingness to pay and the informed decision it took not to intervene reflects the economic value that the DH/NHS ascribes to LIO.*'[949]

c. Factors taken into account by Advanz when setting the price of Liothyronine Tablets

5.246 The CMA asked Advanz what factors it took into account in determining the price of Liothyronine Tablets during the Infringement Period. Advanz responded that it took into account '*the following competitive and regulatory constraints in determining its price […]:*

(a) alternative treatments;

(b) threat of generic entry from other suppliers;

(c) MHRA requirements;

(d) PPRS until Liothyronine ceased to be available under a brand name; and

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[947] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', page 62; see also document LIO0221, '*Glacier Management Presentation_vFINAL.pdf*', page 30; and document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf*', page 47.
[948] See, for example, document LIO6288, Advanz RSO, paragraphs 4.3–4.7, 4.11–4.18 and 4.19–4.65. See also Document LIO6330, Cinven RSO, paragraphs 2.4, 5.79, 5.90, 5.102, 10.13, and 10.65–10.66; Document LIO6258, HgCapital RSO, paragraphs 165, 180 and 183.
[949] Document LIO6288, Advanz RSO, paragraph 6.164.

(e) DH control of pricing through direct intervention to ensure that prices are reasonable under Scheme M'.[950]

5.247 The CMA followed this question up by asking Advanz to identify specific non-cost related factors which it considered had a bearing on the level of selling price justified for Liothyronine Tablets. Advanz submitted that its price for Liothyronine Tablets represented the '*fair economic value of the product*' but did not provide supporting evidence or identify any specific non-cost related factors.[951]

5.248 The CMA concludes that none of the factors raised by Advanz provides '*additional benefits not reflected in the costs of supply*'[952] or any '*particular enhanced value from the customer's perspective*'.[953]

5.249 The Parties made other representations challenging the CMA's conclusion concerning the economic value of Liothyronine Tablets. The CMA rejects these arguments. The Parties' representations, together with the CMA's response, are set out in Annex 6.

III. Advanz's prices are unfair in themselves

5.250 The CMA concludes that Advanz's prices for Liothyronine Tablets during the Infringement Period were unfair in themselves. Advanz was able to exploit its dominant position to set prices which bore less and less relationship to the economic value of Liothyronine Tablets, to the detriment of the NHS and patients.

5.251 In coming to this conclusion, the CMA has had regard to the following factors:[954,955]

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[950] Document LIO3061, Advanz's response to question 25 of the CMA's s.26 notice dated 25 January 2017; see also Advanz's response to questions 7–8.
[951] Document LIO2589, Advanz's response to question 2 of the CMA's s.26 notice dated 27 February 2017.
[952] *Albion Water II* [2008] CAT 31, paragraph 7.
[953] *Albion Water II* [2008] CAT 31, paragraph 222.
[954] With regards to factor (a), the Court of Appeal has made clear that a price which '*significantly exceeds*' the economic value of the product supplied '*will be prima facie excessive and unfair*' (see *Attheraces CoA* [2007] EWCA Civ 38, paragraph 204. See also *Albion Water II* [2008] CAT 31, paragraph 265 where the CAT relied upon the substantial disparity between the First Access Price and economic value as one of the relevant factors supporting the conclusion that such price was unfair in itself). The CAT accepted that factor (b) was relevant in *Albion Water II* [2008] CAT 31, paragraph 266. The CAT accepted that factors (c) to (e) were relevant in *Phenytoin CAT* [2018] CAT 11, paragraph 369. Together, there is no reason why these factors should not be sufficient for an assessment of whether Advanz's prices are unfair in themselves.
[955] Advanz and Cinven argue that there can be no abuse in this case because: (i) the relevant market is capable of self-correcting; and (ii) Advanz's pricing conduct was not accompanied by an exclusionary practice. This submission is incorrect in law. Section 18(2)(a) of the Act is not qualified in these terms, it provides that conduct may constitute an abuse if it consists in '*directly or indirectly imposing unfair… selling prices*…'. See, *inter alia*, document LIO6288, Advanz RSO, paragraph 3.48 and document LIO12052, Cinven RSSO-2020, paragraph 4.4ff.

(a) The substantial disparity between Advanz's prices and the economic value of its Liothyronine Tablets;

(b) The competitive conditions prevailing during the Infringement Period, including the absence of alternative Liothyronine Tablet suppliers, lack of regulatory constraint, high demand inelasticity, high barriers to entry and lack of countervailing buyer power, enabled Advanz to sustain prices which bore no relationship to economic value;

(c) The commercial purpose of Advanz's pricing strategy, which was to exploit the lack of competitive pressure on its pricing resulting from the competitive conditions set out at (b) above;

(d) The increases in price were significant, amounting to a 6,021% increase in Advanz's prices (from £4.05 to £247.87) between the decision to de-brand and Advanz's highest price; and a 1,110% increase over the Infringement Period (from £20.48 to £247.87), with no material increase in production costs or innovation;

(e) Advanz's price increases have had a significant adverse impact on the NHS and patients; and

(f) There is no independent or objective justification for the conduct.

a. The substantial disparity between Advanz's prices and the economic value of its Liothyronine Tablets

5.252 The CMA has found that there are no demand-side factors which would add (or materially add) to the economic value of Advanz's Liothyronine Tablets.[956] In the absence of any relevant non-cost related factors, there was at all times a substantial disparity between Advanz's prices for Liothyronine Tablets during the Infringement Period and the economic value of the product, as Advanz's excesses rose significantly above Cost Plus (and therefore above economic value) from 900% in 2009 to 2,434% for the part year to July 2017 (see Table 5.4 above). The CMA therefore concludes that Advanz's prices significantly exceeded the economic value of Liothyronine Tablets and were, consequently, *prima facie* unfair in themselves.[957]

5.253 Moreover, and as set out at paragraph 5.225 above, even if the CMA were to attribute additional economic value over and above Cost Plus, given the very high disparity between Cost Plus and Advanz's prices during the Infringement

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[956] See section 5.E.II ('*Economic value*') above.
[957] *Attheraces CoA* [2007] EWCA Civ 38, paragraph 204.

Period, this would not change the CMA's conclusion that there was a substantial disparity between Advanz's prices and the economic value of Liothyronine Tablets. As also noted above in paragraph 5.225, even if an amount equal to the entire price of Levothyroxine Tablets at the relevant time were added over and above Cost Plus (which would clearly significantly overstate any potential additional therapeutic value), this would not change the outcome of the CMA's analysis in this regard.

b. The competitive conditions prevailing on the relevant market

5.254 The competitive conditions prevailing on the relevant market during the Infringement Period further support the CMA's conclusion that Advanz's prices were unfair in themselves.

5.255 The competitive conditions prevailing during the Infringement Period are set out in detail in the CMA's assessment of Advanz's dominance (see section 4.C above). They include the absence of alternative Liothyronine Tablet suppliers and high inelasticity of demand, the lack of sufficient constraints from potential entry owing to high barriers to entry (in particular the fact that the product is difficult to manufacture, rigorous regulatory requirements and – at least in the early part of the Infringement Period – the cost of entry relative to the market size) and lack of countervailing buyer power or other regulatory constraint.[958] These competitive conditions which prevailed during the Infringement Period enabled Advanz to sustain prices which bore no relationship to economic value.

5.256 Based on the CMA's conclusion that Advanz was dominant in the UK market for the supply of Liothyronine Tablets, and unavoidable trading partner to the NHS/CCGs, Advanz had a special responsibility not to abuse its dominant position. However, Advanz exploited its market power by imposing and sustaining supra-competitive prices throughout the Infringement Period. The duration of the Infringement Period (more than 8.5 years) shows that prices were not merely '*temporarily high*'.[959]

c. The commercial purpose of Advanz's pricing strategy

5.257 Advanz's price optimisation strategy in relation to Liothyronine Tablets is set out in detail in section 5.B above and further supports the CMA's conclusion that its prices for Liothyronine Tablets were unfair in themselves. In summary, Advanz's price increases for Liothyronine Tablets represent the successful

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[958] See section 4.C.IV above (*Assessment of possible constraints on dominance*).
[959] See paragraph 5.74 above, *Albion Water II* [2008] CAT 31, paragraph 213.

implementation of its price optimisation strategy, which enabled it to remove Liothyronine Tablets from regulatory pricing constraints and take advantage of the lack of competition in relation to Liothyronine Tablets to increase prices with no underlying pro-consumer rationale. As [✂], a Cinven Partner observed in July 2012, shortly before Cinven's acquisition of the Advanz business from HgCapital: the business's '*primary "tail wind" is price increases passed on the payor because of the oligopolistic nature of most segments it operates in, rather than a real growth in volume for each drug*' and the business model relied upon the '*European healthcare systems … under very strong pressures [not reacting because] "it is too below the radar screen/noise"*'.[960]

5.258 Advanz identified Liothyronine Tablets as a suitable candidate for this approach in 2007, prior to the start of the Infringement Period. Within just a few months, Advanz had de-branded Tertroxin, launched unbranded Liothyronine Tablets in a smaller pack size and nearly doubled its price. Within a year of de-branding, Advanz had more than doubled its price again and by January 2009, its ASP for Liothyronine Tablets had reached £20.48. By July 2017, nearly 10 years later, the ASP was £247.87, representing a price increase of 6,021% since September 2007 and 1,110% since the start of the Infringement Period.

5.259 During this period, Advanz's direct costs of supply only increased from an average of £0.35 per pack at the start of the Infringement Period to an average of £3.23 per pack in 2017. There are no other supply-side reasons that could credibly have led to the price increases and the price increases appear to have been entirely independent of cost considerations.

d. The increases in price

5.260 The CMA concludes that the scale of Advanz's price increases over time supports the conclusion that Advanz's Liothyronine Tablet prices are unfair in themselves.

5.261 As both the CAT and the Court of Appeal recognised in *Phenytoin*, the increase in price is a relevant factor when considering the application of the 'unfair in itself' test.[961]

5.262 As noted above at paragraph 5.251(d), Advanz's ASP increased by 6,021% between September 2007 and the end of the Infringement Period, and by 1,110% during the Infringement Period. In September 2007, the ASP was the

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[960] Document LIO6537.23, Email from [✂] [Cinven Partner] to IC Members dated 30 July 2012.
[961] *Phenytoin CAT* [2018] CAT 11, paragraph 369; *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 243.

equivalent of £4.05.[962] Having de-branded the drug, in November 2007 Advanz introduced an ASP of £8.05 per pack. A series of price changes followed until January 2017, when Advanz's ASP reached £247.87.

5.263 Advanz was required, prior to de-branding, to set the price of Liothyronine Tablets at a level which ensured that its overall portfolio of branded products complied with the restrictions on profitability set out in the PPRS (see paragraph 3.138 above).

5.264 Any constraint on Advanz's pricing that may have arisen from the operation of the PPRS did not, however, prevent Liothyronine Tablets from being profitable. Advanz's internal documents show that Liothyronine Tablets were profitable in 2007, before Advanz implemented its strategy to de-brand them, remove them from the PPRS and increase their prices. Indeed, although Liothyronine Tablets were Advanz's tenth largest product by revenues at that time, they were its seventh largest product by gross profit.[963] The scale of Advanz's prices when compared to prices for the same product at earlier points in time (in particular from before the time the drug was de-branded) supports the conclusion that the prices were unfair in themselves.

5.265 The increases in the ASP over the Infringement Period were achieved in respect of a very old drug, which was long off-patent, had been genericised, and in respect of which Advanz had made no material investments or innovations since genericisation.[964] Advanz has added no material additional benefits for patients beyond those already available through Glaxo's Liothyronine Tablets product since the 1950s.

5.266 Advanz's approach towards exploiting its pricing freedom is further illustrated by its strategy in the latter part of the Infringement Period. In 2015, Advanz anticipated (accurately, as it turned out) that entry would occur in July 2017. It forecast this would result in a 50% volume decline and therefore proposed to increase prices just prior to entry.[965]

5.267 This approach (increasing prices prior to entry) had two benefits for Advanz. The first was to gain the greatest possible revenue from Advanz's monopoly position in Liothyronine Tablets prior to price erosion through entry.[966] This

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[962] As noted at paragraph 3.22 above, Advanz reduced the number of tablets per pack from 100 to 28.
[963] Document LIO0010, '*UK Retail Brands Business Plan.doc*', page 2.
[964] To the extent that Advanz incurred costs in relation to its supply chain and regulatory compliance, these costs are captured in the CMA's Cost Plus assessment.
[965] Document LIO0513, Advanz's '*Finance Model 2015 - 2019 GD inputs.xlsx'*, 'Assumptions – 24 Feb' and 'Assumptions – 7 May' tabs.
[966] See [Advanz CEO]'s remarks in an email dated May 2013: ''*[A]ctually think that we should continue with Prednisolone price increase because I am pretty sure that we are going to get competition within the next year or so. … Therefore we should take what we can from it now. I think Liothyronine maybe [sic] a similar story'*.'

increased Advanz's profit above Cost Plus from £21.1 million in 2015 to £33.9 million above Cost Plus in 2016. The second consequence was to inflate the price of Liothyronine Tablets and so influence the entry price of the new entrants, thereby maintaining an artificially high price for a further period in the longer term after entry, albeit with lower volumes.

5.268 Indeed, the sharp increase in prices immediately before entry did lead to the new entrants' prices being higher, as entrants set their prices at a level only slightly below the prevailing prices. Upon entry, Morningside's initial prices for Liothyronine Tablets in August and September 2017 were set just below Advanz's prices in those months.[967] Similarly, Teva's ultimate prices on entry were set near the level of Advanz and Morningside prices, [✂] (see paragraph 5.331 below).

e. Advanz's price increases have had a significant adverse impact on the NHS and patients

5.269 The CMA concludes that Advanz's price increases had a significant adverse impact on the NHS and patients.

5.270 As set out in paragraphs 5.35 to 5.45 above, Advanz's strategy has resulted in the NHS paying significantly more for Liothyronine Tablets than it would have paid absent the Infringement. This has inevitably reduced the money available for other healthcare services.

5.271 Advanz argues that its prices had no adverse effect on the NHS on the basis that the CMA has not identified the detriment caused, and that the NHS benefited from competitive prices on other products in Advanz's portfolio and across the generics industry.[968] Advanz does not explain which prices were reduced as a result of the higher Liothyronine Tablet prices, nor do its internal documents indicate that there was a link between high Liothyronine Tablet prices and lower drug prices elsewhere.

5.272 On the contrary, Advanz's strategy for Liothyronine Tablets was not to '*catch eyes of DH, due to price increase*' – which would not have been necessary if it was seeking to balance its portfolio.[969]

(emphasis added), Document LIO3779, Email chain between (i) [Advanz CEO] and [Advanz Commercial Servies Director] and (ii) [Advanz Commercial Servies Director] and [Advanz employee] dated between 30 May 2013 and 31 May 2013.

[967] Document LIO3973, Morningside's response to question 1 of the CMA's s.26 notice dated 25 September 2017.

[968] Document LIO6288, Advanz RSO, paragraphs 6.208–6.218.

[969] Document LIO0279, Email from [Advanz employee] to [Advanz Commercial Servies Director] dated 29 May 2013.

5.273 Moreover, there is clear harm arising from Advanz's prices, which have resulted in the NHS paying significantly more for Liothyronine Tablets than it would have paid absent the Infringement. Julie Wood, former chief executive of the NHSCC has explained to the CMA that:

> 'the financial impact of the significant price increases of liothyronine will have had effects on patient care, as CCGs will have sought to offset the additional price by changing their other commissioning priorities in order to achieve financial balance or to hit financial control totals. I believe that the impact of having to offset the additional price will have resulted in funds being unavailable for services or increases in thresholds for the other treatments funded by CCGs. It also means there is less available financial resource to invest in new technologies, including new drugs and improvements in patient care.'[970]

5.274 Advanz's prices have also had a significant impact on patients. Some have suffered harm to their quality of life. Others have suffered financial harm. Some patients have turned to self-medicating using unlicensed liothyronine and/or unlicensed NDT. The impact on patients is set out in more detail at paragraphs 5.40 to 5.43 above.

5.275 There is no evidence to indicate that Advanz considered whether it was appropriate and fair for it to significantly increase the price of Liothyronine Tablets and to impose greater costs on the NHS or private patients.

f. Lack of justification

5.276 As set out in further detail in section 5.F below, there is no objective justification for Advanz's pricing conduct in relation to Liothyronine Tablets during the Infringement Period.

g. Representations on the relevance of Post-Entry Prices to the CMA's assessment of whether prices were unfair in themselves

5.277 Cinven submits that the CMA should take account of Post-Entry Prices as a relevant benchmark within its assessment of whether Advanz's prices were unfair in themselves.[971] The CMA rejects this submission. Post-Entry Prices are not the prices which are alleged to be unfair, so they cannot inform an assessment of whether the prices were unfair 'in themselves'. Rather, the CMA assesses Post-Entry Prices in the framework of 'unfair compared to

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[970] Document LIO12042, Julie Lizbeth Wood's witness statement, paragraph 30.
[971] Document LIO7791, Cinven RSSO-2019, paragraphs 8.21 and 8.23(a).

competing products' (see section 5.E.IV.a) and finds that they do not show that the prices charged during the Infringement were fair under the second alternative of the Unfair Limb of the *United Brands* test.

5.278 However, even assuming that Post-Entry Prices did properly fall for consideration within the first alternative of the Unfair Limb, the CMA still concludes that Advanz's prices were unfair in themselves:

(a) As discussed in detail below in section 5.E.IV, the CMA acknowledges that Post-Entry Prices have been generated since the end of the Infringement Period through a process of competition, with three players currently in the market, reducing the price over time from a starting point of £247.87 which resulted from Advanz's decade-long pricing strategy which had driven prices up by 6,021%. However, the prevailing Post-Entry Prices continue to be significantly inflated by Advanz's abusive exercise of market power during the Infringement Period for the reasons explained in section 5.E.IV.a.

(b) The six factors listed at paragraph 5.251 above continue to demonstrate that Advanz's prices were unfair in themselves for the reasons set out in section 5.E.III. Considering the Post-Entry Prices within the framework of the second alternative of the Unfair Limb of the *United Brands* test therefore does not alter the CMA's finding.

IV. Assessment of whether Advanz's prices were unfair compared to competing products

5.279 Having concluded that Advanz's prices for Liothyronine Tablets were unfair in themselves, and given the alternative nature of the Unfair Limb, it is not necessary for the CMA to assess Advanz's prices under the second alternative of the Unfair Limb ('unfair when compared to competing products').

5.280 However, if relied upon by an undertaking in its defence,[972] the CMA is required to fairly evaluate a *prima facie* valid comparator or argument advanced evidentially by the undertaking under investigation that prices were fair compared to competing products as part of its duty of good administration.[973] It may reject comparators so advanced, but should give reasons for doing so.[974] The CMA has therefore considered whether any of the comparators proposed by the Parties amount to a *prima facie* valid comparator or argument and, if so, whether they are meaningful.[975]

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[972] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97(viii).
[973] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 260.
[974] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 273.
[975] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 373.

5.281 The Parties argue the CMA should take into account the following proposed comparators in its analysis: Post-Entry Prices, Cournot modelling, competitors' Forecast Prices, Entry Plan Prices, and Multi-Firm Prices. The Parties' representations were not all consistent as to where in the analysis the comparators should be applied, but they included representations that they should be assessed as competing products for the purpose of an assessment under the second alternative of the Unfair Limb of the *United Brands* test.[976]

5.282 The CMA assesses Post-Entry Prices in section 5.E.IV.a below and the Parties' other proposed comparators in section 5.E.IV.b.

a. Post-Entry Prices

5.283 For the reasons set out below, the CMA finds that Post-Entry Prices may in principle provide a *prima facie* valid comparator or argument for the purpose of assessing whether Advanz's prices of Liothyronine Tablets in the Infringement Period may be fair under the second alternative of the Unfair Limb of the *United Brands* test, because they include prices actually charged for Liothyronine Tablets by Advanz's competitors (see paragraphs 5.288 to 5.291 below).

5.284 The CMA acknowledges that the entry of Morningside and Teva means that there are now competitors in the market for Liothyronine Tablets. This has led to significant declines in ASPs since their peak level under monopoly in July 2017. The Parties claim that the prevailing Post-Entry Prices (the latest available data show [✂] in February 2021) provide a meaningful indication of prices for Liothyronine Tablets in an effectively competitive market. Having carefully evaluated the evidence, the CMA concludes that the prevailing Post-Entry Prices remain contaminated by Advanz's abusive exercise of market power. The process of competition which has taken place has not been sufficient to eliminate the impact of Advanz's abuse. Accordingly, the CMA rejects the Parties' contention that the prevailing Post-Entry Price shows that the prices charged during the Infringement Period were fair under the second alternative of the Unfair Limb of the *United Brands* test.

5.285 The prevailing Post-Entry Price ([✂] in February 2021) has not reached the effectively competitive price level that would be expected in a mature market for the supply of a generic medicine. The term 'mature generics market' is used in this Decision to refer to a market where the effect of the market power held by the original incumbent before the entry of competing manufacturers

[976] For example, see document LIO6330, Cinven RSO, paragraph 7.18.

has been eliminated through the process of competition and in which effectively competitive prices prevail (see paragraphs 5.292 to 5.299):

(a) A mature generics market would be expected to provide for effectively competitive prices, i.e. prices that:

(i) are substantially below the price charged before the entry of competing generic manufacturers;

(ii) fluctuate around a new equilibrium level; and

(iii) are close to (though will typically exceed) the underlying costs of production (see paragraphs 5.292 to 5.299 below).

(b) The current market prices of Liothyronine Tablets have not reached this level. In particular:

(i) prices have consistently declined since entry (see paragraphs 5.300 to 5.301 below).

(ii) price levels for Liothyronine Tablets remain significantly above those which would be expected in mature generics markets (including levels observed in small markets) and bear no relation to costs of production (see paragraphs 5.302 to 5.308 below).

(iii) ongoing attempts by other manufacturers to enter the market would, if successful, be likely to lead to a further downward impact on prices (see paragraphs 5.309 to 5.310 below).

(c) Although more than three and a half years have passed since the entry of competitors (the latest available data is from February 2021), the current market price of Liothyronine Tablets remains contaminated by Advanz's abusive exercise of market power during the Infringement Period:[977]

(i) Prices are sticky and their level continues to be affected by Advanz's pricing conduct – a degree of price stickiness is consistent with observed pricing patterns in other generics markets (see paragraphs 5.311 to 5.316 below).

(ii) In the circumstances of this case, where prices were exceptionally high at the time of entry, competition may be expected to require more time to eliminate

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[977] It is well-known that post-infringement price observations may not be suitable to help estimate an overcharge. See, in the context of infringments of Article 101 TFEU, the discussion at paragraph 153 of the European Commission Staff Working Document '*Practical Guide – Quantifying Harm in actions for damages based on breaches of Article 101 or 102 of the Treaty on the Functioning of the European Union*' SWD(2013) 205 of 11 September 2013.

the impact of the Infringement and to reach effectively competitive levels (see paragraphs 5.317 to 5.319 below).

5.286 The CMA's conclusion that the current prices of Liothyronine Tablets remain inflated by Advanz's abusive conduct does not imply that the prevailing Post-Entry Prices have not been generated through a competitive process, but that the competitive process has not yet had sufficient time to eliminate the impact of the Infringement such as to bring prices to effectively competitive levels.

5.287 These findings are supported by the levels of pricing observed in the supply of Levothyroxine Tablets and in the sale of liothyronine in other countries (see paragraphs 5.321 to 5.326 below).

i. Post-Entry Prices may provide a prima facie valid comparator

5.288 The Parties have all submitted that the CMA has failed to consider Post-Entry Prices and that such pricing is relevant evidence.[978]

5.289 The CMA concludes that Post-Entry Prices are in principle capable of acting as a meaningful comparator.

5.290 On the one hand, Post-Entry Prices represent actual prices paid by customers after the entry of two competing suppliers of Liothyronine Tablets. The Liothyronine Tablets manufactured by Teva and Morningside are identical in all material respects to those manufactured by Advanz[979] and customers do not appear to distinguish between them, suggesting that they are in principle capable of acting as a meaningful comparator. On the other hand, Post-Entry Prices were charged only after the period under investigation and so did not compete with Advanz's prices for Liothyronine Tablets during the period under investigation. Viewing these factors in the round, the CMA concludes that Post-Entry Prices may in principle provide a *prima facie* valid comparator for the purpose of considering unfairness.[980]

5.291 While the CMA accepts that Post-Entry Prices are *prima facie* valid, it remains necessary to establish whether the prevailing Post-Entry Prices constitute a meaningful comparator. This challenge is highlighted by the fact that prices

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[978] See for example, document LIO12043, Advanz RSSO-2020, paragraphs 8.57ff; document LIO12062, HgCapital RSSO-2020, paragraphs 18ff; document LIO12052, Cinven RSSO-2020, paragraphs 5.8ff.
[979] There are some differences between the Liothyronine Tablets manufactured by each of Advanz, Morningside and Teva. For example, the Morningside and Teva products have a shelf life of 24 months, as opposed to 12 months for Advanz's product (see paragraph 3.23 above).
[980] In this regard, evidence which post-dates the impugned conduct may be used to inform the assessment of whether an infringement occurred. By analogy, see *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*.'

have fallen very considerably since the Parties first put the argument to the CMA. In August 2017, when the argument was first made by HgCapital, ASPs were [✂].[981] In September 2018, when Cinven and Advanz also made the argument, ASPs had fallen to [✂].[982] In April 2020, when the Parties once more sought to rely on Post-Entry Prices, ASPs had fallen to [✂].[983] The most recent pricing data available to the CMA reveal ASPs of [✂]. The significant differences in these prices illustrate the need for particular caution when relying on prevailing post-entry prices in the context of this market to inform an analysis of fairness under the Unfair Limb of the *United Brands* test.

ii. Prices in mature generics markets

5.292 To assess whether the latest prices to have emerged in the market for Liothyronine Tablets are consistent with those that would be expected in a mature generic drug market, it is helpful first to set out the expected impact that the introduction of competition has on the supply of generic medicines.

5.293 In the UK, generic competition typically leads to significant declines in prices to levels that are close to the costs of production. These declines in price relative to those prices sustained before entry reflect characteristics of the pharmaceutical sector that lead to intense price competition and markets which often have very low profit margins:

(a) Generic medicines are homogeneous, such that competition between suppliers will inevitably be price-focussed. In its recent report on the supply of generic medicines, Oxera observed that:

(i) '*Companies report that price is the main determinant of the sales they achieve, particularly for commoditised generic products where there are a number of manufacturers. In such cases, suppliers of generic medicines are not able to use brand value or product quality to differentiate themselves. For those products, the price that each supplier receives will be driven by the market as a whole and will therefore be largely out of their control*'.[984]

(ii) '*the competitive interaction between the originator and the generic supplier(s) - as well as between the different generic suppliers if there is more than one - is driven to a large extent by price. Both originators and generic suppliers*

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[981] HgCapital argued that the actual price of [✂] charged by Morningside provided 'useful information', which the CMA should have taken into account (LIO6258 HgCapital RSO, paragraphs 72-73).
[982] Cinven argued that the price of [✂] in September 2018 should be used as an 'informative cross-check' (LIO7791 Cinven RSSO-2019, paragraphs 6.32-6.39). See also LIO7781 Advanz RSSO-2019, paragraphs 7.70-7.79.
[983] Document LIO12043, Advanz RSSO-2020, paragraphs 8.57-8.75; document LIO12062, HgCapital RSSO-2020, paragraphs 35 and 81; document LIO12052, Cinven RSSO-2020, 26 August 2020, paragraph 2.22.
[984] Document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), paragraph 3.21.

compete on the basis of the price that they offer to wholesalers and/or pharmacies (depending on the business model) plus any additional rebates they may offer in order to incentivise them to supply their respective product and therefore gain share'.[985]

(b) The reimbursement mechanisms put in place by the DHSC incentivise pharmacies to dispense the cheapest available product. As observed by Oxera in its report on the sector, '*when faced with an open prescription for a particular molecule, the pharmacy has the incentive to dispense the product with the lowest Price to Pharmacy. This in turn drives price competition between the various suppliers of the relevant branded and generic versions of the relevant product*'.[986]

(c) Low switching costs enable pharmacies and wholesalers rapidly to switch suppliers to obtain the best possible deal, limiting the potential for any supplier profitably to sustain prices that are significantly above those sustained by its rivals.

5.294 Advanz's own documents make similar observations concerning the process of generic competition. A 2012 information memorandum observed that, generally in the UK, '*[a]s the products are interchangeable, the competition pushes un-branded drug providers to compete mainly on price, which in turn lowers the price paid by the NHS. This mechanism successfully drives down the price for the majority of off-patent drugs available and so the NHS pays some of the lowest prices for its off-patent drugs compared to other countries (where [non-branded] prescribing is not as widely encouraged)*'.[987]

5.295 Research in the sector indicates that competition from generic drugs typically results in significant price falls relative to those prices sustained before entry:

(a) A UK trade association found that generic drugs cost between 20% and 90% less than the original price of their brand-name equivalents.[988]

(b) A study by Oxera for the British Generics Manufacturers Association found that, four years after generic entry, prices charged by generic suppliers of a sample of products within Scheme M were on average 70% to 90% lower than the branded price at the time of entry.[989]

5.296 While prices can continue to oscillate, they tend to remain at a low level. The Oxera report observed that '*while the extent and speed of reductions can vary*

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[985] Document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), paragraph 2.13.
[986] Document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), paragraph 2.34.
[987] Document LIO0740, 'Mercury Pharma Confidential Information Memorandum.pdf', page 20.
[988] Document PAD214, British Generics Manufacturers Association: 'About generics'.
[989] Document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), paragraph 4.16.

and prices could increase at a later stage […], the overall average price remains at around 20% of the price of the originator branded product before loss of exclusivity'.[990]

5.297 The Oxera report observed that, such is the intensity of the price-focussed competition that follows generic entry, in some cases prices reduce to below a manufacturer's cost of sales, at least in the short-term.[991]

5.298 This is consistent with the pricing evidence referred to in Figure 5.12 below, which demonstrates that, even for relatively low volume products such as Liothyronine Tablets, generic drugs very rarely cost the NHS more than £10 per pack, and the vast majority cost less than £3 per pack.[992] The manufacturer's selling prices will be lower still, and such price levels necessarily imply low per unit profits.

5.299 Given the features of the sector described above, in a mature generics market, prices would:

(a) be expected to be substantially below the price charged before the entry of competing generic manufacturers;

(b) fluctuate around a new equilibrium level; and

(c) be close to (though they will typically exceed) underlying costs of production.

iii. The price of Liothyronine Tablets has not reached the level that would be expected in a mature generics market with effective competition

- *Prices have consistently declined since entry and have not yet stabilised*

5.300 Since the entry of Morningside in August 2017 and of Teva in September 2017, ASPs for Liothyronine Tablets have decreased from [✂] immediately prior to entry to [✂] in February 2021.[993] As illustrated in Figure 5.9 below,

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[990] Document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), paragraph 4.29.
[991] Document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), paragraph 4.6.
[992] Reimbursement price expressed as equivalent to the price of a pack of 28 tablets or capsules.
[993] CMA analysis of data provided by Advanz, Teva and Morningside. See Advanz's annexes to the CMA's s.26 notices dated 11 May 2018 (document LIO6480.2), 15 October 2018 (document LIO7732), 15 July 2019 (document LIO7815), 8 November 2019 (document LIO7887), 6 May 2020 (document LIO11686) and 8 March 2021 (LIO12183); Teva's annexes to the CMA's s.26 notices dated 11 May 2018 (document LIO6443), 12 October 2018 (document LIO7761), 15 July 2019 (document LIO7817), 8 November 2019 (document LIO7885), 6 May 2020 (document LIO11699) and 8 March 2021 (LIO12182); Morningside's annexes to the CMA's s.26 notices dated 11 May 2018 (document LIO6435.2), 12 October 2018 (document LIO7732), 15 July 2019 (document LIO7812), 8 November 2019 (document LIO7883), 6 May 2020 (document LIO11666) and 8 March 2021 (LIO12177)

prices have continued to fall since September 2017, and there is no evidence that they are stabilising.

Figure 5.9: Liothyronine Tablets ASPs by manufacturer (£ per pack)

[✂]

Source: CMA analysis of data provided by Advanz, Teva and Morningside

5.301 In contrast to the pre-entry ASPs shown in Figures 3.2 and 3.4 above, the post-entry ASPs shown in Figure 5.9 slightly overstate the final prices paid by customers in that they do not take account of the rebates paid by manufacturers on purchases of generic drugs made by some of their customers over certain periods of time. Advanz pays rebates [✂].[994] Morningside and Teva also pay rebates to some of their customers who purchase Liothyronine Tablets, although these are less significant (and in the case of Teva their structure is more complex): Morningside pays rebates [✂];[995] Teva pays rebates [✂].[996] These discounts would not affect the overall trend of declining prices.

- *Price levels for Liothyronine Tablets remain significantly above those which would be expected in mature generics markets (including levels observed in small markets) and bear no relation to costs of production*

5.302 A comparison between the most recent prices of Liothyronine Tablets and prices across a large number of generic drugs shows that current prices remain much higher than would be expected in a mature market.

5.303 In February 2021, the ASP of Liothyronine Tablets was [✂], which is still significantly above the prices of other generic drugs.[997] The CMA has compared the prices of Liothyronine Tablets with a sample of generic drugs which are both in Category M and supplied by members of Scheme M, collected by Oxera.[998] Liothyronine Tablets are currently in Category M, like those in Oxera's sample.[999] Oxera's sample is sufficiently large to make the comparison meaningful.

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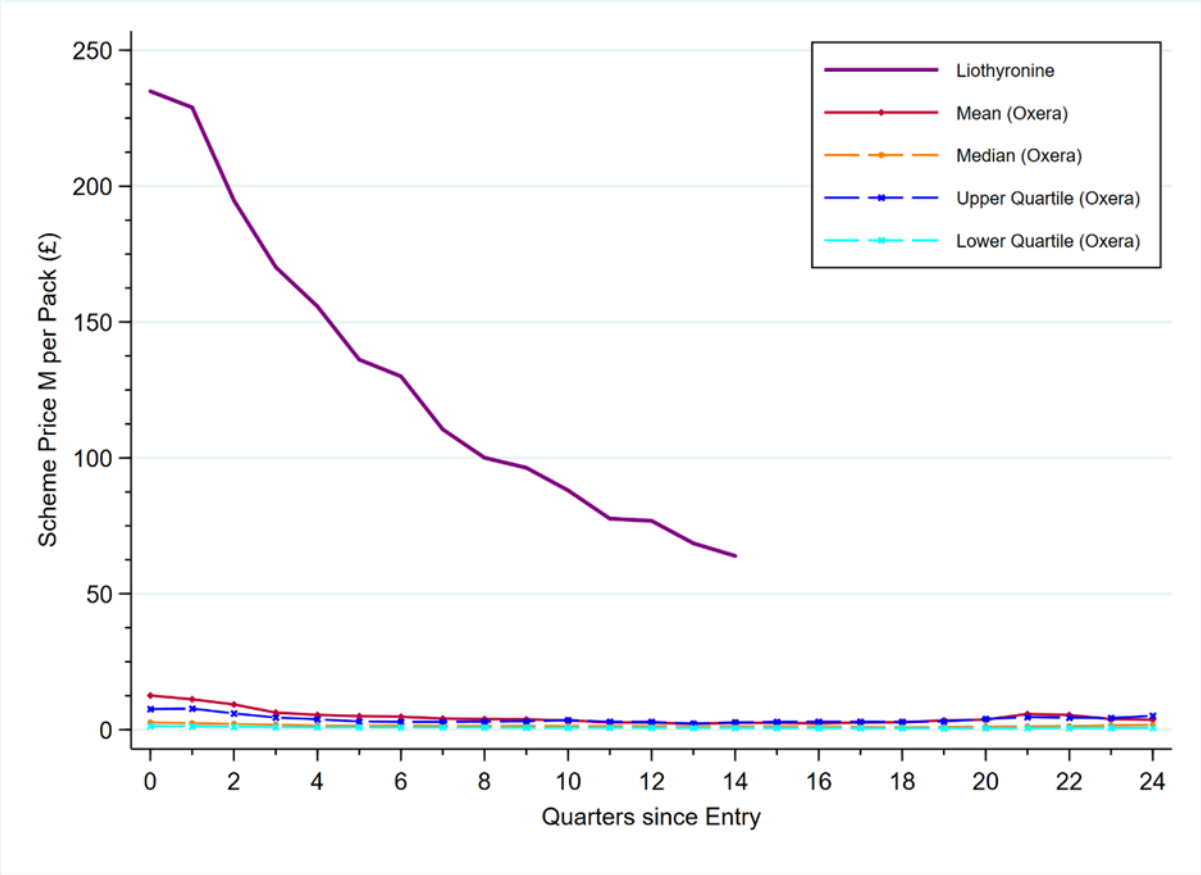
[994] Document LIO12122, Advanz's response to Questions 1 to 4 of the CMA's s.26 notice dated 15 October 2020.
[995] Document LIO12098, Morningside's response to Question 2 of the CMA's s.26 notice dated 9 October 2020.
[996] Document LIO11924, [Director of Portfolio and Pricing, Teva UK] interview transcript, pages 32-33 .
[997] Even assuming an average discount of 6% (which, as explained in paragraph 5.301, significantly underestimates net prices), the ASP of Liothyronine Tablets in February 2021 would be £62 per pack, which is still significantly above the typical prices of generic drugs.
[998] The sample covers 163 molecules. Oxera collected the data as part of a study on competition in the UK market for generic medicines prepared for the British Generic Manufacturers Association, see document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019).
[999] The drugs in Oxera's sample were all in Category M: document LIO7789.13, Oxera Report 'The supply of generic medicines in the UK' (2019), e.g. page 1. Oxera notes that '*the majority of the products in Scheme M are also in Category M*': document LIO12054, Cinven Oxera Report, paragraph 3.8

5.304 Figure 5.10 compares the price of Liothyronine Tablets since September 2017 with the mean, median, upper quartile and lower quartile prices, at each quarter since generic entry, of the drugs in Oxera's sample. The mean price across the sample fluctuates between £2.23 and £12.56 per pack, which is between approximately [✂] and [✂] of the average price of Liothyronine Tablets in February 2021.[1000]

Figure 5.10: The prices of Liothyronine Tablets and of Scheme M drugs



Source: CMA analysis of data collected by Oxera.

5.305 The CMA of course recognises that manufacturing costs are likely to vary between drugs. However, given that Advanz's direct costs of production for Liothyronine Tablets ranged from £0.35 to £3.23 during the Infringement Period, cost differences would be responsible for at most a small part of the difference between the current ASP of Liothyronine Tablets and the average prices of other generic drugs. The CMA also notes that, assuming direct costs of production of £3.23, the current price of Liothyronine Tablets implies a margin of [✂] per pack, which is much higher than the mean, median and

[1000] During quarters 12 to 24, a period which is arguably more relevant to an assessment of long-term generic prices, the mean price across the sample is not higher than £5.78.

upper quartile prices, and therefore the corresponding margins, observed across Scheme M generic drugs.

5.306 Prices (and margins) remain much lower than the current price of Liothyronine Tablets when considering only drugs with an average number of tablet packs dispensed similar to Liothyronine Tablets. To show this, Figure 5.11 presents the price trajectories of all generic drugs in the Oxera sample with between 20,000 and 30,000 tablet packs dispensed every quarter.[1001]

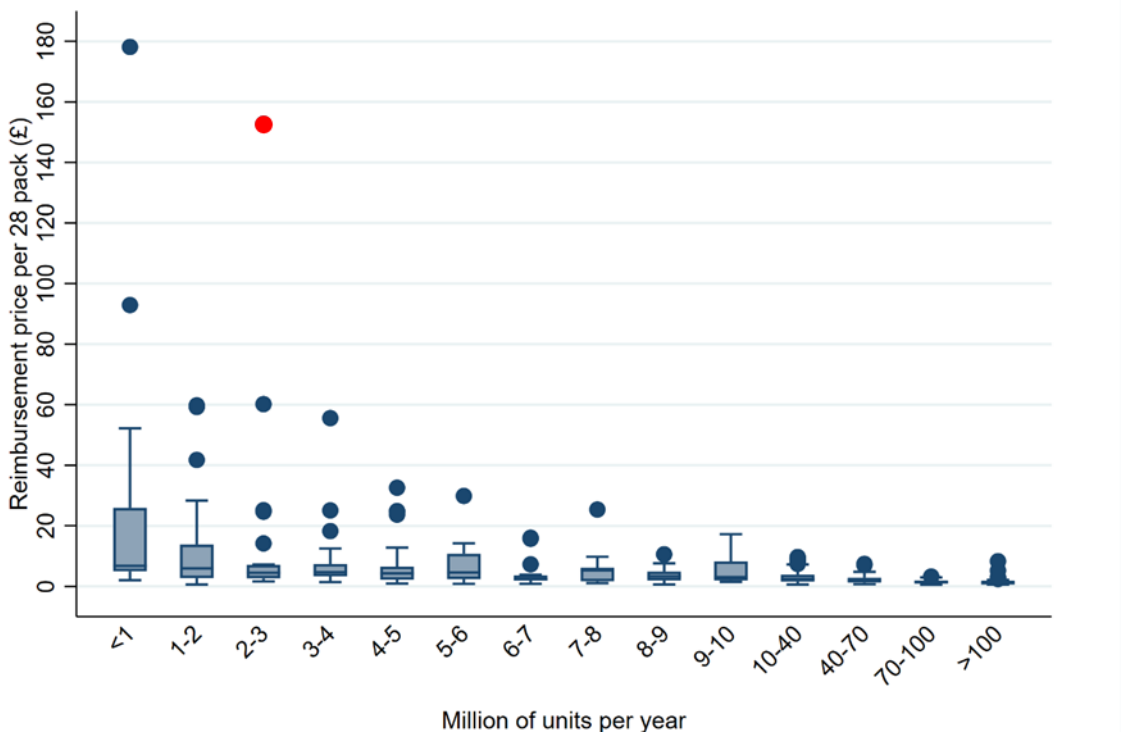
Figure 5.11: The prices of Liothyronine Tablets and of Scheme M drugs with similar market size

[✂]

5.307 The analysis can be expanded to the entire set of Category M drugs sold in tablet or capsule form by considering NHS Reimbursement Prices rather than ASPs. Figure 5.12 shows the distribution of average NHS Reimbursement Prices during 2020 of all Category M drugs in tablet or capsule form (532 in total), disaggregated based on the volume dispensed.[1002] The average NHS Reimbursement Price for Liothyronine Tablets is represented by the red dot. The figure shows that NHS Reimbursement Prices are typically well below £10, even for drugs for which volume dispensed is comparable to that of Liothyronine Tablets. As NHS Reimbursement Prices are typically higher than manufacturer prices,[1003] the ASPs of these drugs would be expected to be lower than the prices shown in the figure.

[1001] [✂].
[1002] This chart can be read as follows: the rectangle of each plot shows the range between the 25th and the 75th percentiles of the distribution; the horizontal line that cuts through the rectangle shows the median; the 'whiskers' that bound the vertical line show the 'adjacent values' (the extreme points of the distribution bar outliers), and the dots show outliers.
[1003] The mechanism used to set the NHS Reimbursement Price of a generic drug is explained in paragraphs 3.141 to 3.146 above.

Figure 5.12: Distribution of NHS Reimbursement Prices over volume intervals under Category M (2020)



Notes:
a) The data include all capsules and tablets listed in Category M between January and December 2020, 532 drugs in total taking into account different strengths of capsules and tablets.
b) The intervals have at least nine different drugs in each of them.
c) Reimbursement price expressed as equivalent to the price of a pack of 28 tablets or 28 capsules.
d) Annual reimbursement price has been calculated as annual NHS expenditure/annual units dispensed.

Source: CMA analysis of PCA data for England only.

5.308 In the third quarter of 2021, the NHS Reimbursement Price for Liothyronine Tablets (£101.29 per pack) was still the second highest among all 660 Category M drugs (the highest one being Primidone).[1004]

- *Ongoing attempts by other manufacturers to enter the market would, if successful, be likely to lead to a further downward impact on prices*

5.309 Two manufacturers – [PE16] and [PE1] – have submitted MA applications for Liothyronine Tablets and decisions by the MHRA on their applications are still pending. As set out at paragraph 3.110 above, [PE16] submitted its MA application in [✂] and [PE1] [✂].

5.310 These ongoing entry attempts, which are both at an advanced stage, are consistent with there being scope for competition to intensify. If one or more of

[1004] See Drug Tariff Part VIII, Category M Prices – Quarter 2 July 2021, available at: https://www.nhsbsa.nhs.uk/sites/default/files/2021-06/part%20viiia%20july%2021.xlsx

these MA applications were to be granted, this would be expected to have a further downward impact on prices.[1005] [✂].

iv. The price of Liothyronine Tablets is still contaminated by Advanz's abusive exercise of market power during the Infringement Period

- *Prices are sticky and continue to be affected by the very high price charged at the end of the Infringement Period*

5.311 The evolution of prices for Liothyronine Tablets indicates that prices do not adjust immediately to competition. Instead, they show a significant degree of stickiness. This implies that, for a significant period after entry, the price of Liothyronine Tablets would continue to be affected by the price charged by Advanz towards the end of the Infringement Period.

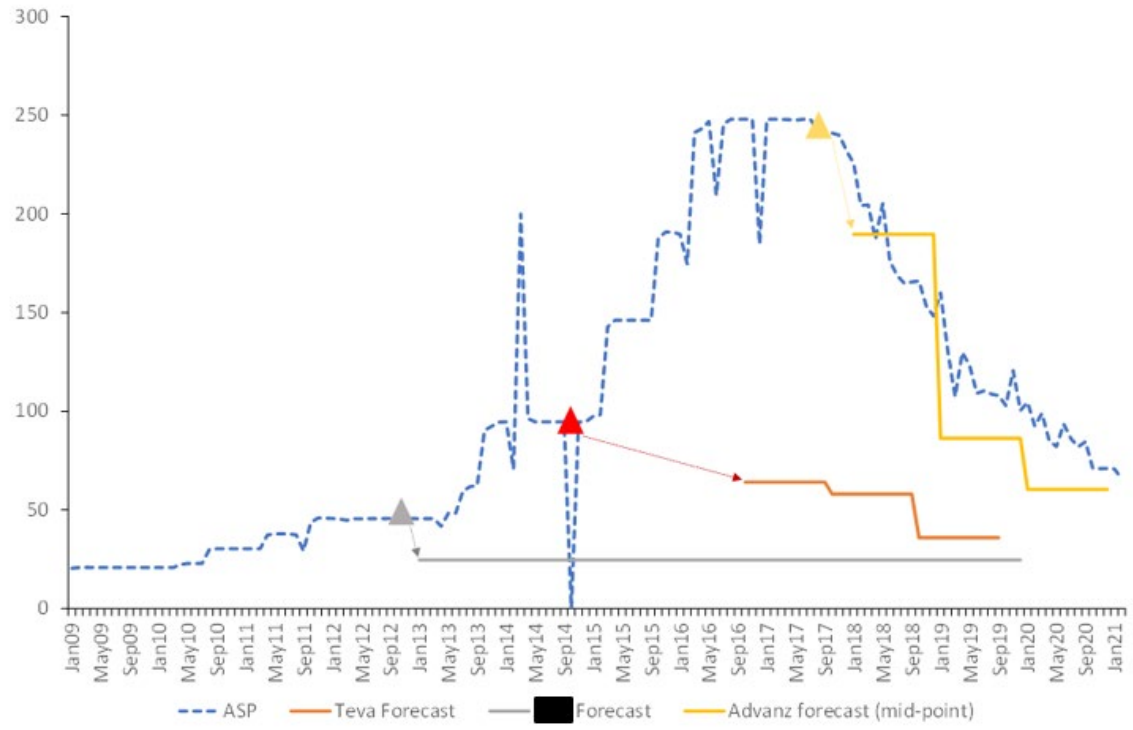
5.312 Price stickiness in the market for Liothyronine Tablets is reflected in the price forecasts made by market participants. Figure 5.13 below shows the price forecasts made by Teva, [PE1] and Advanz prior to market entry; they represent these companies' expectations on the prices of Liothyronine Tablets after entry.[1006] For each forecast, the triangle shows the date at which the forecast was made and the market price prevailing at that date, and the line shows the forecast. If suppliers thought that Post-Entry Prices would simply reflect contemporaneous conditions of competition, then one would expect their forecasts to be fairly similar, irrespective of the date at which they were formulated. Instead, each forecast is 'anchored' in the price prevailing at the time when it was made, and they do not converge to a common price level. This indicates that actual and potential suppliers of Liothyronine Tablets do not expect Post-Entry Prices solely to reflect the contemporaneous conditions of competition, but instead that they expect that prices at any given point in time will reflect the history of prices leading up to that point.[1007]

[1005] This would be consistent with results obtained in the academic literature. For example, Olson and Wendling (2018) find, from an analysis of US data, that the entry of a third competitor (in addition to the original incumbent) has a statistically significant negative impact on price, even in small markets (Olson, L. M., & Wendling, B. W. (2018). Estimating the causal effect of entry on generic drug prices using Hatch–Waxman exclusivity. *Review of Industrial Organization*, *53*(1), 139-172). Grandlund and Bergman (2018), using data from Sweden, find that the effect of the number of firms on prices is well described by constant elasticities; this means that, for example, the percentage effect on generic prices of going from six to nine firms is almost the same as that of going from two to three firms (Granlund, D., & Bergman, M. A. (2018). Price competition in pharmaceuticals–evidence from 1303 Swedish markets. *Journal of health economics*, *61*, 1-12).

[1006] More details on these forecasts are presented in section 5.E.IV.b below.

[1007] [✂]. See Document LIO3321, [PE1]'s response to question 5 of the CMA's s.26 notice dated 30 June 2017.

Figure 5.13: Price forecasts made by market participants



Sources: given in paragraphs 5.330 to 5.334 below.

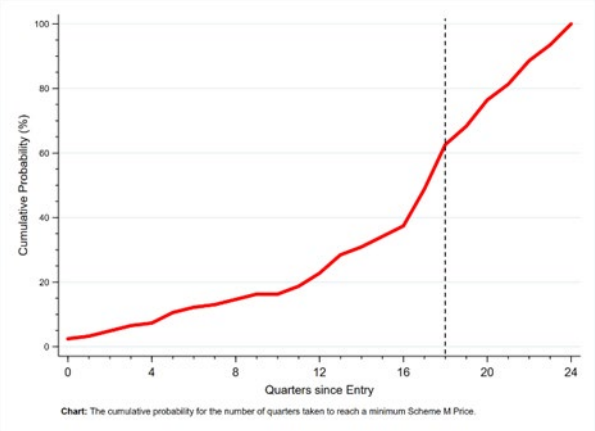
5.313 Price stickiness is common to many generics markets, as can be observed from the data collected by Oxera for a sample of generic drugs regulated under Scheme M. Figure 5.14 below shows the cumulative distribution of observed durations between generic entry and the lowest price observed in the time series for a product.[1008] Generic entry is assumed to correspond to the date when the first Scheme M price is recorded.[1009] Only 23% of products reach their minimum observed price within three years of generic entry, and only 37% of products reach their observed minimum price within four years. The median time taken to reach the minimum price in the sample is 4.5 years (as indicated by the vertical line on the left in Figure 5.14),[1010] while the longest time observed in the sample is six years.

5.314 The CMA acknowledges that, in some cases, the lowest observed price is only recorded for a brief period and may not represent an equilibrium level.[1011] However, even when adding a 20% mark-up to the minimum price, price

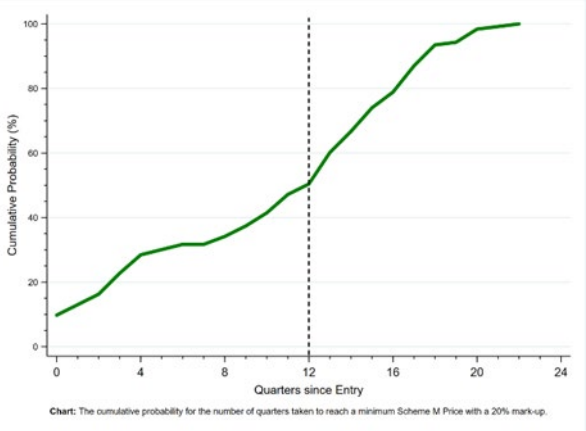
[1008] There might be multiple products for a single molecule, based on different strengths, pack sizes and/or formulations.
[1009] Scheme M is a voluntary scheme, and generic entrants are not necessarily part of it; moreover, some drugs may have been included in Category M sometime after generic entry. In these cases, entry could occur before the first Scheme M price is recorded and the results shown in Figure 5.14 would therefore underestimate the time it takes for the lowest price to be reached.
[1010] The CMA has excluded products for which less than four years of price data is available after generic entry.
[1011] In some cases, low prices may reflect idiosyncratic supply shocks, such as one-off dumping of stock, or price competition temporarily leading to prices below costs, before forcing some of the suppliers out of the market. Data errors are also possible.

Figure 5.14: Distribution of duration between generic entry and lowest price

Duration to minimum price



Duration to minimum price + 20%



Note: each molecule may have several observations based on combinations of strength/packsize/formulation. Date of entry is inferred from the date of the first Scheme M price. Drugs with a Scheme M price in the first quarter of data have been excluded, as entry could have happened earlier. The data are restricted to the observations for which four or more years of price data are available after generic entry. The vertical lines indicate the median time taken to reach the minimum price (on the left) or the minimum price + 20% (on the right).

Source: CMA analysis of data collected by Oxera.

5.315 The underlying data also show that the price paths for individual drugs can exhibit plateaus or spikes before resuming their declines.[1012] The data therefore show not only that the process of adjustment to the introduction of competition can take a long time, but also that it can be irregular and marked by pauses and delays. The ASP of Liothyronine Tablets has itself exhibited temporary plateaus before price declines have then resumed.[1013]

5.316 The 'stickiness' of generic drug prices is consistent with the fact that, when they renegotiate prices, market participants will often take the Drug Tariff as a reference point. For example, AAH told the CMA that its internal target for the purchasing price of products supplied under the 'Hillcross scheme' is to achieve a discount of [✂].[1014] Similarly, Advanz sets the price of drugs supplied under its wholesaling arrangements by reference to the Drug Tariff.[1015] As explained in 3.141 to 3.146, the Drug Tariff is itself constructed

[1012] Examples of molecules whose prices showed plateaus or spikes include Benzydamine, Donepezil, Entacapone, Letrozole, Methylphenidate, Oxcarbazepine and Sildenafil.
[1013] For example, ASPs were in the region of £110 per pack during the months of June 2019 to January 2020. Later, ASPs were in the region of £85 per pack during the months of April 2020 and September 2020.
[1014] Document LIO7878, AAH's response to Question 1 of the CMA's s.26 notice dated 25 October 2019.
[1015] See article 9 of documents LIO1435, '*Alliance Healthcare (Distribution) Limited - Exclusive Wholesaler Distribution Agreement - 01 March 2014.pdf*' and LIO1441, '*Alliance - Dual UK Distribution Agreement - 01 April 2013.pdf*'.

using a trailing average of market prices, so price stickiness is to some extent built into the way drug prices are negotiated in practice.

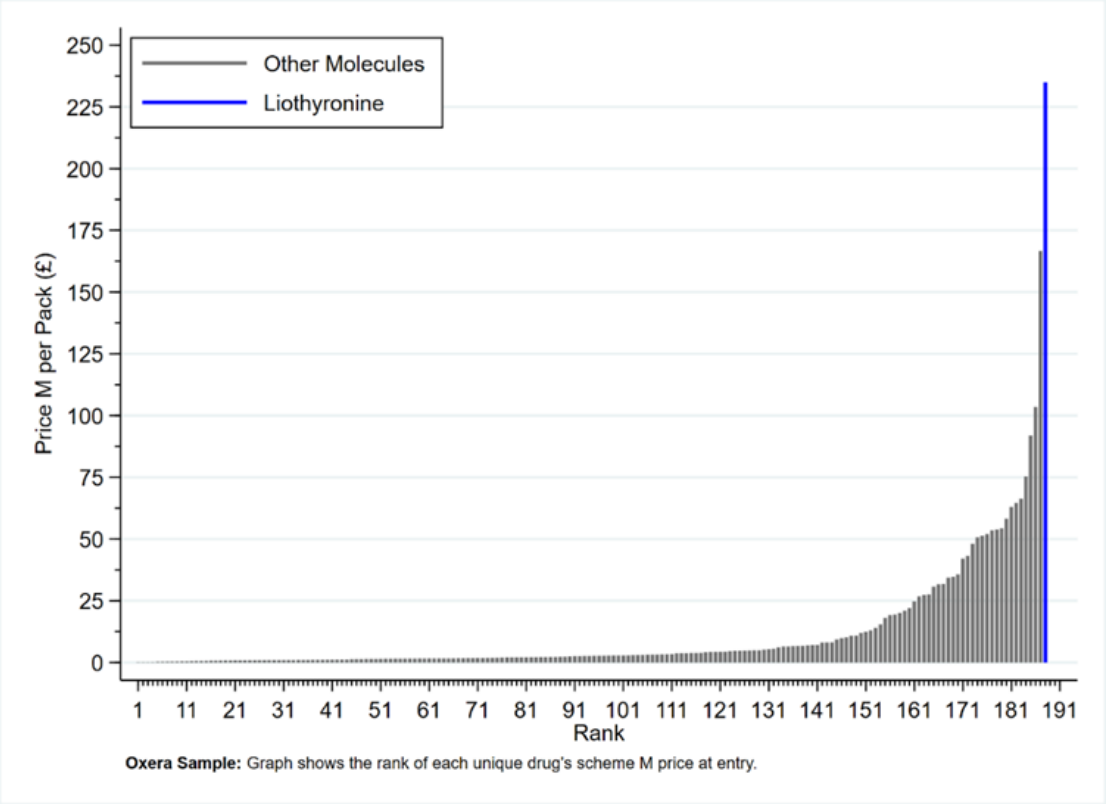
- *Prices were exceptionally high at the time of entry and competition may be expected to require more time to eliminate the impact of the Infringement in order to reach effectively competitive levels*

5.317 The particular circumstances in which new entry occurred for Liothyronine Tablets (notably the price increase of more than 6,000% before entry) indicate that the time before which the minimum price is likely to be reached would be expected to be significantly longer than the median or average time observed in the cases of generic drugs.

5.318 In July 2017, the month preceding the entry of a second supplier (Morningside), the prevailing price of Liothyronine Tablets was extremely high compared to other drugs (with an ASP of £247.87 per pack compared to the production cost of £3.23 per pack). Given the exceptionally high initial price, and stickiness in prices discussed above, competition may be expected to require more time to eliminate the impact of the market power exercised by Advanz before competitors' entry than the average time between entry and the lowest price observed across generic drugs. This is an indication that prevailing Post-Entry Prices significantly exceed the price level which would be expected to prevail in a mature generics market under effective competition.

5.319 Figure 5.15 compares the price of Liothyronine Tablets at the date of entry with the price at the date of entry for any of the generic drugs in Oxera's sample. The price of Liothyronine Tablets at the point of entry is the highest in the sample (by a margin of £68) and is 22 times higher than the mean price (and 90 times higher than the median price) of generic drugs at the date of entry.

Figure 5.15: Price of Liothyronine Tablets compared with other generic drugs at time of entry



Note: each molecule may have several observations based on combinations of strength/packsize/formulation. Tadalafil sold as eight tablets per pack was removed due to it being an outlier. It was only available for three quarters at generic price of £322 - £327 per pack. This price was much higher than Tadalafil sold as four tablets per pack at generic price of £1.45 - £1.68 per pack.

Source: CMA analysis of data collected by Oxera.

v. Prices of other products similar to Advanz's Liothyronine Tablets

5.320 The CMA concludes that the much lower pricing of Levothyroxine Tablets and the pricing of liothyronine in other European countries (Overseas Liothyronine) support the conclusion that Post-Entry Prices do not constitute a meaningful comparator for the purpose of assessing whether Advanz's pricing of Liothyronine Tablets during the Infringement Period was fair.

- *Levothyroxine Tablets*

5.321 As set out at paragraphs 3.38 to 3.47 above, a number of points of similarity can be drawn between Liothyronine Tablets and Levothyroxine Tablets, albeit the differences between them mean that they belong in separate markets.[1016] In particular, Levothyroxine Tablets are the primary treatment for hypothyroidism, the condition which is also treated by Liothyronine Tablets,

[1016] See paragraphs 3.48 to 3.51 above and section 4.B.III above.

and they are both products which are hard to make for essentially the same reasons.[1017] As set out at paragraphs 5.214 to 5.220 above, the therapeutic value of Liothyronine Tablets is likely to be no higher than that of Levothyroxine Tablets.

5.322 However, the prices charged for Levothyroxine Tablets were significantly lower (ranging from [✂] per pack prior to the suspension of Teva's MA in 2012)[1018] compared to Liothyronine Tablets (£20.48 to £247.87 per pack) during the Infringement Period. The differential between Liothyronine Tablet prices and Levothyroxine Tablet prices was significant during the Infringement Period and remained significant following the entry of Morningside and Teva into the market for Liothyronine Tablets. ASPs of all strengths of Levothyroxine Tablets in 2018 were between [✂] (depending on strength) compared with an ASP of Liothyronine Tablets of [✂] in 2018, which had fallen to [✂] by February 2021. The scale of the difference in the prices of these products even after entry is so significant as to cast further doubt on the validity of Post-Entry Prices as a meaningful comparator.

- *Overseas Liothyronine*

5.323 Unlike in the UK, Overseas Liothyronine is generally subject to price regulation[1019, 1020] and there may be different strengths and formulations available in different countries (see paragraph 3.115 above).

5.324 In 2018, the CMA requested information from EEA Member States regarding whether Overseas Liothyronine was licensed for supply in these countries, the price at which it was supplied, the volumes sold and whether the price was constrained by regulation.

5.325 According to the responses received, Overseas Liothyronine is licensed in at least seven EEA Member States, namely the Czech Republic, France, Germany, Malta, the Netherlands, Norway and Sweden.[1021] Information regarding supply in these countries is summarised in Table 3.1 and Table 3.2 above. Evidence from suppliers of 20mcg and 25mcg strengths of Overseas

[1017] See paragraphs 3.35 to 3.37 and 3.47 above.
[1018] See footnote 358 above.
[1019] Most regulatory regimes seek to strike a balance between incentivising innovation and cost-effective pricing for public health bodies.
[1020] In the Czech Republic, where there do not appear to be any such regulatory constraints, the negligible volumes mean that it is unlikely to represent a meaningful comparator.
[1021] See the relevant responses in footnote 231 above.

Liothyronine indicates that they were able to supply it profitably, despite their lower prices.[1022]

5.326 Overall, prices of Overseas Liothyronine in 2018 were significantly below the prices of Liothyronine Tablets in the UK following entry by Morningside and Teva into the market for Liothyronine Tablets (and indeed were below the prices of Liothyronine Tablets throughout the Infringement Period). In 2018, they averaged £7.28 (with a range of £1.58 to £19.23), compared with an ASP of Liothyronine Tablets of [✂] in 2018, which had fallen to [✂] by February 2021. The scale of the difference in the prices of these products even after entry is so significant as to cast further doubt on the validity of Post-Entry Prices as a meaningful comparator.

b. Other comparators advanced by the Parties

5.327 The CMA concludes that the other comparators put forward by the Parties do not provide *prima facie* valid comparators or arguments for the purpose of assessing whether Advanz's prices of Liothyronine Tablets in the Infringement Period may be fair when compared to competing products.

i. Forecast Prices

5.328 Cinven and HgCapital submit that manufacturers' Forecast Prices should be used as a measure of competitive pricing for Liothyronine Tablets.[1023]

5.329 Having evaluated the Parties' representations, the CMA concludes that Forecast Prices do not provide a *prima facie* valid comparator against which to assess whether the pricing of Liothyronine Tablets during the Infringement Period was fair. In particular:

(a) The forecasts in question are likely to have been inflated by Advanz's pricing conduct and its exercise of substantial market power during the Infringement Period; and

(b) The forecasts are short-term in horizon and do not purport to reflect the effectively competitive price level which would prevail in a mature generics market. Their utility is therefore limited.

[1022] Document LIO7874, Takeda's response to the CMA's s.26 notice dated 29 October 2019; document LIO7875, Sanofi's response to the CMA's s.26 notice dated 29 October 2019; document LIO7877, Merck's response to the CMA's s.26 notice dated 4 November 2019.
[1023] See document LIO6331, First Cinven CRA Report, section 3.1.2, and document LIO6259, First HgCapital CRA Report, section 3.1.

- *Overview of Forecast Prices*

5.330 Teva's forecasts were based on the following set of assumptions:

(a) [✂].

(b) [✂].

(c) [✂].

5.331 Based on these assumptions, Teva's predicted prices[1024] were as follows:[1025]

(a) [✂].

(b) [✂].

(c) [✂][1026] [✂].[1027, 1028]

5.332 [✂][1029] [✂][1030] [✂][1031] [✂][1032] [✂].

5.333 Advanz's forecasts[1033] date from 2017 and were based on the following set of assumptions:

(a) Pre-entry price equalled £247.74 in July 2017.

(b) One competitor (Morningside) would enter the market in 2017 and two more (assumed to be Teva and [PE1]) would enter either in 2018 or 2019.

[1024] [✂]: see document LIO6444, Teva's '*66698563_1_Annex 2.xls*', and document LIO6442, Teva's response to question 3(c) of the CMA's s.26 notice dated 11 May 2018.
[1025] These results differ from those reported by HgCapital (document LIO6259, First HgCapital CRA Report, paragraph 60) and Cinven (document LIO6331, First Cinven CRA Report, paragraph 48) in their written representations on the 2017 SO which have been based on an internal presentation from Teva (see document LIO2196, '*45117645_1_Annex 1.pdf *Liothyronine Presentation*' at slide 13), namely: [✂]. The different result in year two is due to a different assumption on the level of competition ([✂]).
[1026] [✂].
[1027] Teva's forecast prices are calculated as [✂]. See document LIO6444, Teva's '*66698563_1_Annex 2.xls*'.
[1028] Teva notes that [✂]. See document LIO6831, Teva's response to question 1(d) of the CMA's s.26 notice dated 2 July 2018.
[1029] See document LIO3325, [PE1]'s '*47278640_1_Annex 2.XLSX*', and document LIO3321, [PE1]'s response to question 2 of the CMA's s.26 notice dated 30 June 2017. For completeness, the CMA notes that [PE1] has provided market projections in documents LIO3324, [PE1]'s '*47278641_1_Annex 1.PPTX*', and document LIO3323, [PE1]'s '*47278638_1_Annex 4.PPTX*'. [✂].
[1030] [✂].
[1031] [✂].
[1032] [✂].
[1033] Document LIO3489, Advanz's response to question 1 of the CMA's s.26 notice dated 30 June 2017; document LIO3489.40, Advanz's '*Annex 19 - Commercial models for generic Liothyronine entry - Liothyronine - 2018-2020 Outlook (draft V1)*', LIO3489.41, Advanz's '*Annex 19 - Commercial models for generic Liothyronine entry - Liothyronine - 2018-2020 Outlook (draft V2)*', and LIO3489.42, Advanz's '*Annex 19 - Commercial models for generic Liothyronine entry - Liothyronine - 2018-2020 Outlook (draft V3)*'.

(c) Level of price reductions through competition was either unspecified, '*moderate*' or '*more significant*'.

(d) NHS England national guidelines remained either unchanged or were formalised.

(e) No DHSC pricing intervention would occur.

5.334 Based on different combinations of the assumptions set out above, Advanz's predicted prices were as follows:

(a) Year 1 (2018): forecasts ranged from [✂] to [✂].

(b) Year 2 (2019): forecasts ranged from [✂] to [✂].

(c) Year 3 (2020): forecasts ranged from [✂][1034] to [✂].

- *Forecast Prices are likely to be inflated by Advanz's pricing conduct and its exercise of its substantial market power*

5.335 The manufacturers' forecasts are likely to have been inflated by Advanz's exercise of substantial market power during the Infringement Period. The manufacturers' forecasts were based on the price prevailing at the time the forecasts were made and estimated changes in prices within the first three years after entry.[1035] As discussed at paragraphs 5.312 above, market participants understood and expected that prices at any given point in time would reflect the history of prices leading up to that point. As a result, the forecasts are likely to be contaminated by Advanz's exercise of its substantial market power. As shown in Figure 5.14 the ASP of Liothyronine Tablets is still falling more than three and a half years after the entry of competitors, and this is not unusual among generic drugs (see paragraph 5.313).

- *Forecast Prices do not purport to reflect an effectively competitive price level*

5.336 The forecasts do not purport to reflect the effectively competitive price level which would prevail in a mature generics market, but only the expected prices in the first three years following the entry of competitors. This means the forecasts are not suitable to predict an effectively competitive price level.

[1034] These are annual ASPs which have been calculated as an average of forecasted monthly ASPs. Given the descending price trend annual figures will overstate the forecasted price at the end of the year.
[1035] [PE1] forecast prices [✂].

5.337 The CMA also notes that even within the confines of their three-year time horizon, the forecasts have certain limitations. Both Teva and [PE1] advised the CMA against treating their forecasts as accurate price predictions. Specifically:

(a) Teva described its model as [✂] and informed the CMA that it [✂] as it was mainly used to provide '*a forecast of the likely demand for a given drug, which can then be used to estimate manufacturing volumes. The tool also gives an indication of possible pricing'* but does not '*in any way determine the selling price'*.[1036]

(b) [✂].[1037]

(c) Advanz's forecasts also appear to be unsophisticated. Its model simply assumed different levels of price decreases, which – as Advanz clarified – '*there is no specific formula or basis for*'. These were based on perceptions of the market at the time rather than credible evidence.[1038]

ii. Cournot modelling

5.338 HgCapital and Cinven have each submitted a Cournot model of competition, which they argue can be used to estimate an equilibrium competitive price. They use the model to estimate prices of Liothyronine Tablets with three competitors at around £126 per pack, falling to £72 to £73 per pack with six competitors and £63 to £64 with seven competitors.[1039] Cinven's economic advisers said that the Cournot model might be '*a pretty good model*' for a product which is difficult to produce such as Liothyronine Tablets.[1040] Similarly, Hg's economic advisers said that the Cournot model was a '*sense-check*' and a simple model which can give '*some indications of price levels that can come out of a competitive process.'*[1041]

5.339 Having evaluated the Parties' representations, the CMA concludes that the results of Cournot modelling do not provide a *prima facie* valid comparator against which to assess whether the pricing of Liothyronine Tablets during the Infringement Period was fair. In particular:

[1036] Document LIO6831, Teva's response to question 1 of the CMA's s.26 notice dated 2 July 2018; document LIO6834, [✂], slide 2.
[1037] [✂].
[1038] Document LIO7734, Advanz's response to question 2 of the CMA s.26 notice dated 17 October 2018.
[1039] Document LIO6259, First HgCapital CRA Report, Table 2; and document LIO6331, First Cinven CRA Report, Table 2.
[1040] Document LIO6677, transcript of Cinven oral hearing of 31 May 2018, p.45, lines 4-9.
[1041] Document LIO6679, transcript of HgCapital oral hearing of 29 May 2018, p.20, line 9 and p.49, lines 19-21.

(a) The Cournot model does not reflect competition in the supply of generic medicines in the real world; and

(b) The results of the modelling are not consistent with the prices typically observed in generic medicines or with observed Post-Entry Prices.

- *Cournot modelling does not reflect competition in generic medicines*

5.340 Cournot competition assumes quantity competition rather than price competition. Under Cournot competition, the production quantity of rivals is relatively fixed so that firms decide what output to produce and then set a single price in order to sell all that output.[1042] These assumptions do not reflect real world competition in off-patent, unbranded generic medicines where capacity is not typically constrained and where multiple prices are negotiated with different customers. As discussed in paragraphs 5.292 to 5.299, markets for generic medicines are typically characterised by intense price competition. Advanz's own documents make similar observations, noting that generally in the UK, '*[a]s the products are interchangeable, the competition pushes un-branded drug providers to compete mainly on price, which in turn lowers the price paid by the NHS*'.[1043]

5.341 [✂].[1044] There are no significant capacity constraints in this respect so rivals cannot take each other's capacity as fixed, as is assumed to be the case in the Cournot model.

5.342 In addition, generic manufacturers typically negotiate different prices with wholesalers rather than setting a single fixed price for all customers.[1045] These negotiations suggest that where there is competition to supply a generic medicine, price is the main parameter of competition rather than capacity.

[1042] Motta, M (2004), '*Competition Policy: Theory and Practice*', pages 556–569.
[1043] Document LIO0740, 'Mercury Pharma Confidential Information Memorandum.pdf', page 20.
[1044] [✂]. See document LIO6435.1, Morningside's response to question 2 of the CMA's s.26 notice dated 11 May 2018.
[1045] See, for example, document LIO11924 [Director of Portfolio and Pricing, Teva UK] (Teva) interview transcript, pages 25-26- document LIO09857, AAH Pharmaceuticals response to question 1 of the CMA's s.26 notice dated 25 October 2019; document LIO8160, '*RE: Advanz August 2019 Price Challenges*'; document LIO8161, '*RE: Advanz October 2019 Price Challenges*'; document LIO8172, '*RE: Morningside August 2019 Price Challenges*'; document LIO09861, Alliance Healthcare response to question 2(iii) of the CMA's s.26 notice dated 29 October 2019; document LIO7871, Phoenix Healthcare response to question 4 of the CMA's s.26 notice dated 25 October 2019; and document LIO11659, [Director of Trading in Generics] and [Director] (Phoenix) interview transcript, pages 13-14 and 48-50.

- *The results of HgCapital and Cinven's Cournot modelling are not consistent with the prices typically observed in generic medicines or with observed Post-Entry Prices*

5.343 Even with the seven competitors modelled by HgCapital, which given the number of current and prospective suppliers is an unrealistic assumption, the Cournot modelling submitted by the Parties predicts mark-ups of at least £62 per pack, over 6,000% of marginal costs.[1046] These mark-ups are far in excess of the fixed costs per pack of Liothyronine Tablets, which did not exceed £6.34 during the Infringement Period.[1047]

5.344 These high mark-ups are a consequence of the assumptions (quantity competition rather than price competition) of the Cournot model and the low price-sensitivity of demand for Liothyronine Tablets.[1048]

5.345 The high prices and mark-ups predicted by HgCapital and Cinven's modelling are not what would be expected for mature generics markets. This can be seen from the prices of other generic drugs in Figure 5.15 above. Figure 5.12 shows that the majority of these drugs have reimbursement prices below £3 per pack of 28 tablets or capsules, and very few drugs have prices above £10 per pack, even in markets characterised by small volumes, outcomes which are inconsistent with HgCapital and Cinven's modelling.[1049] Moreover, NHS Reimbursement Prices are higher than the prices charged by manufacturers, so the ASPs of the drugs would be even lower than the prices shown in Figure 5.12. This demonstrates that the Cournot modelling carried out by the Parties is highly unlikely to reflect pricing dynamics in generic drugs markets.

5.346 The high prices predicted by the Parties' Cournot model are also inconsistent with the observed ASPs of Liothyronine Tablets following entry. With three competitors in the market, the model predicts a price for Liothyronine Tablets of around £126 per pack, almost twice as high as the ASP in February 2021 (see paragraph 5.300 above).

iii. Entry Plan Prices

5.347 HgCapital and Cinven submit that the CMA's approach would result in dominant companies being required to price at a level that would foreclose

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[1046] Assuming marginal costs of £1, the model predicts a price of £63, which gives a mark-up of £62. This mark-up is over 6,000% of marginal costs.
[1047] See Table 5.1. £6.34 is the sum of all bar direct costs for 2017.
[1048] Competition is weaker under the assumption that competition is over quantities rather than prices. See Motta, M (2004), '*Competition Policy: Theory and Practice*', page 558.
[1049] HgCapital and Cinven's modelling is based on simple assumptions (low production costs and low price-sensitivity of demand) that would be equally applicable to many other generic drugs as they are to Liothyronine Tablets.

entry. They submit that the prices which incentivised entry attempts (Entry Plan Prices) provide a potential measure of competitive pricing for Liothyronine Tablets.[1050] HgCapital and Cinven argue that for Liothyronine Tablets, the Entry Plan Price is £45.52 per pack, which was the price prevailing in 2012 when Morningside began its entry efforts.

5.348 Having evaluated the Parties' representations, the CMA concludes that Entry Plan Prices do not provide a *prima facie* valid comparator against which to assess whether the pricing of Liothyronine Tablets during the Infringement Period was fair.

5.349 Contrary to the Parties' submissions, the CMA does not consider that there is a requirement, either in law or in terms of economic logic, for its intervention threshold to enable market entry, where that entry occurs *as a direct consequence* of vastly inflated prices. If the CMA were prevented from intervening when prices are below the entry incentivising level, it would be effectively precluded from intervening in any situation where prices have not attracted entry, even in cases where barriers to entry are very high.[1051] Absent enforcement of the Chapter II prohibition, an incumbent insulated from competition by very high barriers to entry could lawfully extract high economic profits from consumers indefinitely by pricing slightly below the entry-incentivising level. In fact, the greater the barriers to entry protecting an incumbent's market position, the higher the economic profits it could lawfully extract.[1052] This would defeat the purpose of the law against excessive pricing, which is to require companies with significant market power to exercise restraint. Such an interpretation would significantly reduce the effectiveness of the Chapter II prohibition on excessive pricing.

5.350 Cinven argues that Advanz's price increases were not unfair since it implemented them in the knowledge that they would lead to new entry, increased competition, and a subsequent reduction in prices.[1053] The CMA accepts that in an effectively competitive market a temporary period of higher prices, which promptly leads to efficient new entry and to prices returning to

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[1050] Document LIO12062, HgCapital RSSO-2020, section 1.2; document LIO12052, Cinven RSSO-2020, paragraph 2.18.
[1051] The CMA notes that it is not the prevailing starting price point as such which determines whether a rival firm will seek to enter, but rather it is that firm's expectation of how prices will evolve following entry which influences its decision whether or not to attempt entry. In generics markets firms recognise that prices exhibit 'stickiness' (see paragraphs 5.311ff above) and it is price stickiness which enables new entrants to recoup the upfront costs of entry.
[1052] A firm will rationally refrain from entering a market even if it perceives that prevailing prices are substantially above the level that would exist in conditions of normal and effective competition where it anticipates that it will not be able to earn supernormal profits sufficiently long enough for it to recoup the costs of entry. The greater the barriers to entry, the greater will be the costs of entry. Entry is therefore only likely to be incentivised if the glidepath back to effectively competitive prices is particularly long in duration.
[1053] Document LIO12052, Cinven RSSO-2020, paragraph 9.10.

effectively competitive levels within a reasonable period, may not give rise to consumer harm. As the Court of Appeal noted in *Phenytoin*: '*Where there are no material barriers to entry, high prices can act as a magnet to entry which, in due course, drives prices down. Many markets are thus self-correcting.*'[1054] However, the converse is also true: in some markets which are not effectively competitive owing to high barriers to entry or other factors, market forces will not bring about self-correction within a reasonable period. The market for Liothyronine Tablets, which is characterised by high barriers to entry, is such an example. Nine years after the first successful entry attempt was begun prices remain significantly in excess of the level at which the first successful entrant began developing its own product. Specifically, prices were around £45.52 per pack in 2012 when Morningside began its entry attempt, and they were £65.64 per pack nine years later in February 2021.

5.351 If competition takes time to develop, as is likely to be the case in markets with significant barriers to entry, it cannot be assumed that the negative impact of higher prices charged initially will be offset by the positive impact of lower prices charged once entry has been established (either within a reasonable period or at all).

5.352 In the case of Liothyronine Tablets, the DHSC would have been significantly better off if Advanz had not de-branded Liothyronine Tablets and had continued to be subject to the PPRS, even if this would have likely resulted in entry being precluded indefinitely. By way of illustration, if Advanz had charged a price of £4.05 (adjusted monthly for inflation)[1055] from November 2007 onwards, the cost of Liothyronine Tablets for the DHSC would have been £110 million lower than in a scenario where actual prices prevailed until February 2021 and then continued to decrease at the same average rate observed since August 2017 until reaching the level of marginal costs (£3.23

[1054] *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 104. Similarly, the CAT has noted that: '*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.' Albion Water II* [2008] CAT 31, paragraph 213. See also the CAT's comments in *Napp* [2002] CAT 1, paragraphs 390-391, where it approved the DGFT's statement that high profits would only constitute an abuse if they were unlikely to stimulate new entry within a '*reasonable period*'. See also the Commission Enforcement Priorities Guidance, paragraph 16: '*An undertaking can be deterred from increasing prices if expansion or entry is likely, timely and sufficient. … For expansion or entry to be considered timely, it must be sufficiently swift to deter or defeat the exercise of substantial market power*' (emphasis added).

[1055] Using the actual CPI rate (sourced from the Office of National Statistics) until May 2021 and assuming a 2% annual rate of inflation thereafter.

per pack).[1056, 1057] The same would hold true even when comparing the prices actually charged with the lowest price that the CMA has found to infringe the Chapter II prohibition;[1058] that is, if Advanz had de-branded Liothyronine Tablets and indefinitely charged £20.48 from 2009 onwards. In this scenario the DHSC would still have been better off by at least £84 million compared to a scenario where prices fell to marginal costs.[1059]

5.353 The CMA also does not consider that, in the case of Liothyronine Tablets, entry is likely to generate the non-price benefits – increased output, quality improvements, efficiency enhancement, introduction of new and better products – that competition can bring in other markets:[1060]

(a) Since demand for Liothyronine Tablets is inelastic, 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 Liothyronine Tablets are an old and established drug with limited scope for improvement, entry has not resulted in substantially increased quality or better products and is unlikely to lead to production efficiencies large enough to compensate for the higher cost to the DHSC.[1061]

5.354 The emergence of competition is not an end in itself.[1062] In the vast majority of markets, competition is the most effective market structure to promote consumer welfare. However, in the case of Liothyronine Tablets, had Advanz exercised pricing restraint in line with its special responsibility as a dominant supplier rather than abusing its market power, the end consumer would have benefitted even though entry may ultimately not have been incentivised. While similar cases in other markets are often handled under systems of *ex ante*

[1056] The calculation assumes that from March 2021 onwards, the volume of Liothyronine Tablets dispensed monthly would equal the average monthly volume dispensed between September 2020 and February 2021. The other assumptions of the calculation are the same used in a modelling exercise undertaken by and submitted by Advanz (see Compass Lexecon 'Economic observations on the SSO'). In particular, the nominal social discount rate is assumed to be 5.57%. This is obtained using a real social discount rate of 3.5% (as used in the Central Government Guidance on Appraisal and Evaluation), and a long-term inflation rate of 2% (which corresponds to the target set by the Government for the Bank of England). The present value is computed as at October 2007. As the long-term price in the 'factual' scenario is not adjusted for inflation, the calculation under-estimates the difference in the present values of Liothyronine Tablets costs between the 'factual' scenario and the case with no de-branding.
[1057] Even in the unlikely scenario where prices immediately drop to marginal costs immediately after February 2021, the difference would still be high (£103 million).
[1058] As set out at paragraph 5.105, the CMA has not prioritised investigating Advanz's prices prior to January 2009.
[1059] The present value is computed as in January 2009. Even in the unlikely scenario where prices drop to marginal costs immediately after February 2021, the difference would still be high (£76 million).
[1060] See Merger Assessment Guidelines (CMA129), paragraph 2.2.
[1061] In the CMA's view the benefit of any incremental improvement in security of supply and shelf-life that has arisen as a result of new entry is disproportionately small compared to the cost to consumers of stimulating that entry via increased prices.
[1062] The primary interest to be protected under the Chapter II prohibition is that of the consumer: *Albion Water II* [2008] CAT 31, paragraph 218. See also *Attheraces CoA* [2007] EWCA Civ 38, paragraph 215.

regulation (with licensing regimes and price controls), room should be retained to require firms to police their own prices in cases where they hold significant market power, subject to *ex post* enforcement.

iv. Multi-Firm Prices

5.355 The Parties argue that in a competitive market there would be multiple suppliers of Liothyronine Tablets, which would mean that unit costs per supplier would be higher because firms would need to recover fixed costs over lower volumes,[1063] and that the CMA's analysis should be adjusted to take into account this issue. The Parties argue that so-called '**Multi-Firm Prices**' are relevant under both the Excessive and the Unfair Limbs of the *United Brands* test, albeit they do not contend that the multi-firm adjustment can be used to estimate an equilibrium competitive price. The CMA has found that Multi-Firm Prices are not relevant to the assessment under the Excessive Limb of the *United Brands* test for the reasons given at paragraphs 5.197 to 5.202 above. This section evaluates whether Multi-Firm Prices are relevant to the CMA's assessment under the Unfair Limb.

5.356 Having evaluated the Parties' representations, the CMA concludes that Multi-Firm Prices do not provide a *prima facie* valid comparator against which to assess whether the pricing of Liothyronine Tablets during the Infringement Period was fair. As a matter of economic logic, and from the perspective of effective competition policy enforcement, it is not appropriate to apply a multi-firm adjustment.

5.357 Fundamentally, the multi-firm adjustment is flawed because it is premised on the incorrect assumption that the CMA's intervention threshold must leave room for entry (see paragraph 5.349 above). A multi-firm adjustment models the long-run average total costs of a market with more than one participant. Accordingly, a Multi-Firm Price necessarily increases as the number of firms modelled increases and as entry costs increase. In a market which is characterised by high entry costs relative to market size, as is the case for Liothyronine Tablets, applying a multi-firm adjustment would defeat the purpose of the law, which is to require companies with significant market power to exercise restraint.

5.358 Permitting an incumbent to charge a Multi-Firm Price in such a scenario would be perverse as it would enable the incumbent to recoup as pure economic

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[1063] Document LIO12043, Advanz RSSO-2020, paragraphs 7.56 to 7.64 and document LIO7784, Second Compass Lexecon Report, paragraphs 3.24-3.31 and 7.6 to 7.8; document LIO12063, Third HgCapiral CRA Report, paragraphs 11 to 19; document LIO12052, Cinven RSSO-2020, paragraph 8.9, and document LIO12055, Third Cinven CRA Report, paragraphs 100 to 116.

profit the modelled costs of operating in a hypothetical multi-player market. This would result in significant harm to consumer welfare. Accordingly, in such a scenario, the multi-firm adjustment is divorced from economic reality, since the significantly higher prices produced by the adjustment bear no relationship to the incumbent's costs or the product's economic value.[1064]

5.359 In any event, even if a multi-firm adjustment did generate a meaningful comparator (which is not accepted for the reasons outlined above), Advanz's actual prices materially exceed it. For example, a three-player multi-firm adjustment generates a Multi-Firm Price of £12.64 per pack in 2009, rising to £17.89 per pack in 2017.[1065] If three hypothetical firms had charged Advanz's actual prices (£20.80 on average in 2009 rising to £247.77 on average in 2017) they would each have made economic profits of £8.16 per pack in 2009, rising to £229.88 per pack in 2017; these equate to a differential above Cost Plus adjusted for multi-firm of around 65% in 2009, rising to around 1,285% in 2017. Such a multi-firm adjustment significantly understates the actual differential which Advanz earned above its costs (900% in 2009, rising to 2,434% in 2017), since it never incurred the modelled costs of operating in a hypothetical multi-player market.

F. Lack of objective justification

5.360 It is open to a dominant undertaking to provide a justification for behaviour that is liable to be caught by the Chapter II prohibition. A dominant undertaking may do so either by demonstrating that its conduct is objectively necessary or that its conduct produces substantial efficiencies which outweigh any anticompetitive effects on consumers.[1066]

5.361 It is incumbent upon the dominant undertaking to provide all the evidence necessary to demonstrate that the conduct concerned is objectively justified.

[1064] On the other hand, in markets characterised by low entry costs relative to market size, a multi-firm adjustment would not significantly change the results of a Cost Plus analysis, and would therefore be unnecessary.

[1065] In response to the 2017 SO, the Parties proposed a multi-firm adjustment in which the fixed costs would be allocated over 'competitive' volumes (the volume share would depend on the number of firms in the market). See Document LIO6361.1, First Compass Lexecon Report, paragraphs 5.28(b) and 5.44; document LIO6331, First Cinven CRA Report, paragraph 111; document LIO6259, First HgCapital CRA Report,paragraph 79. The CMA applies the Parties' approach and estimates the effect of a multi-firm adjustment on the CMA's sensitised Cost Plus (with the £2.1m Product Rights valuation), i.e. sharing the 'fixed costs' over one-third of the market volumes to reflect a three-player market. It results in a significant increase in the unit cost per pack, increasing from the CMA's sensitised Cost Plus of £4.94 to the multi-firm adjusted Cost Plus of £12.64 in 2009; and from £11.88 to £17.89 in 2017.

[1066] See judgment in case *Post Danmark v Konkurrencerådet*, C-209/10, EU:C:2012:172, paragraphs 40 and 41 and case law cited therein. See also case law cited in the Commission Enforcement Priorities Guidance, paragraph 28.

5.362 As the CAT recognised in *Albion Water II*:

> 'It is for the party alleging an infringement to prove it and not for the dominant undertaking to demonstrate its absence. It is then for the dominant undertaking to raise any plea of objective justification and to support it with arguments and evidence.'[1067]

5.363 The CMA concludes that the Parties have failed to provide any objective justification for Advanz's pricing conduct in this case. In particular, Advanz's prices were not justified by non-cost related factors reflecting '*additional benefits not reflected in the costs of supply*' or any '*particular enhanced value from the customer's perspective*' (see section 5.E.II above).

5.364 Advanz has made no investment in Liothyronine Tablets, other than with respect to packaging and investments which benefitted the business more generally, including [✂], improvements in regulatory compliance and improvements to Advanz's supply chain.[1068] The costs of these items are small and have been captured in the CMA's Cost Plus assessment. In addition, the investments which relate to the business as a whole did not lead to significant price increases in products other than Liothyronine Tablets.

5.365 By contrast with this lack of investment, the cost of Liothyronine Tablets to the NHS soared during the Infringement Period. In 2006, the year before Liothyronine Tablets were de-branded, total NHS spend on Liothyronine Tablets in the UK was only around £604,000 per annum;[1069] by 2009, the first year of the Infringement Period, this figure had grown to more than £2.3 million; and, by 2016 (the last full year in the Infringement Period) the figure had grown to over £30 million.[1070] In addition, there is no evidence to suggest that the substantial Differential identified in Table 5.4 above and the resulting significant increase in cost to the NHS are the result of the creation of any additional benefits by Advanz.

5.366 Advanz has sought to justify its prices for Liothyronine Tablets on the basis that, in the pharmaceutical sector, '*[Advanz], and the industry more broadly, allocate costs and set prices not on a single product basis but on a portfolio basis*'.[1071] As set out at paragraph 5.195 above, it has provided evidence that

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[1067] *Albion Water II*, paragraph 70.
[1068] See Annex 6.3, paragraphs 6.102 to 6.105.
[1069] CMA calculations were based on PCA data for England, Wales, Scotland and Northern Ireland.
[1070] The trend is similar when looking at Advanz's figures, with total revenues of £800,000 in 2007 increasing to £35 million in 2016 (CMA calculations based on data submitted by Advanz).
[1071] Document LIO6288, Advanz RSO, paragraph 6.77.

it says would show that '*the profitability of [Advanz's] UK medicine portfolio as a whole was within the well-established PPRS guidelines*'.[1072]

5.367 The CMA concludes that Advanz's argument that pricing for Liothyronine Tablets should be assessed on a portfolio, rather than an individual, basis is contrary to clear precedent relating to the pricing of pharmaceuticals by undertakings in relation to products in which they hold a dominant position (see paragraph 5.196 above).[1073]

G. Other matters

I. No exclusions

5.368 The CMA finds that no exclusions from the Chapter II prohibition apply to the Infringement as a result of Section 19 of the Act or as a result of Schedules 1 or 3 of the Act.

II. Effect on trade

5.369 The Infringement was implemented in the UK and had an effect on the price paid in the UK for Liothyronine Tablets. Accordingly, the CMA finds that the Infringement affected trade in the buying and selling of drugs within the whole or part of the UK.[1074]

[1072] Document LIO6361.5, [✂] witness statement, paragraphs 62–77.
[1073] *Napp* [2002] CAT 1, paragraphs 406–426.
[1074] The Chapter II prohibition applies only to conduct by a dominant undertaking which may affect trade within the UK: section 18(1) of the Act. For the purposes of the Chapter II prohibition, the UK includes any part of the UK: section 18(3) of the Act. To infringe the Chapter II prohibition, a dominant undertaking's conduct does not actually have to affect trade as long as it is capable of doing so. See, for example, *Irish Sugar plc v Commission*, T-228/97, EU:T:1999:246, paragraph 170. There is also no need for the effect on trade within the UK to have been appreciable: *Aberdeen Journals* [2002] CAT 4, paragraphs 459 and 460.

6. Undertaking and attribution of liability

A. Summary

6.1 The CMA finds that during the Infringement Period, the following entities constituted an undertaking for the purposes of the Chapter II prohibition, referred to as Advanz:

(a) From at least 1 January 2009 to 29 December 2009, Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited and Mercury Pharma Group Limited (together, the Mercury Pharma Companies);

(b) From 30 December 2009 to 30 August 2012, the Mercury Pharma Companies and HgCapital LLP (referred to as HgCapital);

(c) From 31 August 2012 to 20 October 2015, the Mercury Pharma Companies, Cinven Capital Management (V) General Partner Limited, Cinven (Luxco 1) S.A. and Cinven Partners LLP (together, the Cinven Entities); and

(d) From 21 October 2015 until 31 July 2017, the Mercury Pharma Companies and Advanz Pharma Corp (formerly known as Advanz Pharma Corporation and Concordia International Corporation).

6.2 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 undertaking that supplied Liothyronine Tablets in the UK at excessive and unfair prices.

6.3 In summary, and as explained in the sections that follow:

(a) Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited directly participated in the Infringement.

(b) Each of Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited was wholly owned by Mercury Pharma Group Limited throughout the Infringement Period. The *Akzo* presumption (see paragraph 6.22 below) therefore applies between Mercury Pharma Group Limited and each of Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited and has not been rebutted, such that they formed a single undertaking.

(c) From 30 December 2009 until 30 August 2012, the Mercury Pharma Companies were majority owned by HgCapital. The *Akzo* presumption does not apply. However, for the reasons explained in section 6.F below, the CMA concludes that HgCapital exercised decisive influence over the Mercury

Pharma Companies during this period, such that the Mercury Pharma Companies and HgCapital formed a single undertaking.

(d) From 31 August 2012 until 20 October 2015, the Mercury Pharma Companies were majority owned by the Fifth Cinven Fund. The *Akzo* presumption does not apply. However, for the reasons explained in section 6.G below, the CMA concludes that each of the Cinven Entities exercised decisive influence over the Mercury Pharma Companies during this period, such that the Mercury Pharma Companies and the Cinven Entities formed a single undertaking.

(e) From 21 October 2015 until 31 July 2017, the Mercury Pharma Companies were wholly owned by Advanz. The *Akzo* presumption therefore applied between Advanz and each of the Mercury Pharma Companies and has not been rebutted, such that they formed a single undertaking.

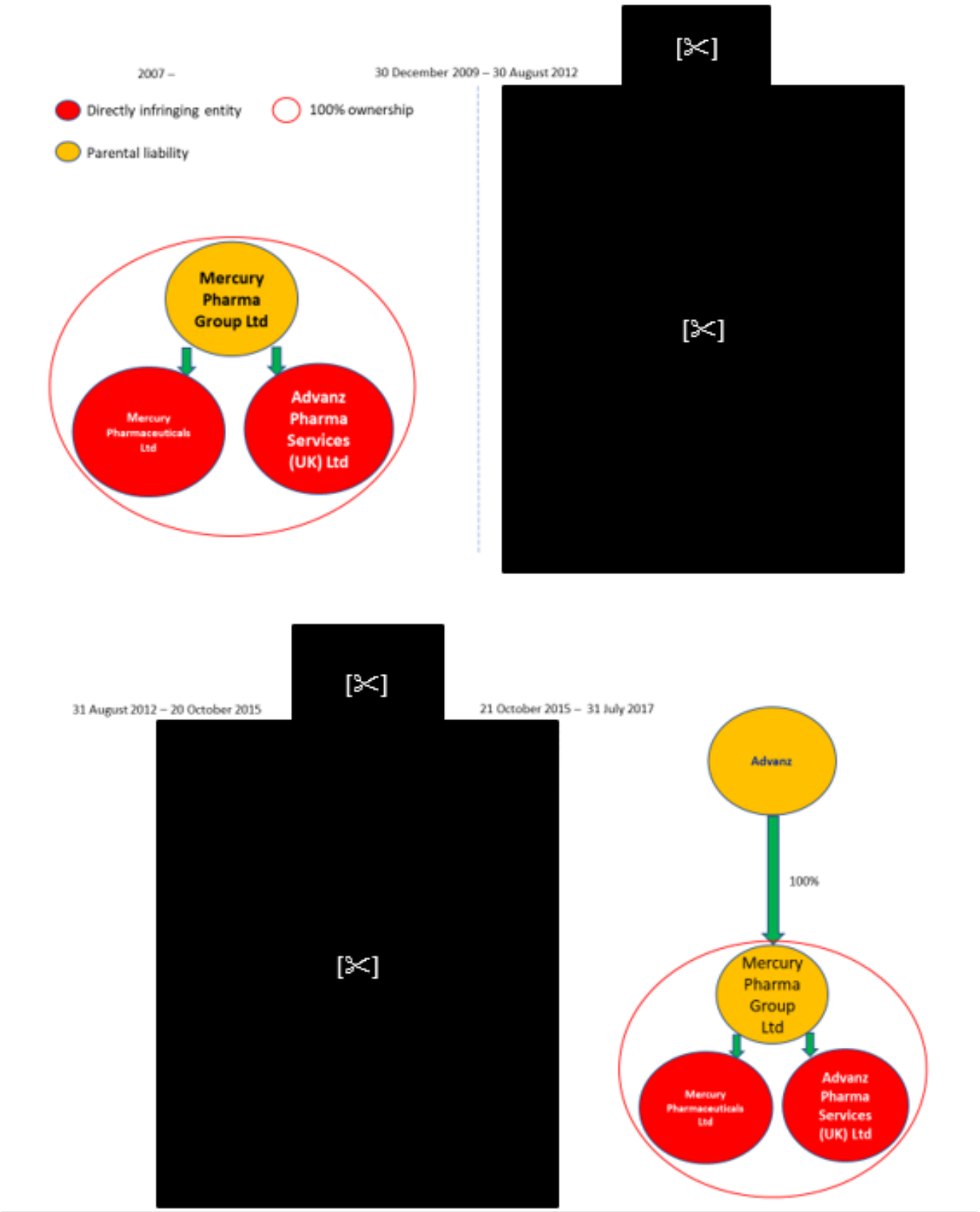
6.4 The CMA attributes liability for the Infringement to:

(a) Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited, the legal persons that directly participated in the Infringement; and

(b) Mercury Pharma Group Limited, HgCapital, the Cinven Entities and Advanz Pharma Corp, as legal persons that exercised decisive influence over the direct participants Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited during their respective ownership periods, and are therefore jointly and severally liable with them for the Infringement.

6.5 The relationships between these legal entities during the Infringement Period are summarised in the simplified diagrams below.

Figure 6.1: Simplified structure charts



Source: CMA analysis

B. Legal framework

I. Undertaking

6.6 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.[1075] 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*'.[1076]

6.7 The definition of an undertaking is therefore a functional one that is '*context-sensitive*'.[1077] 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*'.[1078]

6.8 It is therefore 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 therefore comprise one or more legal and/or natural persons.[1079]

II. Attribution of liability

6.9 Where an undertaking infringes the competition rules, it falls to that undertaking to answer for that infringement.[1080]

6.10 However, in order to enforce competition law it is necessary to attribute liability to legal entities.[1081]

6.11 The Act, The Competition Act 1998 (Competition and Markets Authority's Rules) Order 2014 and the CMA's guidance do not stipulate which legal or natural person the CMA should hold responsible for the infringement or punish by the imposition of a financial penalty.[1082]

[1075] *Hofner and Elser v Mactrotron*, C-41/90, EU:C:1991:161, paragraph 21; *Akzo Nobel v Commission* ('***Akzo Nobel***'), C-97/08P, EU:C:2009:536, paragraph 54 and the case law cited.
[1076] *Commission v Italian Republic*, 118/85, EU:C:1987:283, paragraph 7.
[1077] *Sainsbury's v MasterCard* [2016] CAT 11 ('***Sainsbury's v MasterCard***'), paragraph 360.
[1078] *Hydrotherm*, 170/83, EU:C:1984:271, paragraphs 11-12. See also *Confederación Española de Empresarios de Estaciones de Servicio v CEPSA*, C-217/05, EU:C:2006:784, 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*'.
[1079] *Sepia Logistics Limited v OFT* [2007] CAT 13, paragraph 70.
[1080] *Bolloré II*, T-372/10, EU:T:2012:325, paragraph 52.
[1081] *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 54-57.
[1082] The same is true for the European Commission under the EU competition rules: see *Akzo Nobel and Others v Commission*, C-516/15P, EU:C:2017:314, paragraph 51 and the case-law mentioned there.

6.12 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*'.[1083] 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…'*[1084]

6.13 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'.[1085]

[1083] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(21).
[1084] Opinion of AG Mengozzi in *Commission v Siemens*, C-231/11P, EU:C:2013:578, paragraphs 80-81 (emphasis added), quoted in *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(8).
[1085] *Sainsbury's v MasterCard* [2016] CAT 11, paragraph 363(22).

6.14 When attributing liability, the starting point is therefore that those legal entities that directly '*participated in th[e] breach*' are liable.

6.15 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*'.[1086] 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.[1087]

6.16 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.[1088]

6.17 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:

> '[I]t 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 General Court].
>
> …
>
> [T]he 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.

[1086] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).
[1087] 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): *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 29-36, upholding *Goldman Sachs v Commission* ('***Goldman Sachs***'), T-419/14, 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 *Fresh Del Monte v Commission*, C-293/13P, 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: *Fresh Del Monte v Commission*, C-293/13P, EU:C:2015:416, paragraphs 79-80.
[1088] See, for example, Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:2009:262, paragraphs 42-45. The Court of Justice followed the Advocate General's Opinion. See also *Alliance One v Commission* ('***Alliance One***'), C-628/10P and C-14/11P, EU:C:2012:479, paragraphs 42-44; *Total v Commission*, C-597/13P, EU:C:2015:613 paragraphs 32-35; *Akzo Nobel and Others v Commission*, C-516/15, EU:C:2017:314, paragraphs 46-53.

…

> 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'.[1089]

6.18 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 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*.'[1090]

6.19 The Court of Justice summarised the legal framework 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

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[1089] *Bolloré II*, T-372/10, EU:T:2012:325, paragraphs 37, 51-52 (emphasis added) and the case law cited. Compare *Schunk v Commission*, T-69/04, EU:T:2008:415, paragraphs 73-74, and Opinion of AG Kokott in *Akzo Nobel*, C-97/08 P, EU:C:2009:262, paragraph 98. The principles of attributing liability to a parent apply equally, whether the underlying infringement is of Chapter I / Article 101 TFEU, or Chapter II / Article 102 TFEU. 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; *Europemballage Corporation and Continental Can Company v Commission*, 6/72, EU:C:1973:22, paragraph 15; and *Istituto Chemioterapico Italiano and Commercial Solvents v Commission*, 6/73 and 7/73, EU:C:1974:18, paragraphs 36-41.

[1090] *Commission v GEA Group AG* ('***GEA***'), C-823/18P, EU:C:2020:955, paragraphs 70 and 72.

company, without having to establish the personal involvement of the latter in the infringement'.[1091, 1092]

6.20 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*'.[1093] 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:

> '[T]he 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'.[1094]

6.21 This does not require that the parent was involved in, or even aware of, the infringement by its subsidiary.[1095] However, evidence that the parent was aware of the infringement and did not intervene can be relevant.[1096]

[1091] *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 58-59 (emphasis added). See also *Evonik Degussa GmbH v Commission*, C-155/14P, EU:C:2016:446, paragraph 27 citing *Commission and Others v Versalis and Others*, C-93/13 P and C-123/13P, EU:C:2015:150, paragraph 40; *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479, paragraph 44; *Durkan Holdings Ltd v OFT ('**Durkan**')* [2011] CAT 6, paragraphs 15-22.
[1092] 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 AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262, paragraphs 97-99. Nor does this legal framework infringe the right to be presumed innocent: *Goldman Sachs*, T-419/14, EU:T:2018:445, paragraphs 187-191. See also *Pirelli v Commission*, C-611/18P, EU:C:2020:868, paragraphs 70, 73 and 95.
[1093] *Dow v Commission*, T-77/08, EU:T:2012:47, paragraph 77, upheld in *Dow v Commission*, C-179/12 P, EU:C:2013:605, referring to the Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262, paragraphs 87-94.
[1094] *Akzo Nobel v Commission*, C-516/15P, EU:C:2017:314, paragraphs 56-58.
[1095] *General Química SA v Commission*, C-90/09P, 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 *Akzo Nobel*, C-97/08, EU:C:2009:536, paragraphs 59 and 77, and *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 367 and the case law cited.
[1096] See, for example, *Servier*, in which the fact that Mylan was aware of the relevant agreement involving its subsidiary Matrix Laboratories through its due diligence for the acquisition of that subsidiary, but did not raise any objections, was a relevant factor in the Commission's decision to hold Mylan liable: paragraphs 3041-3044. The Commission's attribution of liability to Mylan was upheld on appeal in *Mylan v Commission*, T-682/14, EU:T:2018:907. The 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 Mylan did not dispute that it was aware of the infringing agreement (paragraphs 349-368).

a. The presumption of decisive influence (the Akzo presumption)

6.22 It is settled case law that where a parent company holds (directly or indirectly)[1097] 100% (or nearly 100%)[1098] of the shares or voting rights[1099] 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 jointly and severally liable for the infringement and any resulting fine.[1100]

6.23 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.[1101]

6.24 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 in the subsidiary.[1102]

6.25 For example, in the *Power Cables*[1103] 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.[1104]

[1097] *General Química and Others v Commission*, C-90/09P, EU:C:2011:21, paragraphs 86-87.
[1098] *Arkema France, Altuglas International SA, Altumax Europe SAS v Commission*, T-217/06, EU:T:2011:251, paragraph 53.
[1099] *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraphs 50 to 52 and 64, upheld in *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 35-36.
[1100] *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479, paragraphs 46-48; *Evonik Degussa GmbH v Commission*, C-155/14P, EU:C:2016:446, paragraph 28 and the case law cited; *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 60-61; see also *Allgemeine Elektricitäts-Gesellschaft AEG-Telefunken AG v Commission*, 107/82, EU:C:1983:293, paragraph 50; *Durkan* [2011] CAT 6, paragraphs 15-18.
[1101] *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479, paragraph 47, citing *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraph 61; see also *Durkan* [2011] CAT 6, paragraphs 19-21.
[1102] *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479, paragraph 49.
[1103] AT.39610 Power Cables ('***Power Cables***'), Commission Decision of 2 April 2014.
[1104] *Goldman Sachs*, T-419/14, EU:T:2018:445.

6.26 The Court of Justice upheld the General Court and rejected Goldman Sachs' argument that these factors did not suffice to establish decisive influence.[1105]

b. Cases where the Akzo presumption does not apply

6.27 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 subsidiary], that would necessarily imply that they were in a position to do so*'.[1106]

6.28 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]*'.[1107] 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*'.[1108]

6.29 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.[1109] 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 the light of those economic,

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[1105] *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73.
[1106] *Alliance One and Others v Commission*, T-24/05, EU:T:2010:453, paragraphs 165-167, upheld in *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479. See also *Toshiba Corp. v Commission*, ('***Toshiba v Commission***'), T-104/13, EU:T:2015:610, paragraph 95. See also *EI du Pont de Nemours v Commission*, C-172/12P, EU:C:2013:601, paragraph 44; and *Sasol v Commission*, T-541/08, EU:T:2014:628, paragraph 43.
[1107] *Durkan* [2011] CAT 6, paragraph 22.
[1108] Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262, paragraph 87, approved in *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 73-74: '*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 *Alliance One & Others v Commission*, T-24/05, 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 *Holding Slovenske v Commission* ('***Holding Slovenske***'), T-399/09, EU:T:2013:647, paragraph 32, and *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 347.
[1109] *Akzo Nobel*, T-24/05, EU:C:2009:536, paragraphs 72-74.

organisational and legal links, the parent can be said to have exercised decisive influence.[1110]

i. Economic, organisational and legal links indicating decisive influence

6.30 There is no exhaustive set of criteria or 'checklist' to complete in assessing the economic, organisational and legal links indicating decisive influence.[1111] The Court of Justice has also confirmed that '*[t]he 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*'.[1112] Examples of links that have been considered to confer decisive influence include:

(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*

6.31 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

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[1110] *Commission v Stichting Administratiekantoor Portielje and Gosselin Group NV* ('***Stichting Gosselin***')) C-440/11P, EU:C:2013:514, paragraphs 66-68. The Court of Justice followed the Opinion of AG Kokott, EU:C:2012:763, paragraphs 71-76: '*the decisive factor is ultimately economic reality, since competition law is guided not by technicalities, but by the actual conduct of undertakings*'. Compare *Toshiba v Commission* ('***Toshiba***'), C-623/15P, EU: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 *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce* ('***Del Monte***'), C-293/13P and C-294/13P, EU:C:2015:416, paragraph 76.

[1111] *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479, paragraph 45; *General Technic-Otis v Commission*, T-141/07, EU:T:2011 :363, paragraph 103.

[1112] *Knauf Gips v Commission* ('***Knauf Gips***'), C-407/08P, EU:C:2010:389, paragraph 65.

decisive influence over its subsidiary and, in particular, over the subsidiary's market conduct.[1113]

- *Rights under a shareholders' agreement*

6.32 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.[1114] 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.[1115]

6.33 For example, the General Court has held that:

> '[T]he 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'.[1116]

6.34 Further, veto rights constitute an important legal link between the parent and the subsidiary, which can enable the parent to exercise decisive influence over the subsidiary.[1117] 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*'.[1118]

6.35 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

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[1113] *Fuji Electric Co. Ltd v Commission* ('***Fuji Electric***'), T-132/07, EU:T:2011:344, paragraph 182; *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 96.
[1114] *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 183.
[1115] *Avebe v Commission*, T-314/01, EU:T:2006:266, paragraph 138.
[1116] *Goldman Sachs*, T-419/14, EU:T:2018:445, paragraph 91 (emphasis added).
[1117] For example, in *Toshiba v Commission*, T-104/13, EU:T:2015:610, factors in the General Court's finding that Toshiba exercised decisive influence over a joint venture company (upheld by the 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 106-113, upheld in *Toshiba*, C-623/15P, EU:C:2017:21).
[1118] Opinion of AG Kokott in *Del Monte*, C-293/13P, EU:C:2014:2439, paragraph 89 (followed by the Court of Justice).

influence.[1119] 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.[1120] 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*'.[1121]

6.36 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.[1122] The parent's influence over strategic decisions such as whether the subsidiary's business activities shall be expanded or down-sized, whether investments or acquisitions shall be made and whether it shall be sold and for what price, can be particularly important.[1123]

- *The presence of parent company representatives on the subsidiary's board*

6.37 The General Court has held that:

> '[T]he 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'.[1124]

[1119] *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63-67. Compare *RWE v Commission*, T-543/08, EU:T:2014:627, paragraphs 30-32: '*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*'. See also *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraph 47; upheld in P *FLS Plast A/S v Commission*, C-243/12, EU:C:2014:2006.

[1120] Compare *Toshiba*, C-623/15P, EU: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*'.

[1121] *Goldman Sachs*, T-419/14, EU:T:2018:445, paragraph 114 and the case law cited, upheld in *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73.

[1122] *Dow v Commission*, T-77/08, EU:T:2012:47, paragraph 77, upheld in *Dow v Commission*, C-179/12P, EU:C:2013:605. See also *Durkan* [2011] CAT 6, paragraph 22(b). See also *Evonik Degussa GmbH v Commission*, C-155/14P, EU:C:2016:446, paragraph 41, citing *Del Monte*, C-293/13P, EU:C:2015:416, paragraphs 96 and 97.

[1123] *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*': *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraph 47; upheld in *FLS Plast A/S v Commission*, C-243/12P, EU:C:2014:2006.

[1124] *Goldman Sachs*, T-419/14, EU:T:2018:445, paragraph 100; see also *CEPSA v Commission*, T-497/07, EU:T:2013:438, paragraph 176.

6.38 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.[1125]

6.39 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;[1126] or other personal links between the companies.[1127] 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.

6.40 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, 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.[1128]

6.41 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 General Court confirmed that '*[t]hat objective can be attained even though member(s) of the parent company who take on managerial*

[1125] *Holding Slovenske*, T-399/09, EU:T:2013:647, paragraphs 75-77.
[1126] *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 184; *EI du Pont de Nemours and others v Commission*, T-76/08, EU:T:2012:46, paragraphs 70 and 74.
[1127] *Stichting Gosselin*, C-440/11P, EU:C:2013:514, paragraphs 67 and 68.
[1128] 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*': *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraphs 53-60; upheld in *FLS Plast A/S v Commission*, C-243/12P, EU:C:2014:2006.

functions within the subsidiary do not have authority as agents of the parent company'.[1129]

6.42 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 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*'.[1130]

6.43 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 the European 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*'. 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.'*[1131]

6.44 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.[1132]

[1129] *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 184.
[1130] *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 14-17. See also *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 116: the Court of Justice upheld the General Court's judgment (see in particular paragraph 77).
[1131] *Goldman Sachs v Commission*, C-595/18 P, EU:C:2021:73, paragraphs 89 and 93-95.
[1132] *Toshiba*, C-623/15P, EU: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 *General Química v Commission*, C-90/09P, 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]*'.

- *The receipt of information on strategic and commercial plans*

6.45 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*'.[1133]

6.46 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.'*[1134]

6.47 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.[1135]

- *The nature of the parent's business model*

6.48 The nature of the parent's business model may be a relevant factor demonstrating its exercise of decisive influence over the subsidiary.

6.49 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 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

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[1133] *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 121, referring to the Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262, paragraph 73.
[1134] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 351.
[1135] *General Química v Commission*, C-90/09P, EU:C:2011:21, paragraphs 104-107.

three- to five-year timeframe), noting that it was difficult to see how this could be achieved without exercising decisive influence over its subsidiary.[1136]

6.50 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*'.[1137] There may be cases of pure financial investors; but any such finding can only be made on a case by case basis.

6.51 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:

> '[T]he 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 monitoring may offer better guarantees for increased profitability than a policy of non-intervention'.[1138]

6.52 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 European 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.[1139]

[1136] *Gigaset AG v Commission* ('***Gigaset***'), T-395/09, EU:T:2014:23, paragraphs 37-38.
[1137] *1. garantovaná a.s. v Commission*, T-392/09, EU:T:2012:674, paragraph 52, citing the Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262.
[1138] *Kendrion v Commission*, T-54/06, EU:T:2011:667, paragraph 66 (judgment only available in French and Dutch; English summary from the Opinion of AG Sharpston in *Kendrion v Commission*, C-50/12P, EU:C:2013:350, paragraph 53).
[1139] *Gigaset*, T-395/09, EU:T:2014:23.

(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.[1140] 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.[1141] 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*' – i.e. seconded from Mylan.[1142] The General Court upheld the Commission's analysis of both cases in two separate appeals.[1143] 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.[1144]

(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.[1145] This aspect of the decision was not appealed.[1146]

[1140] *Servier*, paragraphs 3017-3019.
[1141] *Servier*, paragraph 3016.
[1142] *Servier*, paragraphs 3028-3036.
[1143] *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89; and *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraphs 344-361. Currently on appeal to the Court of Justice: C-166/19 P and C-197/19 P.
[1144] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraphs 350 and 359.
[1145] *Case AT.39.226 - Lundbeck*, Commission decision of 19 June 2013 ('***Lundbeck***'), paragraphs 1274-1283.
[1146] In Alpharma's appeal, *Xellia Pharmaceuticals and Alpharma v Commission*, T-471/13, 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).

(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.[1147] 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 6.25 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 investment*'.[1148] The Court of Justice upheld the General Court in all respects.[1149]

(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.[1150]

C. Liability of Mercury Pharmaceuticals Limited

6.53 The CMA attributes liability to Mercury Pharmaceuticals Limited for the Infringement, for the entire Infringement Period, and for the resulting financial penalty.

[1147] In *Power Cables*, 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, European Commission: '*Introductory remarks on two cartel decisions: Power Cables and Steel Abrasives*'.
[1148] *Goldman Sachs*, T-419/14, EU:T:2018:445, paragraph 180.
[1149] *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73.
[1150] Decisions 6306_20/217_OV (20 November 2014) and *6306_20/259* (11 September 2015); District Court of Rotterdam judgment of 26 January 2017 ('***Meneba***'), NL:RBROT:2017:588.

6.54 This is because Mercury Pharmaceuticals Limited directly participated in the Infringement. Mercury Pharmaceuticals Limited was the legal entity that sold Liothyronine Tablets in the UK throughout the Infringement Period, and the holder of Advanz's MA for Liothyronine Tablets.[1151] The CMA has found that the prices charged for Liothyronine Tablets during the Infringement Period were excessive and unfair and constitute an abuse of a dominant position in the UK market for Liothyronine Tablets, within the meaning of section 18 of the Act (see chapter 5 of this Decision (*Abuse*)).

D. Liability of Advanz Pharma Services (UK) Limited

6.55 The CMA attributes liability to Advanz Pharma Services (UK) Limited for the Infringement for the entire Infringement Period, and for the resulting financial penalty.

6.56 This is because Advanz Pharma Services (UK) Limited (previously known as Concordia International Rx (UK) Limited, Amdipharm Mercury Company Limited, Mercury Pharma Management Services Limited, and Goldshield Management Services Limited) also directly participated in the Infringement during the Infringement Period.

6.57 Advanz Pharma Services (UK) Limited was the management services company of Advanz in the UK throughout the Infringement Period.[1152] As such, Advanz Pharma Services (UK) Limited was the employing entity for Advanz's UK staff. The key Advanz senior management involved in determining the group's UK strategy and directing its commercial operations, including overseeing the setting of Advanz's prices for Liothyronine Tablets – including [✂] (Advanz's Chief Executive Officer and subsequently International President) – were employed by Advanz Pharma Services (UK) Limited during the Infringement Period.[1153]

6.58 Advanz Pharma Services (UK) Limited therefore participated in the Infringement, via its employees.[1154]

[1151] Document LIO2665, '*2. Source system data mapping.xlsx*'; document LIO4427, Advanz's response to question 2 of the CMA's s.26 notice dated 25 September 2017.
[1152] Advanz Pharma Services (UK) Limited was the management services company of the Advanz group in the UK throughout the Infringement Period, responsible for providing marketing and other support services on behalf of the group, in return for which it received management charges and other advisory fees. Within the Advanz group, Advanz Pharma Services (UK) Limited is the lessee of UK property and the counterparty to contracts with professional service firms in the UK. Document LIO4427, Advanz's response to question 2 of the CMA's s.26 notice dated 25 September 2017. 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 *Servier*, paragraph 3008.
[1153] Document LIO4427, Advanz's response to question 2 of the CMA's s.26 notice dated 25 September 2017.
[1154] 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. *Sainsbury's v MasterCard* [2016] CAT 11,

E. Liability of Mercury Pharma Group Limited

6.59 The CMA attributes liability to Mercury Pharma Group Limited for the Infringement for the entire Infringement Period, and for the resulting financial penalty, jointly and severally with Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited.

6.60 Mercury Pharma Group Limited is held liable by application of the law on parental liability.

6.61 Mercury Pharma Group Limited – the owner of the underlying intellectual property associated with Advanz's Liothyronine Tablets[1155] – was the ultimate parent company of the Mercury Pharma group until the management buyout backed by HgCapital in December 2009. Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited were wholly owned (or almost entirely wholly owned) by Mercury Pharma Group Limited throughout the Infringement Period.[1156] Implementation of strategy for Advanz's principal UK operating subsidiaries was delegated to Mercury Pharma Group Limited.[1157]

6.62 Accordingly, Mercury Pharma Group Limited had the ability to exercise decisive influence over Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited, and the *Akzo* presumption that Mercury Pharma Group Limited did actually exercise such decisive influence over Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited throughout the Infringement Period applies.

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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*'. Compare *Lundbeck*, paragraphs 1256-1257, 1272 and 1288-1290, 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. See also *Servier*, paragraph 3047, in which Teva Pharmaceuticals BV was held liable '*through the involvement of top management … in the preparations for the conclusion of the Teva Settlement Agreement*'.

[1155] Document LIO4427, Advanz's response to question 2 of the CMA's s.26 notice dated 25 September 2017.

[1156] The annual returns of Advanz Pharma Services (UK) Limited show that it has been wholly owned by Mercury Pharma Group Limited since its first annual return, in 2004. The annual returns of Mercury Pharmaceuticals Limited state that until September 2009, it was 99% owned by Mercury Pharma Group Limited (then known as Goldshield Group plc), and 1% owned by [✂]. Since 7 September 2009, it has been 100% owned by Mercury Pharma Group Limited. The structure of the group during the HgCapital and Cinven ownership periods is described in the sections below. The structure of the group following its acquisition by Advanz Pharma Corporation is shown in document LIO0875, '*Confidential Annex 5.1 - Corporate Structure Chart for the AMCo Group af....pdf*'; document LIO0876, '*Confidential Annex 5.2 - Current Corporate Structure Chart of the AMCo G....pdf*'; and document LIO3954, '*Annex 2: Updated structure chart*'.

[1157] '*The strategic direction of the AMCo group is set by the board of its ultimate parent company Amdipharm Mercury Limited. The board of Amdipharm Mercury Limited delegates the implementation of the strategy for the principal operating subsidiaries of the group to the board of Mercury Pharma Group Limited*': document PAD004, Advanz: '*Annual Review 2013*', page 16.

6.63 The application of the *Akzo* presumption has not been disputed and has therefore not been rebutted.

F. Liability of HgCapital

6.64 From 30 December 2009 until 30 August 2012 (the '**HgCapital Period**') each of the Mercury Pharma Companies was indirectly owned by the HgCapital 6 Fund:

(a) The Mercury Pharma Companies were wholly owned by Midas Equityco S.à.r.l. ('**Equityco**'), a company registered in Luxembourg.[1158]

(b) The HgCapital 6 Fund held a majority of the shares in Equityco.

6.65 For the reasons set out in this section, the CMA concludes that as a result of the economic, organisational and legal links between HgCapital LLP (defined above as HgCapital) and the Mercury Pharma Companies, HgCapital exercised decisive influence over each of the Mercury Pharma Companies throughout the HgCapital Period:

(a) HgCapital had the ability to exercise decisive influence over the Mercury Pharma Companies:

(i) The CMA concludes, on the basis of the *Akzo* presumption, that Equityco exercised decisive influence over its wholly-owned subsidiaries, the Mercury Pharma Companies. This has not been disputed and the *Akzo* presumption has therefore not been rebutted.

(ii) HgCapital had the ability to exercise decisive influence over Equityco (and through Equityco, over each of Equityco's wholly-owned subsidiaries, including the Mercury Pharma Companies), through (i) its control of the majority of shares and voting rights in Equityco; and (ii) its control of the HgCapital 6 Fund's rights (including veto rights) under a shareholders' agreement (the '**Equityco Shareholders' Agreement'**).[1159]

(b) HgCapital did actually exercise decisive influence over the Mercury Pharma Companies by:

(i) Exercising the rights it controlled under that shareholders' agreement, including to appoint and remove directors to the boards of Equityco and other

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[1158] Document LIO2940.6, HgCapital's '*A34207250 v0.1 2.3 Mercury - Structure Charts*'.
[1159] As explained in section 6.F.I.a below, the shareholders in Equityco were [✂] limited partnerships. HgCapital controlled those limited partnerships, had exclusive authority to act on their behalf, and exercised their rights as shareholders in Equityco.

Mercury Pharma group companies,[1160] including the Mercury Pharma Companies; to approve the Mercury Pharma group budget; and to obtain strategic and operational information about the Mercury Pharma group's performance; and

(ii) Overseeing the Mercury Pharma group's commercial conduct.

6.66 HgCapital and the Mercury Pharma Companies therefore formed an economic unit for the purpose of the Infringement.

6.67 The CMA therefore holds HgCapital liable, jointly and severally with the Mercury Pharma Companies, for Advanz's participation in the Infringement, and for the resulting financial penalty, during the HgCapital Period.

I. HgCapital had the ability to exercise decisive influence over the Mercury Pharma Companies

a. HgCapital's control of the majority of shares and voting rights in Equityco

6.68 HgCapital controlled a majority of the shares in Equityco throughout the HgCapital Period: [✂] of the ordinary share capital.[1161]

6.69 The holder of the HgCapital 6 Fund's stake in Equityco [✂] limited partnerships forming part of the HgCapital 6 Fund (the '**HgCapital Limited Partnerships**').[1162] [✂].[1163] HgCapital managed the stakes [✂] of the HgCapital Limited Partnerships, and exercised their rights as shareholders in Equityco on their behalf.[1164] This made HgCapital equivalent to a majority shareholder in Equityco and the *de facto* holder of the HgCapital 6 Fund's

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[1160] In this section, the CMA uses the phrase the '**Mercury Pharma group**' to mean Equityco and all its wholly-owned subsidiaries during the HgCapital Period (including the Mercury Pharma Companies).
[1161] Document LIO2940.6, HgCapital's '*A34207250 v0.1 2.3 Mercury - Structure Charts*'. Document LIO2940, HgCapital's response to questions 1 and 2 of the CMA's s.26 notice dated 26 May 2017; document LIO2940.24, '*Mercury Pharma group shareholding summary*'.
[1162] [✂]: document LIO2940, HgCapital's response to question 6 of the CMA's s.26 notice dated 26 May 2017.
[1163] [✂].
[1164] Document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017. See also responses to questions 4 and 5; and clause 5.14 of document LIO2940.8, management agreement relating to the HgCapital Limited Partnerships, which states that [✂]. The HgCapital Limited Partnerships were legal entities owned by a number of limited partners: mainly third-party institutional investors, but also HgCapital partners, employees and consultants. The limited partners did not participate in the control or management of the HgCapital Limited Partnerships: document LIO2940, HgCapital's response to question 2(c) of the CMA's s.26 notice dated 26 May 2017. See also clause 6.5 of the HgCapital Limited Partnerships' limited partnership agreements (for example, document LIO2940.12, limited partnership agreement of HgCapital 6 C LP): [✂].

rights over Equityco (and, through it, the Mercury Pharma Companies) deriving from that shareholding.[1165]

6.70 The stakes of the other shareholders were fragmented [✂].[1166]

6.71 [✂].[1167] Since HgCapital exercised the rights of the HgCapital Limited Partnerships, this meant that in practice HgCapital controlled the majority of voting rights in Equityco [✂], and therefore the Mercury Pharma Companies.

6.72 HgCapital's control of the majority of shares and voting rights in Equityco therefore enabled HgCapital to exercise decisive influence over Equityco, and in particular over Equityco's and the Mercury Pharma Companies' market conduct.[1168,1169]

b. HgCapital's control of the HgCapital 6 Fund's rights under an Equityco shareholders' agreement

6.73 During the HgCapital Period, the relationship between the shareholders in Equityco was governed by the Equityco Shareholders' Agreement.[1170]

6.74 The Equityco Shareholders' Agreement gave the HgCapital Limited Partnerships important rights over Equityco and over the Mercury Pharma Companies (both directly, where rights explicitly referred to the Mercury Pharma group, and indirectly, through Equityco as the 100% owner of the

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[1165] 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): *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 29-36, upholding *Goldman Sachs v Commission*, T-419/14, 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 *Fresh Del Monte v Commission*, C-293/13P, 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: *Fresh Del Monte v Commission*, C-293/13P, EU:C:2015:416, paragraphs 79-80.
[1166] [✂]. Document LIO2940.24, '*Mercury Pharma group shareholding summary*', and document LIO2940.6, '*A34207250 v0.1 2.3 Mercury - Structure Charts*'.
[1167] Document LIO2940.4, HgCapital's '*A11935969 v0.0 002_001 Amended and Restated Investment Agreement relating to Equityco*', Schedule 5 clauses 1.2 and 2.
[1168] As explained in the 'Legal Framework' section above, the 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*'. *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 182; *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 96.
[1169] Although HgCapital did not dispute that Equityco exercised decisive influence over the Mercury Pharma Companies, [✂] (Document LIO3271, HgCapital's response to question 8 of the CMA's s.26 notice dated 30 June 2017). [✂] (Document LIO3489, Advanz's response to question 30(a) of the CMA's s.26 notice dated 30 June 2017). [✂], this would not prevent its exercise of decisive influence over the Mercury Pharma Companies: the Court of Justice has held that '*[t]he mere fact that the holding entity did not adopt any management decision in a manner consistent with the formal requirements of company law*' does not prevent its exercising decisive influence (*Stichting Gosselin*, C-440/11P, EU:C:2013:514, paragraphs 65-66. The General Court therefore erred in taking the view that '*decisive influence may be exerted over the author of the infringement by the holding entity only where that entity adopts management decisions which comply with the formal requirements of company law*').
[1170] Document LIO2940.4, Equityco Shareholders' Agreement.

Mercury Pharma Companies). These rights were controlled by HgCapital because:

(a) The Equityco Shareholders' Agreement gave these rights to the HgCapital Limited Partnerships (defined as the '**Lead Investors**').

(b) HgCapital has confirmed to the CMA that, throughout the HgCapital Period, [✂].[1171]

6.75 [✂].[1172, 1173] Although the Equityco Shareholders' Agreement [✂].[1174] HgCapital explained [✂].[1175] [✂].[1176]

6.76 [✂].[1177] [✂].[1178]

6.77 This meant that HgCapital [✂].

6.78 This right in itself gave HgCapital the ability to exercise decisive influence over Equityco – and over all its subsidiaries, including the Mercury Pharma Companies.[1179]

6.79 [✂]:[1180]

(a) [✂].

(b) [✂].

(c) [✂].

(d) [✂].

[1171] Document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017. See also responses to questions 4 and 5. See also clause 6.6(c) of the HgCapital Limited Partnerships' limited partnership agreements (for example, document LIO2940.12, limited partnership agreement of HgCapital 6 C LP): HgCapital had [✂].
[1172] [✂].
[1173] [✂]. Document LIO2940.4, Equityco Shareholders' Agreement, clause 3.1.
[1174] [✂].
[1175] Document LIO2940, HgCapital's response to question 8 of the CMA's s.26 notice dated 26 May 2017.
[1176] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 3 Part A, clause 1.2.
[1177] Document LIO2940.4, Equityco Shareholders' Agreement, clause 3.2. [✂] – Schedule 5, clause 3.1.
[1178] [✂].
[1179] As explained above, 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.*' *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraph 91 (emphasis added). Upheld in *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73.
[1180] Document LIO2940.4, Equityco Shareholders' Agreement, clause 4.1 and Schedule 4 Part B. See also Schedule 12, clause 2.1. Compare *Toshiba*, C-623/15P, EU: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 71-72 of the judgment).

6.80 [✂].[1181]

6.81 [✂][1182] [✂].[1183]

6.82 [✂].[1184]

6.83 [✂].[1185] [✂].

6.84 [✂][1186] [✂].[1187]

6.85 [✂]:

(a) [✂].[1188]

(b) [✂].[1189]

(c) [✂].[1190]

(d) [✂].[1191]

(e) [✂].[1192]

6.86 [✂].

6.87 HgCapital's control of the HgCapital 6 Fund's rights under the Equityco Shareholders' Agreement therefore gave it the ability to exercise decisive influence over Equityco, and over each of its subsidiaries (including the Mercury Pharma Companies).

6.88 HgCapital submitted that [✂].[1193] [✂].[1194]

6.89 The exercise of decisive influence does not require proof of interference in day-to-day management or operational matters (though where this takes

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[1181] Document LIO2940.4, Equityco Shareholders' Agreement, clause 4.1 and Schedule 4 Part B. See also Schedule 12, clause 2.1.
[1182] Depicted in document LIO2940.6, HgCapital's, '*A34207250 v0.1 2.3 Mercury - Structure Charts*'.
[1183] Document LIO2940.4 Equityco Shareholders' Agreement, clause 4.2.
[1184] Document LIO2940.4, Equityco Shareholders' Agreement, clause 4.3 and Schedule 4 Part C.
[1185] Compare *RWE v Commission*, T-543/08, EU:T:2014:627, paragraphs 30 to 32; *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraph 47 (upheld in *FLS Plast A/S v Commission*, C-243/12P, EU:C:2014:2006).
[1186] Depicted in document LIO2940.6, HgCapital's '*A34207250 v0.1 2.3 Mercury - Structure Charts*'.
[1187] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 12 and clause 14.1.
[1188] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 12, clause 2.1.
[1189] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 12, clause 2.2.
[1190] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 12, clauses 2.3 and 2.4.
[1191] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 12, clause 2.5.
[1192] Document LIO2940.4, Equityco Shareholders' Agreement, Schedule 12, clause 2.7.
[1193] Document LIO5140, submission from HgCapital to the CMA dated 16 October 2017, paragraph 28. See also Document LIO2940, HgCapital's response to questions 8 and 9 of the CMA's s.26 notice dated 26 May 2017.
[1194] Document LIO5140, submission from HgCapital to the CMA dated 16 October 2017, paragraph 29.

place, this can be relevant evidence).[1195] HgCapital's statement that it was [✂][1196] [✂].

6.90 In any event, the evidence shows that HgCapital exercised the rights it controlled in practice.

II. HgCapital did actually exercise decisive influence over the Mercury Pharma Companies

a. HgCapital exercised the right to appoint (and remove) directors to the boards of Equityco and other Mercury Pharma group companies

6.91 HgCapital exercised the right to appoint directors to the board of Equityco; to appoint Investor Directors to the board of Debtco; [✂].

6.92 During the HgCapital Period, HgCapital appointed the entirety of the board of Equityco. The directors of Equityco were:[1197]

(a) [✂] an HgCapital Partner, and was a member of the Services team specialising in healthcare investments.[1198] Public sources describe [✂] as having been '*head of the healthcare team at HgCapital*'.[1199]

(b) [✂]. According to HgCapital press releases, [✂] joined HgCapital in [✂], and was promoted [✂], when [✂] was also a member of the healthcare team.[1200]

(c) [✂], [✂] is described in public sources as a [✂] that HgCapital.[1201]

(d) [✂] is described in public sources as an [✂] at HgCapital.[1202]

(e) [✂] worked at HgCapital from [✂] and was [✂] of its healthcare investment team in the UK.[1203]

6.93 HgCapital has confirmed to the CMA that [✂].[1204]

6.94 HgCapital therefore exercised the HgCapital Limited Partnerships' rights under the Equityco Shareholders' Agreement to ensure that it controlled the

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[1195] *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 121, referring to *Akzo Nobel*, C-97/08P, EU:C:2009:262, paragraph 73.
[1196] Document LIO5140, submission from HgCapital to the CMA dated 16 October 2017, paragraph 28.
[1197] List of Goldshield/Mercury Pharma Group directors December 2009 to August 2012: document LIO2940.25, '*Mercury_Goldshield Directors (005)*'.
[1198] According to [✂] profile on the HgCapital website, since deleted following [✂] departure.
[1199] Document PAD049, Sourcewatch: [✂]; document PAD050, InsiderMedia: '*Solor Care sold to Voyage*'.
[1200] Document PAD051, HgCapital: '*Announces new hires*'; document PAD052, HgCapital: '*Promotions*'.
[1201] Document PAD053, Linkedin: [✂].
[1202] Document PAD054, Linkedin: [✂].
[1203] Document PAD055, Avedon Capital: [✂].
[1204] Document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017.

board of Equityco, the holding company of the Mercury Pharma group, throughout the HgCapital Period. HgCapital therefore exercised decisive influence over Equityco, and through Equityco over the Mercury Pharma Companies, '*through its prevailing presence on [Equityco]'s Board of Directors*'.[1205]

6.95 In addition, HgCapital exercised the HgCapital Limited Partnerships' rights [✂]. As explained at paragraph 6.75 above, this company was the direct wholly-owned subsidiary of Equityco, which HgCapital described as [✂] during the HgCapital Period.[1206]

6.96 The Investor Directors were [HgCapital Partner] and [HgCapital Director] (who also sat on the board of Equityco); and they sat on the board of Debtco throughout the HgCapital Period (with the exception of the period from 19 July 2012 to 31 August 2012, when [HgCapital Director] was replaced by another HgCapital individual, [HgCapital Investor Director] (who also sat on the board of Equityco)).[1207]

6.97 From 11 January 2010 until 31 August 2010, the former managers of the Goldshield group ([Goldshield Chief Financial Officer], [Goldshield CEO], [Goldshield Founder and Group Board Director] and [Goldshield Marketing Director]) also sat on the board of Debtco. For that period, therefore, the Investor Directors were numerically in a minority on the Debtco board. HgCapital nonetheless exercised decisive influence via the Investor Directors,[1208] its control of Equityco and the veto rights in the Equityco Shareholders' Agreement.

6.98 [✂].[1209]

[1205] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3017, upheld on appeal in *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89. 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 case law 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 nine members of its subsidiary's board was a relevant factor in the Commission's decision to hold it liable (paragraph 1283).
[1206] Document LIO2940, HgCapital's response to question 8 of the CMA's s.26 notice dated 26 May 2017.
[1207] List of Goldshield/Mercury Pharma Group directors December 2009 to August 2012: document LIO2940.25, '*Mercury_Goldshield Directors (005)*'.
[1208] The Court of Justice has held that even the presence of a single parent company representative on a subsidiary's board can be an organisational and personal link among others conferring decisive influence. *Toshiba*, C-623/15P, EU:C:2017:21, paragraph 76. Compare *General Química v Commission*, C-90/09P, 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]*'.
[1209] Document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017.

6.99 [✂]. From that point until the end of the HgCapital Period, the Investor Directors were the only directors on the board of Debtco.[1210] HgCapital therefore [✂] that it controlled absolutely the board of the main operational company of the Mercury Pharma group for the majority of the HgCapital Period.

6.100 [✂].[1211] [✂].[1212]

6.101 In addition, HgCapital exercised the HgCapital Limited Partnerships' rights under the Equityco Shareholders' Agreement to ensure that it had extensive representation on the boards of other Mercury Pharma group companies, including the Mercury Pharma Companies. These directors were influential individuals whose appointment to multiple companies throughout the Mercury Pharma group served further to entrench HgCapital's decisive influence:

(a) Throughout the HgCapital Period, the boards of directors of all the companies below Debtco and above Mercury Pharma Group Limited in the Mercury Pharma group structure[1213] were composed entirely of HgCapital appointees. HgCapital's Investor Directors, [✂] and [✂], were the sole directors of [✂] (the [✂] owner of Mercury Pharma Group Limited).[1214]

(b) In addition to [✂] and [✂], [HgCapital Partner],[1215] [HgPartner],[1216] and [HgPartner][1217] sat on the board of Mercury Pharma Group Limited, the immediate [✂] parent of: Mercury Pharmaceuticals Limited, the selling entity and MA holder for Liothyronine Tablets; and Advanz Pharma Services (UK) Limited (then known as Mercury Pharma Management Services Limited). From mid-2010 ([✂]) onwards, HgCapital appointees formed a majority of the

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[1210] List of Goldshield/Mercury Pharma group directors December 2009 to August 2012: document LIO2940.25, HgCapital's '*Mercury_Goldshield Directors (005)*'. [Advanz General Counsel and Secretary] and (before him) [✂] also served as company secretary. [✂] (document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017). However, no other individuals were appointed as directors during the HgCapital Period, according to Companies House. HgCapital has confirmed based on its records and the relevant company registers that the director details it submitted to the CMA included all the directors who held office from time to time during the HgCapital Period (document LIO3271, response to question 6 of the CMA's s.26 notice dated 30 June 2017).
[1211] [✂] (Document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017). [✂]. As explained above, the mere fact that the holder of a veto right does not veto a business plan or budget does not mean it did not exercise its veto right and hence decisive influence, since it must necessarily have been consulted and have approved (by refraining from vetoing): *Toshiba*, C-623/15P, EU:C:2017:21, paragraph 73.
[1212] *Goldman Sachs*, EU:T:2018:445, paragraph 100 (upheld in *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73); see also *CEPSA v Commission*, T-497/07, EU:T:2013:438, paragraph 176.
[1213] Depicted in document LIO2940.6, HgCapital's '*A34207250 v0.1 2.3 Mercury - Structure Charts*'.
[1214] List of Goldshield/Mercury Pharma Group directors December 2009 to August 2012: document LIO2940.25, '*Mercury_Goldshield Directors (005)*'. As before, [HgCapital Director] was replaced by [HgCapital Investor Director] from 19 July 2012 to 31 August 2012.
[1215] Document PAD086, Spring Ventures: '*People:* [✂]'.
[1216] Document PAD075, '*HgCapital announces senior management changes to position the firm for the next stage in its evolution and growth*'.
[1217] Document PAD080, HgCapital: [✂].

directors on the Mercury Pharma Group Limited board ([✂]).[1218] HgCapital told the CMA that during the HgCapital Period, board meetings relating to the management of the Mercury Pharma group were held at the level of Mercury Pharma Group Limited.[1219]

(c) [✂] and [✂] sat on the boards of Mercury Pharmaceuticals Limited and Advanz Pharma Services (UK) Limited (then known as Mercury Pharma Management Services Limited) from March 2010 until April 2012.[1220]

(d) [✂] also sat on the boards of every other company in the Mercury Pharma group. [✂] sat on the boards of every other company [✂]. [✂] sat on the boards of [✂] other group companies.[1221]

6.102 Through the appointment of these individuals to key companies in the Mercury Pharma group, HgCapital consolidated its decisive influence over the Mercury Pharma Companies. As board members, they had legal responsibility for the activities of those companies, including their conduct on the market.[1222]

6.103 This '*accumulation of posts*' on the Equityco and Debtco boards and the boards of Mercury Pharma group companies enabled HgCapital to ensure that the Mercury Pharma group's conduct was consistent with HgCapital's strategy.[1223]

b. HgCapital exercised the HgCapital Limited Partnerships' veto rights

6.104 HgCapital's exercise of the HgCapital Limited Partnerships' veto rights under the Equityco Shareholders' Agreement – [✂] – are in themselves sufficient to demonstrate that it exercised decisive influence over Equityco and the Mercury Pharma Companies.[1224]

[1218] List of Goldshield/Mercury Pharma Group directors December 2009 to August 2012: document LIO2940.25, '*Mercury_Goldshield Directors (005)*'. [HgCapital Investor Director] also sat on this board during July and August 2012. Aside from these HgCapital individuals, six other individuals sat on the board from time to time during the HgCapital Period. Three of these individuals were former Goldshield group management, who resigned in mid-2010, leaving HgCapital appointees in a majority on the board from that point onwards.
[1219] Document LIO3271, HgCapital's response to question 7 of the CMA's s.26 notice dated 30 June 2017. HgCapital also stated that no board meetings of HgCapital LLP were held during the HgCapital Period. As noted above, the fact that a parent company does not adopt any formal management decisions during its ownership period does not suffice to determine that the parent did not exercise decisive influence: *Commission v Stichting Gosselin*, C-440/11P, EU:C:2013:514, paragraph 66.
[1220] List of Goldshield/Mercury Pharma Group directors December 2009 to August 2012: document LIO2940.25, '*Mercury_Goldshield Directors (005)*'.
[1221] List of Goldshield/Mercury Pharma Group directors December 2009 to August 2012: document LIO2940.25, '*Mercury_Goldshield Directors (005)*'.
[1222] *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraph 77 and case law cited.
[1223] Compare *Fuji Electric,* T-132/07, EU:T:2011:344, paragraph 184.
[1224] Compare *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63 to 67.

6.105 As explained in paragraph 6.35 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.[1225] 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*'.[1226] The contemporaneous evidence shows that HgCapital exercised the veto rights it controlled in this way:

(a) [✂].[1227] [✂].[1228]

(b) A March 2011 budget preparation document lists as an objective: '*Identify new acquisition opportunities for products and companies. Liaise closely with CEO and Hg Capital to agree approach for each opportunity*'.[1229]

(c) Also in March 2011, Mercury Pharma group CEO [✂] sent [HgCapital Partner] and [HgCapital Partner] an updated budget pack, with changes, seeking their permission to circulate it to the former Goldshield management ('*[w]ith your permission I would like to send this pack to* [✂], [✂] *and* [✂]').[1230]

(d) When attending board meetings, HgCapital individuals were conscious of their veto rights: for example, at a Mercury Pharma Group Limited board meeting, in response to a query, [HgCapital Partner] '*clarified that capex, if in approved budget, need not be put up again for approval of the Board – though a reference may be made in the respective management report*'.[1231] The implication was that any capex not in the HgCapital-approved budget would need to be submitted for separate board approval.

6.106 The Investor Directors (who represented HgCapital, the legal entity that exercised the rights of the Lead Investors) [✂]. [✂], and their involvement in its preparation along with other HgCapital appointees, demonstrates in itself

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[1225] Compare *Toshiba*, C-623/15P, EU: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*'.
[1226] *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraph 114 and case law cited, upheld in *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73. See also *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 350 (currently on appeal to the Court of Justice: C-197/19 P).
[1227] Document LIO3271, HgCapital's response to question 3 of the CMA's s.26 notice dated 30 June 2017.
[1228] Document LIO3265, [✂]: document LIO4436, [✂].
[1229] March 2011 budget preparation document: document LIO0112, '*Budget 2011-2012 _15_03_2011_version 2.docx*'; see also Final 2011 budget, which includes the same statement: document LIO0115, '*Budget 2011-2012 _final.docx*'.
[1230] Document LIO0117, Email from [Advanz CEO] to [HgCapital Partner] and others dated 28 March 2011.
[1231] Document LIO3270, '*Board minutes of Mercury Pharma Group Limited 10 February 2010*'.

that HgCapital exercised decisive influence over Equityco and the Mercury Pharma Companies.[1232]

c. HgCapital exercised the HgCapital Limited Partnerships' rights to obtain strategic and operational information about the Mercury Pharma group's performance

6.107 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 allow the parent to monitor and control the activities of its subsidiary in order to take specific measures in relation to it.[1233]

6.108 As explained above, HgCapital controlled the rights of the HgCapital Limited Partnerships, as Lead Investors in Equityco, to obtain detailed information about the performance of the Mercury Pharma group.

6.109 [✂].[1234] [✂].[1235] [✂].

d. HgCapital oversaw the Mercury Pharma group's commercial conduct and strategy

6.110 As explained at paragraph 6.28 above, decisive influence does not require influence on a subsidiary's commercial conduct: this is not the only factor that is relevant.[1236] However, where such influence can be demonstrated (whether indirectly, from the totality of the economic, legal and organisational links between the parent and subsidiary,[1237] or directly from positive evidence of a shared commercial strategy) that is strong evidence of decisive influence.[1238]

[1232] Compare *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63 to 67.
[1233] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 351 (currently on appeal to the Court of Justice: C-197/19 P) and the case law cited.
[1234] HgCapital did not retain any copies of these board packs as they were always provided in hard copy: document LIO2940, HgCapital's response to question 9 of the CMA's s.26 notice dated 26 May 2017.
[1235] 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: *General Química v Commission*, C-90/09P, 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 *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89.
[1236] See also, 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 *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89.
[1237] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 347 (currently on appeal to the Court of Justice: C-197/19 P) and the cases cited.
[1238] *Durkan* [2011] CAT 6, paragraph 22; *Akzo Nobel*, C-97/08P, EU:C:2009:356, paragraphs 73-74, approving the Opinion of AG Kokott, EU:C:2009:262, paragraph 87. See also *Alliance One & Others v Commission*, T-24/05, EU:T:2010:453, paragraph 170; and *Holding Slovenske*, T-399/09, EU:T:2013:647, paragraph 32.

In particular, influence over '*the company's commercial policy in the broadest sense*',[1239] and over strategic commercial decisions such as whether its business activities shall be expanded or down-sized, whether investments or acquisitions shall be made and whether it shall be sold and for what price, can be particularly important.[1240]

6.111 The contemporaneous evidence demonstrates that HgCapital exercised decisive influence over the Mercury Pharma group's commercial conduct and strategy (and therefore that of the Mercury Pharma Companies).

6.112 First, HgCapital representatives were well-informed about the Mercury Pharma group's commercial performance; contributed to the group's strategic plans; intervened in its financial reporting; and were involved in day-to-day operations.[1241] For example:

(a) HgCapital individuals regularly attended meetings at which updates were given on the group's trading and product performance. In addition to the board meetings of Mercury Pharma Group Limited, which included CEO updates on the pharmaceuticals business, for example, [HgCapital Partner] and [HgCapital Partner] attended a meeting on 30 July 2010 at which [✂], Mercury Pharma group CEO, was given an action point to circulate a status report on the top 10 products every month at the directors' management meeting, '*to know risks and opportunities*'.[1242] Following a board meeting of Mercury Pharma Group Limited, a schedule of further meetings was agreed to discuss matters including: supply chain/operations overview; licensing and business development; core product review; divestment of non-core assets; '*Strategic Options*'; and shared services. These meetings were to be attended by (among others) [HgCapital Partner] and [HgCapital Partner].[1243]

(b) HgCapital individuals also made detailed (day-to-day level) interventions in the Mercury Pharma group's reporting. For example, at a Mercury Pharma Group Limited board meeting, [HgCapital Partner] '*requested for split in the*

[1239] Opinion of AG Kokott in *Del Monte*, C-293/13P, EU:C:2014:2439, paragraph 89 (followed by the Court of Justice).
[1240] *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*': *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraph 47; upheld in *FLS Plast A/S v Commission*, C-243/12P, EU:C:2014:2006.
[1241] HgCapital's decisive influence is apparent, as a matter of economic reality, even from seemingly minor details. For example, until March 2012, Mercury Pharmaceuticals Limited – the selling entity for Liothyronine Tablets – was known as Goldshield Pharmaceuticals Limited. Meetings of this company were held at its offices in Croydon. After its name was changed to Mercury Pharmaceuticals Limited, its board meetings were held at the offices of HgCapital in London. Compare, for example, the board minutes of Goldshield Pharmaceuticals Limited, 24 February 2012 (document LIO4438, '*MPL Board Minutes – 24 February 2012*') with those for Mercury Pharmaceuticals Limited for 20 March 2012 (document LIO4437, '*MPL Board Minutes – 20 March 2012*').
[1242] Document LIO3263, '*Board minutes of Mercury Pharma Group Limited, 30 July 2010*'.
[1243] Document LIO3262, '*Supplementary discussion post GBD meeting of Mercury Pharma Group Limited, 10 February 2010*'.

presentation of cash flow – separately for normal and exceptional items'.[1244] At another meeting, [HgCapital Partner] '*suggested to include in the Board Pack quality measures (e.g. no. of BSV [batch specific variations], pending SmPC [summaries of product characteristics], pending Periodical Safety Update Reports (PSURs), pending License Renewals etc)*'; and '*a brief matrix on all products*'. In relation to the management accounts, she '*queried the working capital balance with payments made rapidly versus collections*'.[1245]

(c) HgCapital individuals were also involved in the operational details of the Mercury Pharma group's ongoing operations. For example, at that same board meeting, [HgCapital Partner] '*mentioned that there seems to be a fundamental issue in supply chain in as much as that we have out of stock (OOS) situations and at the same time we have high inventory value in stock*'. She also '*suggested that staff bonuses … be finalised as a matter of urgency*'. [HgCapital Partner] added that '*there is a need to significantly improve the reputation of the Group with MHRA*'. [✂]. [HgCapital Partner] agreed '*to assist in getting some good CVs*' for a new Head of Business Development.[1246]

(d) At a Mercury Pharma group management meeting, [Advanz CEO] '*explained that strategic action plans had been identified at the September senior management meeting facilitated by* [HgCapital Partner] *… At a further meeting in October these plans would be exposed to a wider group … 40-45 staff … would meet in Dubai in November with a view to a final business plan being written thereafter*'.[1247]

6.113 Secondly, HgCapital's strategy for the Mercury Pharma group directly contributed to price increases such as those in the Infringement:

(a) The Mercury Pharma group was an attractive investment for HgCapital, at least in part, because of its ability to exploit lack of competition and weak pricing regulation to increase the price of drugs. A due diligence report prepared for HgCapital by McKinsey in advance of the 2009 management buyout of the Goldshield group '*based on various assumptions that we have developed with [HgCapital's] management team*' noted that the Goldshield group's success '*is based on identifying market niches with limited or no competition and leveraging favourable pricing regulation mechanisms in the UK*'.[1248] In the public reporting of its acquisition of the Goldshield group in 2009, HgCapital noted that: '*Goldshield owns a portfolio of niche generic and*

[1244] Document LIO3269, '*Board minutes of Mercury Pharma Group Limited 2 November 2010*'.
[1245] Document LIO3270, '*Board minutes of Mercury Pharma Group Limited 10 February 2010*'.
[1246] Document LIO3270, '*Board minutes of Mercury Pharma Group Limited 10 February 2010*'.
[1247] Document LIO3264, '*Minutes of Mercury Pharma Group management meeting 7 October 2010*'.
[1248] Document LIO0733, '*20090814 Trojan Final Commercial DD Report 1600 SENT.PDF*', slides 2 and 21.

patented pharmaceutical products which service markets often overlooked by other generics players. The company's management has considerable experience in extending the life and maximising the revenue streams arising from long established products'.[1249]

(b) A management presentation produced by Jefferies International in July 2012 in connection with HgCapital's prospective sale of the Mercury Pharma group positioned the group as a changed business under HgCapital's ownership – a '*[r]efocused pharmaceutical business under a new senior management team and private equity ownership*'. This presentation noted that during the HgCapital Period the Mercury Pharma group had '*"[i]nstitutionalised" the senior management team through key hires … Divested all non-core operations resulting in a pure-play niche speciality pharmaceutical company … Rationalised the inherited pipeline*'. The presentation also included a case study on Liothyronine Tablets, describing the '*value maximising strategy*' as follows:

> *'Strong pricing power as Glacier [Mercury Pharma] is the sole market provider in the UK – Glacier has doubled the price of Liothyronine in the last three years. Stable growth in historical volumes demonstrates the acceptability of price increases by the market … Consistent price increase without any negative impact in volumes'.*[1250]

(c) At a meeting of Mercury Pharma group management, [HgCapital Partner] '*requested an analysis of top Pharma product sales year on year, dividing up growth between volume and price*' and '*commented the company should show both volume and value growth in order to attract a premium exit multiple and we should look to acquire further products with sales potential in the £10-20m range*'. In response, [✂] (the Mercury Pharma group's CEO) '*commented that there were further sales growth opportunities*' including '*[p]rice increases on a number of products*'.[1251]

(d) At a board meeting of Mercury Pharma Group Limited, attended by HgCapital appointees [HgCapital Partner] and [HgCapital Partner], the discussion included options for increasing the price of individual drugs (in this case, Eltroxin), either by introducing a generic form or changing the pack size.[1252]

6.114 Thirdly, HgCapital made very significant changes to the Mercury Pharma group's business during its ownership period. For example, HgCapital

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[1249] See document PAD081, '*HgCapital Trust plc announces completion of its participation in the £179 million management buyout of Goldshield plc*'.
[1250] Document LIO0217, Advanz's '*Glacier Management Presentation.pdf*', slides 2, 34 and 35.
[1251] Document LIO3264, '*Minutes of Mercury Pharma Group management meeting 7 October 2010*'.
[1252] Document LIO4439, '*GGL Minutes – 20 September 2011*'.

individuals were invited to comment on a draft pre-marketing presentation for the sale of the Mercury Pharma group in 2012. This document identified the following changes as having taken place since the '*[t]ake-private led by HgCapital in December 2009*':

> *'Appointed a new leadership team by mid-2010 … Completed divestment of its loss-making consumer health division by June 2011 to refocus on the highly attractive and profitable core pharmaceutical business. The move also reduced headcount from circa 700 to 200 today. Significantly strengthened supply chain and regulatory compliance and therefore also the Company's relationship with the UK MHRA. Rationalised a pipeline of [228] molecules to focus on a more practical set of [33] molecules within its core competency'.*[1253]

6.115 HgCapital has explained that the Mercury Pharma group was an attractive investment because of factors such as its '*core, but underinvested, platform in well established, niche pharmaceuticals*' and '*strong cash generation of the business*' – '*a key value driver of our investment thesis was cash-generation / de-leveraging*'. HgCapital's commercial strategy was '*to focus on achieving the value increase in the Company*' by pursuing its objectives. HgCapital considered that '*we achieved our goals*' by closing all non-core businesses and investing in business development and supply chain, leading to an increase in growth rate.[1254] When HgCapital sold the Mercury Pharma group in 2012, public sources noted that it received '*more than double what it paid just three years ago*'.[1255] HgCapital's listed investment trust, HgCapital Trust plc, noted in relation to its own share in the investment that '*[t]he initial proceeds and residual value from the sale represent an investment multiple of 4.2x (which could increase to 4.3x once all further potential proceeds have been received) and a gross IRR of 67% p.a. over the investment period*'.[1256]

6.116 The purchase by an investment company with a view to sale in itself implies the exercise of decisive influence by that investment company. Indeed, the General Court has held that where a parent company's commercial strategy relies on buying and restructuring companies in order to sell them for a higher price, it is difficult to see how this could be achieved without exercising decisive influence.[1257]

[1253] Document LIO0170, '*Glacier_Pre-Marketing_v24.pptx*', attached to document LIO0169, Email from [✂] to [Advanz CEO] and [HgCapital Investor Director] dated 1 March 2012.
[1254] Document LIO2940, HgCapital's response to question 12 of the CMA's s.26 notice dated 26 May 2017.
[1255] Document PAD094, '*Hg Capital doubles money with Mercury Pharma sale*'.
[1256] See document PAD095, '*HgCapital Trust plc 2012 annual report and accounts*', page 19.
[1257] *Gigaset*, T-395/09, EU:T:2014:23, paragraphs 37-38.

6.117 HgCapital made limited representations on the CMA's provisional finding that it should be held jointly and severally liable for the Infringement during the HgCapital Period.

6.118 HgCapital submitted that the CMA should exercise its discretion not to hold it jointly and severally liable with the Mercury Pharma Companies. It submitted that pursuing HgCapital would be disproportionate; serve no policy purpose, given in particular the remoteness in time of the investment in the Mercury Pharma group, the closure of HgCapital's pharmaceutical investments division, and the distribution of profits from the Mercury Pharma group investment to investors; and disincentivise future investment in the pharmaceutical sector. It stated that its role in relation to the Mercury Pharma group was limited to oversight of senior management; that it did not encourage or facilitate the conduct that the CMA has found to infringe competition law; that it could not have anticipated '*the novel nature of the CMA's case*' and that [✂].[1258]

6.119 The CMA finds that it is appropriate to attribute liability to HgCapital notwithstanding these submissions.

6.120 Where a parent exercises decisive influence over subsidiaries by means including [✂] and taking steps to restructure their business and determine their commercial strategy, and as a result contributes to an infringement by those subsidiaries and makes a substantial profit, it is right that it should answer for that infringement.

6.121 It is irrelevant that the profit the parent made has subsequently been distributed to investors; that the CMA may not have held parent companies liable in different circumstances; and that the parent no longer invests in that specific sector. Holding a parent jointly and severally liable with its former subsidiaries in these circumstances ensures that it and others like it take more care with their investments, in whatever sector, in future.[1259] Indeed, HgCapital accepted that in principle, '*in the context of a financial sponsor like HgCapital, a finding of parental liability may … serve to encourage financial sponsors to better diligence and monitor their investments*'.[1260]

[1258] Document LIO6258, HgCapital RSO, paragraphs 21, 184-186 and 189-190; document LIO7798, HgCapital RSSO-2019, paragraphs 233-235; document LIO5140, submission from HgCapital to the CMA dated 16 October 2017, paragraphs 3 and 22-34.
[1259] See, eg, *Pirelli v Commission*, C-611/18P, EU:C:2020:868, paragraphs 95-100.
[1260] Document LIO5140, submission from HgCapital to the CMA dated 16 October 2017, paragraph 25(ii).

6.122 As explained in paragraphs 7.36ff below and in paragraphs 7.33ff of Annex 7, the CMA's case is not novel.[1261]

G. Liability of the Cinven Entities

6.123 From 31 August 2012 until 20 October 2015 (the '**Cinven Period**') each of the Mercury Pharma Companies was indirectly majority-owned by the Cinven private equity house (referred to as Cinven, see paragraph 3.12 above):

(a) The Mercury Pharma Companies were wholly-owned by Amdipharm Mercury Limited ('**AML**') (formerly known as CCM Pharma Limited).

(b) Cinven held more than 55% of the shares in AML (and therefore the Mercury Pharma Companies) but less than 100%.

6.124 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 Mercury Pharma Companies, the Cinven Entities each exercised decisive influence over each of the Mercury Pharma Companies throughout the Cinven Period.[1262] Throughout the Cinven Period, the Cinven Entities and the Mercury Pharma Companies therefore formed an economic unit for the purpose of the Infringement.

6.125 The CMA therefore holds each of the Cinven Entities liable, jointly and severally with the Mercury Pharma Companies, for AMCo's participation in the Infringement, and for the resulting financial penalty, during the Cinven Period.

6.126 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).

6.127 The CMA has structured its analysis of the decisive influence each Cinven Entity exercised in sections 6.G.IV to 6.G.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

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[1261] See section 7.C.III below (*Financial Penalties: Intent and negligence*) in relation to the potential to 'diligence' an excessive pricing infringement.

[1262] 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 LIO6321, Cinven RSO, paragraph 12.2). 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 Mercury Pharma Companies, which demonstrate the exercise of decisive influence by each Cinven Entity.

wholly-owned subsidiaries during the Cinven Period (including the Mercury Pharma Companies)). This analysis is necessarily detailed because of the complex way Cinven structured its investment in the AMCo group.

6.128 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*';[1263] that Cinven publicly described its investment in the AMCo group as '*transformative*';[1264] and that in achieving that transformation, three key Cinven Entities and in particular a handful of key Cinven individuals were involved, following what Cinven publicly described as '*a 'one-team' approach*'.[1265]

6.129 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 in 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 Mercury Pharma Companies during the Cinven Period and is therefore jointly and severally liable with them for the Infringement.

I. Cinven's approach to investment and creation of the AMCo group

6.130 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*'[1266]) 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.

6.131 Cinven's own descriptions of its approach to investments confirm that it is not a '*pure financial investor*'.[1267] Its public documents describe it as '*an active*

[1263] Document LIO7765, Cinven: '*Annual Review 2011*', page 22.
[1264] Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*'.
[1265] Document LIO7766, '*Cinven Annual Review 2012*', page 7.
[1266] Document LIO7766, '*Cinven Annual Review 2012*', page 26.
[1267] See paragraph 6.50 above.

and engaged investor in companies'[1268] 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
>
> …
>
> We act as a catalyst for change; driving revenue, EBITDA and margin growth through active engagement with our portfolio companies and their management.[1269]
>
> …
>
> We seek to improve all aspects of the companies we invest in, for the full duration of our ownership.'[1270]
>
> 'A key differentiating factor in the Cinven offer is … the active investor model that we pursue with all our investments.'[1271]

6.132 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*'.[1272] Cinven's approach is, in its own words, to '*acquire control positions in market-leading, cash-generative companies with attractive market dynamics*'.[1273]

6.133 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*

[1268] 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.
[1269] LIO7765, Cinven: '*Annual Review 2011*', page 22 (emphasis added).
[1270] 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).
[1271] Document LIO7765, '*Cinven Annual Review 2011*', page 18 (emphasis added).
[1272] Document LIO7767, '*Cinven Annual Review 2013*', page 25.
[1273] Document LIO7766, '*Cinven Annual Review 2012*', page 23. See also page 26: '*We leverage control ownership positions*'.

case and strategy, from initial acquisition, through the ownership period and finally to ultimate exit.' [1274]

6.134 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*'.

a. Developing the 'investment case and strategy'

6.135 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).

6.136 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

[1274] Document LIO7766, '*Cinven Annual Review 2012*', page 7.

relatively fragmented market, offering opportunities for significant value creation through consolidation.'[1275]

6.137 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.

6.138 Cinven's Healthcare sector team was led by two Cinven Partners: [✂].[1276] Both were appointed to the boards of AMCo group companies during the Cinven Period. [Cinven Partner] 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 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 [✂] dubbed "little jewellery boxes", can still attract strong sales. Amdipharm generates annual revenues of more than £110m.
>
> Such drugs include Liothyronine, a treatment for underactive thyroid glands'.[1277]

6.139 [✂].[1278] [✂].

6.140 The investment recommendation for Cinven's acquisition of the Mercury Pharma group stated under '*investment attractions*':

> [✂].[1279]

6.141 The recommendation went on to state:

[1275] Document LIO7766, '*Cinven Annual Review 2012*', page 8.
[1276] Document LIO7767, '*Cinven Annual Review 2013*', page 109.
[1277] Document PAD067, FT: '*Cinven accelerates into UK healthcare*', 15 October 2012 (emphasis added).
[1278] Document LIO7791, Cinven RSSO-2019, footnote 558.
[1279] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 3 (emphasis added).

'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'.[1280]

6.142 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.

6.143 [✂]. The investment recommendation for Cinven's acquisition of the Amdipharm group stated:

'The primary growth levers for Amdipharm [✂]'.[1281]

6.144 [✂].[1282]

6.145 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 [✂], its Chief Executive. Cinven has publicly stated that it cultivates an early relationship with portfolio company

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[1280] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', pages 3, 6 and 8 (emphasis added).
[1281] Document LIO6490.4, '*Annex 2.2 - memorandum to the IC titled 'Amdipharm - initial investment recommendation' dated 9 July 2012*', page 4.
[1282] Document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf.pdf*', page 14.

management so that '*when the time comes we already have a strong affinity with the management team and are able to move quickly*'.[1283] In its internal documents, Cinven noted that '*the levers* [Advanz CEO] *has pulled on pricing etc. would be applicable to Amdipharm*'.[1284] 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 [Advanz CEO] and the team have successfully executed at Mercury'.[1285]

6.146 In November 2012 [Advanz CEO] and [✂], at that time AMCo's Head of Strategic Business Development, gave a presentation to rating agencies. The presentation highlighted the '*Favourable position in UK regulatory framework*' of the combined AMCo business: '*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 in 2012, so is not as material to overall healthcare spending as actual service provision, which is the primary focus of healthcare reform*'.[1286]

6.147 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.

6.148 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

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[1283] Document PAD156, Cinven: '*Annual Review 2014*', page 21 (emphasis added).
[1284] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 2.
[1285] 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).
[1286] Document LIO0242, November 2012 rating agency presentation, slides 14 and 20.

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.

b. 'Through the ownership period'

6.149 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.*'[1287]

6.150 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.

6.151 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 paragraph 6.218 below);

(b) appointed key individuals to positions on the boards of numerous other AMCo group companies to further entrench its influence (see paragraphs 6.223 to 6.225 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 6.240 to 6.246 below).

[1287] 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*'.

6.152 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 [Advanz CEO], to oversee '*UK portfolio optimisation: Price increases, De-branding, Cross-selling*'.[1288] 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*'.[1289] 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.

6.153 The combined AMCo group prepared consolidated management accounts from January 2013 onwards, which were presented to Cinven by [Advanz CEO].[1290]

6.154 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 functional expertise*'.[1291] 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'.[1292]

6.155 Throughout the Cinven Period, in addition to the 'follow-on' acquisitions (acquisitions by the AMCo group, financed in part by Cinven) that formed part

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[1288] Document LIO6537.69, '*Review of investments and Valuations at 31 December 2012*', page 5.
[1289] 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*'.
[1290] See, for example, document LIO2866, AMCo group February 2013 management accounts and CEO's report.
[1291] Document PAD156, Cinven: '*Annual Review 2014*', page 24.
[1292] 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*'.

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 for drugs such as Liothyronine Tablets. Cinven oversaw this. 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: [✂].[1293]

6.156 Cinven therefore implemented its investment strategy by exercising decisive influence over the AMCo group's business, including through adopting a 100-day action plan and a Value Creation Plan, acquiring additional assets, appointing individuals to key positions on AMCo group boards, putting in place reporting lines to ensure it was able effectively to monitor its investment, and overseeing the AMCo group's commercial conduct, ensuring that the AMCo group continued the strategy to focus on '*niche drugs*'.

c. Preparing for the 'ultimate exit'

6.157 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.

6.158 Cinven's '*AMCo exit paper*', prepared in February 2015, stated:

> 'We have worked with McKinsey 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
>
> …

[1293] Document LIO3746, 'AMCo overview' slide pack August 2014, slide 2.

> 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'.[1294]

6.159 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*';

(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).

6.160 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. [✂]'.[1295]

6.161 The exit paper therefore also made clear that the strategic business initiatives devised at the time of disposing of the AMCo group were [✂].

6.162 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,[1296] and sold the combined AMCo group three years later for £2.3 billion,[1297] making a profit of £1.5 billion. Its (approximately three-year) investment '*returned cash proceeds of 3.5x cost*'.[1298] In its own press release announcing the sale to Concordia

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[1294] 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.*'
[1295] Document LIO6494.3, '*AMCo Exit Paper' dated 27 February 2015*', page 11 (emphasis added).
[1296] Document LIO7766, '*Cinven Annual Review 2012*', page 9.
[1297] 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*'.
[1298] See document PAD096, Cinven: '*Annual Review 2015*', page 4.

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'.

6.163 [Cinven Partner] 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 [✂], in further strengthening the senior team, internationalising the business, 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'.

6.164 [Advanz CEO] 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'.[1299]

6.165 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

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[1299] Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*' (emphasis added).

…

> 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. [✂], a partner in Cinven, said it was one of his most successful deals.'[1300]

6.166 Cinven submitted that [✂].[1301] However, as explained in paragraph 6.50 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*'.[1302] 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 did – are likely to exercise decisive influence over them.[1303] 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.[1304]

6.167 In this case, Cinven's '*active*' and '*engaged*' ownership;[1305] its '*targeted, systematic and on-going*' operational input;[1306] its instigation of '*the transformative merger*'[1307] 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 such as Liothyronine Tablets,[1308] 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

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[1300] Document PAD157, The Times: '*Firm's £1.5bn drug profit is bitter pill for taxpayer*', June 2016 (emphasis added).
[1301] Document LIO6321, Cinven RSO, paragraphs 12.1(b)(iv) and 12.79-12.85.
[1302] *1. garantovaná a.s. v Commission*, T-392/09, EU:T:2012:674, paragraph 52, citing the Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262.
[1303] For example, *Gigaset*, T-395/09, EU:T:2014:23, paragraphs 37-38.
[1304] See, for example, *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, upheld in *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73; Commission decision in *Lundbeck*, upheld in *Xellia Pharmaceuticals and Alpharma v Commission*, T-471/13, EU:T:2016:460; Commission decision in *Servier*, upheld in *Unichem v Commission*, T-705/14, EU:T:2018:915 and *Mylan v Commission*, T-682/14, EU:T:2018:907; *Gigaset*, T-395/09, 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.
[1305] Document PAD156, Cinven: '*Annual Review 2014*', page 120. Document LIO7765, '*Cinven Annual Review 2011*', page 18.
[1306] Document PAD156, Cinven: '*Annual Review 2014*', page 24.
[1307] Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*'.
[1308] Document PAD067, FT: '*Cinven accelerates into UK healthcare*', 15 October 2012.

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 Partner] and [Advanz CEO] to Cinven's active management of the AMCo group.

6.168 For all these reasons, the CMA considers it appropriate to hold entities associated with Cinven liable for the Infringement during the Cinven Period and rejects Cinven's submission that [✂].[1309]

II. The roles of the Cinven Entities

6.169 It is therefore clear that Cinven exercised decisive influence over the AMCo group.

6.170 The law requires that liability for the infringement committed by the Mercury Pharma Companies is attributed to legal persons on whom fines may be imposed.[1310] The CMA must therefore identify the legal entities within Cinven to which liability for the Infringement can be attributed.[1311]

6.171 Cinven bought the Amdipharm and Mercury Pharma groups, and sold the combined AMCo group, through the Fifth Cinven Fund. [✂].[1312] [✂].

6.172 [✂].

Figure 6.2: [✂]

[✂]

6.173 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 its decisive influence over the Mercury Pharma Companies:

[1309] Document LIO6321, Cinven RSO, paragraphs 12.3 and 12.86.
[1310] *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 54 to 57.
[1311] Cinven submitted that [✂] (document LIO7791, Cinven RSSO-2019, paragraph 10.19. See also document LIO6321, Cinven RSO, 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 Mercury Pharma Companies. In the following sections, the CMA has set out how that decisive influence was exercised through specific legal entities, as the law requires.
[1312] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 9.7. See also document LIO3913, limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership, clause 4.1.3: [✂].

(a) [✂].[1313] [✂];

(b) [✂]; and

(c) [✂].

6.174 Cinven MGP, Luxco 1 and Cinven Partners are together defined at paragraph 1.1 above as the **Cinven Entities**.

6.175 Notwithstanding the complexity of the Fifth Cinven Fund, the Cinven Entities were structurally and – most importantly – personally connected:

(a) [✂].[1314]

(b) [✂].[1315] [✂].

(c) [✂].[1316] [✂].

(d) [✂].[1317]

(e) [✂].

6.176 These connections ensured that the Cinven Entities acted as one in relation to the AMCo group investment.

6.177 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 Mercury Pharma Companies. Cinven's Managing Partner 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:

[1313] [✂]. Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraphs 9.4-9.5. See also document LIO3913, limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership (annex 37 to document LIO3872), recital (1), definitions and clauses 4.1.1 and 4.2.
[1314] Document LIO6497.1, '*Cinven Partners LLP Partnership Agreement dated 17 February 2012*', clause 8. [✂].
[1315] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 9.12.
[1316] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 9.12.
[1317] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 9.14.

> 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'.[1318]

6.178 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'[1319]
>
> 'Ours is a 'one-team' approach.'[1320]

6.179 Cinven submitted that [✂].[1321] 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 Mercury Pharma Companies were aligned in pursuit of their common strategy of exploiting the profit opportunities presented by niche generic drugs.

6.180 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 Mercury Pharma Companies as will be explained in the sections that follow:

(a) [✂];

(b) [✂]; and

(c) [✂].

6.181 [✂].[1322] [✂].

[1318] Document LIO7765, '*Cinven Annual Review 2011*', pages 4 and 7 (emphasis added).
[1319] Document LIO7765, '*Cinven Annual Review 2011*', page 25 (emphasis added).
[1320] 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).
[1321] Document LIO7791, Cinven RSSO-2019, paragraph 10.14(g).
[1322] Document LIO12261, Cinven's response to the CMA's s.26 notice dated 2 December 2020.

III. The legal test for attributing liability to the Cinven Entities

6.182 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.

6.183 Cinven submitted that [✂]:

> [✂].[1323]

6.184 [✂].[1324]

6.185 This submission is misdirected. The phrase '*a specific economic aim on a long-term basis*' derives from the 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, 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.'[1325]

6.186 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.[1326] This has been specifically confirmed in more recent case law. For example, in *Holding Slovenske v Commission* the 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.[1327] The 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

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[1323] Document LIO6321, Cinven RSO, paragraph 12.1(a) (emphasis in original). Cinven repeated this argument in document LIO7791, Cinven RSSO-2019, paragraphs 10.4-10.8.
[1324] Document LIO6321, Cinven RSO, paragraphs 12.7-12.9.
[1325] *HFB v Commission*, T-9/99, EU:T:2002:70, paragraph 54. See also *Shell v Commission*, T-11/89, EU:T:1992:33, paragraphs 308-312.
[1326] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 347 and the cases cited. *Durkan* [2011] CAT 6, paragraph 22; Opinion of AG Kokott in *Akzo Nobel* C-97/08P, EU:C:2009:262, paragraph 87, approved in *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 73 to 74.
[1327] *Holding Slovenske*, T-399/09, EU:T:2013:647, paragraphs 44 and 46.

> 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'.[1328]

6.187 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 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'.[1329]

6.188 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 Mercury Pharma Companies.[1330]

6.189 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 Mercury Pharma 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

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[1328] *Holding Slovenske*, T-399/09, 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*'.

[1329] Opinion of AG Sharpston in *Kendrion v Commission*, C-50/12P, EU:C:2013:350, paragraph 54, followed in C-50/12P, EU:C:2013:771.

[1330] See *Akzo Nobel*, C-97/08P, EU:C:2009:536, paragraphs 58-59.

regulation for niche generic drugs in order to extract high profits. That strategy was driven by Cinven.

6.190 Cinven's second submission was that [✂].[1331]

6.191 The CMA does not agree with this submission. As explained in paragraph 6.30 above, it is clear that there is no exhaustive set of criteria or 'checklist' to be completed when considering parental liability.[1332] Nor is any specific instruction from the parent required.[1333] 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 Mercury Pharma Companies, many of which taken in themselves would be sufficient to establish the exercise of decisive influence (for example, the evidence that Cinven MGP edited and approved the AMCo group budget).[1334] The evidence all points in the same direction.

IV. Liability of Cinven MGP

6.192 Cinven MGP exercised decisive influence over the Mercury Pharma Companies throughout the Cinven Period, as a result of the legal, organisational and economic links between Cinven MGP and the Mercury Pharma Companies:

(a) Cinven MGP had the ability to exercise decisive influence over the Mercury Pharma Companies:

(i) [✂].[1335] The CMA therefore concludes, on the basis of the *Akzo* presumption, that AML exercised decisive influence over the Mercury Pharma Companies.

[1331] Document LIO6321, Cinven RSO, paragraphs 12.6, 12.7 and 12.10-12.14. See also document LIO12196, Cinven's response to the Fourth Letter of Facts, paragraph 2.33.
[1332] See, for example, *Alliance One*, C-628/10P and C-14/11P, 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*'; *General Technic-Otis v Commission*, T-141/07, EU:T:2011:363, paragraph 103. See also *Dow v Commission*, C-179/12P, 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*'.
[1333] *Dow v Commission*, T-77/08, EU:T:2012:47, paragraph 77, upheld in *Dow v Commission*, C-179/12P, EU:C:2013:605. See also *Durkan* [2011] CAT 6, paragraph 22(b); *Evonik Degussa GmbH v Commission*, C-155/14P, EU:C:2016:446, paragraph 41, citing *Del Monte v Commission*, C-293/13P, EU:C:2015:416, paragraphs 96-97.
[1334] 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: *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63-67.
[1335] Document LIO3880, structure chart of the Mercury Pharma group as at 31 August 2012; document LIO3882, structure chart of the Amdipharm Mercury combined group; document LIO0873, structure chart as of 16 December 2013; document LIO0874, structure chart as of 13 January 2015; and document LIO3920, structure chart of the Fifth Cinven Fund.

The parties have not disputed this and the *Akzo* presumption has therefore not been rebutted.[1336]

(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 Mercury Pharma 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.[1337]

(b) Cinven MGP did actually exercise decisive influence over the Mercury Pharma 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 prices of niche generic drugs that Cinven and the AMCo group shared.

a. Cinven MGP had the ability to exercise decisive influence over the Mercury Pharma Companies

i. Cinven MGP's control of Cinven's majority shareholding and voting rights in AML

6.193 Cinven MGP controlled a majority of the shares and voting rights in AML [✂].[1338]

6.194 The shareholders in AML were [✂] legal entities: [✂].[1339] [✂].[1340] Cinven MGP had exclusive authority to make investment and management decisions

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[1336] Document LIO6321, Cinven RSO, paragraph 12.4: '*The Cinven [Entities] do not contest the decisive influence that AML held over its subsidiaries within the AMCo Group.*'
[1337] As explained in section 6.G.IV.a.i below, the shareholders in AML were [✂]. Cinven MGP controlled those [✂], had exclusive authority to act on their behalf, and exercised their rights as shareholders in AML.
[1338] According to the structure charts submitted by Cinven and AMCo (document LIO3880, structure chart of the Mercury Pharma group as at 31 August 2012; document LIO3881, structure chart of the Amdipharm group as at 31 October 2012; and document LIO3882, structure chart of the Amdipharm Mercury combined group; document LIO0873, structure chart as of 16 December 2013; document LIO0874, structure chart as of 13 January 2015; and document LIO3920, structure chart of the Fifth Cinven Fund) [✂] (Cinven MGP's stake at that point can be seen in document LIO3920, structure chart of the Fifth Cinven Fund). See document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 1.8.
[1339] [✂].
[1340] [✂].

for the Cinven Limited Partnerships.[1341] This made Cinven MGP equivalent to a majority shareholder in AML and the *de facto* holder [✂] over AML and, through it, the Mercury Pharma Companies, deriving from that shareholding.[1342]

6.195 The stakes of the other shareholders were fragmented and none of them held any rights other than those typically granted to minority shareholders.[1343]

6.196 [✂].[1344]

6.197 [✂].[1345] [✂],[1346] 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 Mercury Pharma Companies.

6.198 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 Mercury Pharma Companies' market conduct.[1347]

6.199 [✂].[1348] [✂].[1349]

[1341] [✂].
[1342] 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): *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 29-36, upholding *Goldman Sachs v Commission*, T-419/14, 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 *Fresh Del Monte v Commission*, C-293/13P, 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: *Fresh Del Monte v Commission*, C-293/13P, EU:C:2015:416, paragraphs 79-80.
[1343] [✂]. Document LIO3881, structure chart of the Amdipharm group as at 31 October 2012; document LIO3882, structure chart of the Amdipharm Mercury combined group; and document LIO3920, structure chart of the Fifth Cinven Fund.
[1344] Document LIO3885, Articles of Association of Amdipharm Mercury Limited, clause 4.3.1(a) and 4.3.2(a). [✂].
[1345] Document LIO3727.1, Cinven's response to question 1 of the CMA's s.26 notice dated 11 July 2017. [✂] (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).
[1346] Document LIO3727.1, Cinven's response to question 1 of the CMA's s.26 notice dated 11 July 2017. Document LIO3872, 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 LIO3913, limited partnership agreement of Fifth Cinven Fund (No. 1) Limited Partnership).
[1347] As explained in the 'Legal Framework' section above, the 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*'. *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 182; *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 96.
[1348] Document LIO6321, Cinven RSO, paragraphs 12.11 and 12.16 and footnote 685. Cinven repeated these arguments in document LIO7791, Cinven RSSO-2019, paragraphs 10.11-10.12.
[1349] Document LIO6321, Cinven RSO, footnote 696.

6.200 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 Mercury Pharma Companies [✂].[1350] [✂].[1351]

ii. Cinven MGP's control of Cinven's rights under the AML shareholders' agreement

6.201 During the Cinven Period, the relationship between the shareholders in AML was governed by a shareholders' agreement (the '**AML Shareholders' Agreement**').[1352]

6.202 The AML Shareholders' Agreement gave the Cinven Limited Partnerships important rights over AML and over the Mercury Pharma Companies (both directly, where rights explicitly referred to the AMCo group, and indirectly, through AML as the 100% owner of the Mercury Pharma Companies). These rights were controlled by Cinven MGP because:

(a) [✂].

(b) [✂].[1353] [✂].[1354]

6.203 [✂].[1355] [✂].[1356]

6.204 [✂]:

(a) [✂][1357] [✂].[1358] [✂].

(b) [✂].[1359]

(c) [✂].[1360]

6.205 [✂].[1361] [✂].[1362]

[1350] 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.
[1351] [✂].
[1352] Document LIO3883, AML Shareholders' Agreement. [✂] (document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 3.1).
[1353] [✂].
[1354] [✂].
[1355] [✂].
[1356] [✂].
[1357] [✂].
[1358] Document LIO3883, AML Shareholders' Agreement, clause 9.1.1.
[1359] Document LIO3883, AML Shareholders' Agreement, clause 9.3.1.
[1360] Document LIO3883, AML Shareholders' Agreement, clause 9.4.1.
[1361] Document LIO3883, AML Shareholders' Agreement, clause 9.2.
[1362] Document LIO4935, email from [Advanz Chief Strategy Officer] to [Advanz General Counsel and Secretary] and others 11 April 2014: [✂].

6.206 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 Mercury Pharma Companies[1363] – and over all its subsidiaries, including the Mercury Pharma Companies.[1364] As explained above, during the Cinven Period, Cinven described the AML Shareholders' Agreement as '*a Cinven friendly SHA [shareholders' agreement] … where we retain full control*'.[1365]

6.207 [✂]:[1366]

(a) [✂].[1367]

(b) [✂].

(c) [✂].

(d) [✂].

(e) [✂].[1368]

6.208 [✂].[1369] [✂].

6.209 [✂],[1370] [✂].[1371] [✂]:

(a) [✂]; and

(b) [✂].[1372]

6.210 [✂].[1373] [✂].[1374]

[1363] 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*'.
[1364] As explained above, 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*.' *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraph 91 (emphasis added). Upheld in *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73.
[1365] Document LIO6494.3, '*AMCo Exit Paper*' *dated 27 February 2015*', pages 3 and 13.
[1366] Document LIO3883, AML Shareholders' Agreement, clauses 5.2, 6.1 and Schedule 7 Part A. Compare *Toshiba*, C-623/15P, EU: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).
[1367] Document LIO3883, AML Shareholders' Agreement, clause 5.2.
[1368] Document LIO3883, AML Shareholders' Agreement, clause 6.1 and Schedule 7 Part A.
[1369] Document LIO3883, AML Shareholders' Agreement, clause 6.1 and 1.1.
[1370] [✂].
[1371] Document LIO3883, AML Shareholders' Agreement, clause 6.
[1372] Document LIO3883, AML Shareholders' Agreement, clause 9.10 and Schedule 11.
[1373] Document LIO3883, AML Shareholders' Agreement, clause 6 and Schedule 7 Parts B and C.
[1374] Document LIO3883, AML Shareholders' Agreement, clause 9.2.1.

6.211 [✂].[1375] [✂].[1376]

6.212 [✂],[1377] [✂] Cinven MGP, [✂] effectively had control of strategic commercial decisions with respect to the entire AMCo group (and therefore the Mercury Pharma Companies) [✂].[1378] [✂].

6.213 [✂].[1379] [✂]:

(a) [✂].[1380]

(b) [✂].[1381]

(c) [✂].[1382]

(d) [✂].[1383]

(e) [✂].[1384]

6.214 These information rights ensured that Cinven MGP was able to intervene to protect its investment whenever necessary.

6.215 Cinven MGP's control [✂] gave it the ability to exercise decisive influence over AML, and over each of its subsidiaries (including the Mercury Pharma Companies).

b. Cinven MGP did actually exercise decisive influence over the Mercury Pharma Companies

6.216 [✂].

i. Cinven MGP exercised the right to appoint (and remove) directors to the board of AML and other AMCo group companies

6.217 Cinven MGP exercised the right to appoint directors to AML's board (and to remove the one director it did not appoint).

[1375] [✂].
[1376] [✂].
[1377] [✂].
[1378] Compare *RWE v Commission*, T-543/08, EU:T:2014:627, paragraphs 30 to 32; *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraph 47 (upheld in *FLS Plast A/S v Commission*, C-243/12P, EU:C:2014:2006).
[1379] Document LIO3883, AML Shareholders' Agreement, clauses 5.1 and 5.4.
[1380] Document LIO3883, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 2.1.
[1381] Document LIO3883, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 1.
[1382] Document LIO3883, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 3.
[1383] Document LIO3883, AML Shareholders' Agreement, Schedule 6 Part B, paragraph 5.
[1384] Document LIO3883, AML Shareholders' Agreement, Schedule 6 Part A, paragraph 4.3.

6.218 Cinven MGP ([✂]) appointed two Investor Directors to exercise the Majority Investors' rights under the AML Shareholders' Agreement: [✂]. [✂] is a Cinven Partner and [✂].[1385] [✂].[1386]

6.219 The Investor Directors sat on the board of AML throughout the Cinven Period.[1387]

6.220 Between 31 October 2012 and 30 July 2014, [✂] also sat on the AML board as a 'Waymade Director' under the rights given to the former owners of the Amdipharm group in the AML Shareholders' Agreement. On 30 July 2014, having been asked by [Cinven Partner] to leave, he resigned as a director of AML.[1388]

6.221 For the rest of the Cinven Period (31 August 2012 to 30 October 2012[1389] and 31 July 2014 to 20 October 2015) the board of AML was composed entirely of directors appointed by Cinven MGP. [✂][1390] [✂].[1391] [✂].[1392]

6.222 [✂].[1393] Cinven MGP therefore exercised decisive influence over AML, and through AML over the Mercury Pharma Companies, '*through its prevailing presence on [AML]'s Board of Directors*'.[1394] The AMCo group executive management, including [✂], its CEO, did not sit on the AML board but

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[1385] Document PAD082, Cinven: [✂].
[1386] Document PAD076, Cinven: [✂].
[1387] Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015; document LIO3727.1, Cinven's response to the CMA's s.26 notice dated 11 July 2017; clarification in respect of [Cinven Partner] in document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 7.2(a).
[1388] Document LIO4935, email from [Advanz Chief Strategy Officer] to [Advanz General Counsel and Secretary] and others 11 April 2014: '[Cinven Partner] *has now asked* 'Waymade Director] *to leave the Board*'.
[1389] Document LIO3883, AML Shareholders' Agreement, Schedule 9 clause 1.
[1390] Document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 7.1.
[1391] Document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, response to question 5. Documents LIO3951, LIO3952 and LIO3953, engagement letters dated 6 July 2012, 24 September 2012 and 5 November 2012.
[1392] Document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 7.1.
[1393] Cinven told the CMA that its Investor Directors 'ea*ch 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 LIO3872, Cinven's response to the CMA's s.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. *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraphs 53 to 60; upheld in *FLS Plast A/S v Commission*, C-243/12 P, EU:C:2014:2006.
[1394] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 3017, upheld on appeal in *Unichem v Commission*, T-705/14, 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 case law 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 nine members of its subsidiary's board was a relevant factor in the Commission's decision to hold it liable (paragraph 1283).

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).[1395]

6.223 [✂]. 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, [✂] and [✂] were also appointed to the boards of 13 and 21 other AMCo group companies (both holding companies and operating companies) respectively during the Cinven Period.[1396] This included the board of Mercury Pharma Group Limited, the immediate 100% parent of the Mercury Pharma Companies and holding company of the Mercury Pharma group. 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 [✂], its CEO (see section 6.D above).

(b) [✂] 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) [✂] 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.[1397]

(ii) [✂] 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.[1398]

6.224 Through the appointment of these individuals to key companies in the AMCo group, Cinven MGP consolidated its decisive influence over the Mercury Pharma 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.[1399] As explained in section 6.G.VI.b below, each of these individuals played an important role in devising and implementing

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[1395] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 3.4.
[1396] Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015.
[1397] Document LIO3932, list of directors appointed to Mercury Pharma Group Limited.
[1398] Document LIO3932, list of directors appointed to Mercury Pharma Group Limited.
[1399] *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraph 77 and case law cited.

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.

6.225 Cinven MGP also appointed non-executive directors supplied [✂] to the boards of several other companies in the AMCo group.[1400]

6.226 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.[1401]

6.227 [✂].[1402] [✂].

6.228 [✂].[1403] [✂].

6.229 [✂].[1404] [✂]: 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.

ii. Cinven MGP exercised [✂] veto rights

6.230 Cinven MGP's exercise [✂] – in particular, over the AMCo group budget – are in themselves sufficient to demonstrate that it exercised decisive influence over AML and the Mercury Pharma Companies.[1405]

6.231 As explained in paragraph 6.35 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.[1406] 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*'.[1407] The contemporaneous evidence shows that Cinven MGP exercised the veto rights it controlled in this way.

[1400] Document LIO3122, List of AML directors between 31 August 2012 and 21 October 2015.
[1401] Compare *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 184.
[1402] Document LIO6321, Cinven RSO, paragraphs 12.25-12.26.
[1403] Document LIO6321, Cinven RSO, paragraphs 12.26.
[1404] Document LIO6321, Cinven RSO, paragraph 12.26.
[1405] Compare *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63 to 67.
[1406] Compare *Toshiba*, C-623/15P, EU: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*'.
[1407] *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraph 114 and case law cited, upheld in *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73. See also *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 350 (currently on appeal to the Court of Justice: C-197/19 P).

- *The AMCo group budget*

6.232 As explained above, Cinven MGP, [✂], controlled a veto right over the AMCo group budget: it was to be submitted to the Investor Directors appointed by Cinven MGP [✂] and AMCo group management were required to incorporate any amendments they made to it.

6.233 [✂].[1408] The documentary evidence shows that [✂] and [✂] (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 …* [✂] *[*[✂]*, Finance Director] to present initial planning timetable to Cinven by 9th August. Suggestions* [✂]'. 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.[1409] 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.[1410]

(b) On 29 November 2013 AMCo's Chief Financial Officer, [✂], emailed the Investor Directors: '*Thanks again for your approval of our 2014 budget proposal*'. [Advanz Chief Financial Officer] listed a number of '*follow up items*' relating to the details of AMCo's business, on which [Cinven Partner] commented. [Advanz Chief Financial Officer] asked: '*Can you please let me know in what format, level of detail, etc. you would like to get our final budget?*' [Cinven Partner] 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*'.[1411] [Cinven Partner] later followed up to ask '*when we might be able to get the excel model for the plan*'.[1412] [Advanz Chief Financial Officer] then sent the Investor Directors a revised budget pack for 2014;[1413] and separately the underlying Excel file.[1414] These emails demonstrate that the Investor Directors

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[1408] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 3.14.
[1409] Document LIO0314, email between [Advanz General Counsel and Secretary], [Advanz Chief Strategy Officer], [Advanz Finance Director] and [Advanz CEO] dated 1 August 2013.
[1410] Document LIO0378, email from [Advanz Head of Sales UK Brands and Generics] to AMCo staff dated 3 December 2013.
[1411] Document LIO12191, email from [Cinven Partner] to [Advanz Chief Financial Officer] dated 2 December 2013.
[1412] Document LIO12192, email from [Cinven Partner] to [Advanz Chief Financial Officer] dated 13 December 2013.
[1413] Document LIO12191, email from [Cinven Partner] to [Advanz Chief Financial Officer] dated 2 December 2013.
[1414] Document LIO12192, email from [Cinven Partner] to [Advanz Chief Financial Officer] dated 13 December 2013.

were closely involved in preparation of the AMCo 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, [Advanz Chief Financial Officer] noted, '*[w]e have now included support slides and included various commentaries. Most of the data requests that* [Cinven Partner] *has asked for (the pricing table is still missing but we will get that done on Monday morning)*'.[1415] The budget preparation template submitted to Cinven representatives included an appendix showing the price of Liothyronine Tablets increasing by more than 100% from March 2013 to January 2014.[1416]

(d) Ahead of a meeting to discuss the draft budget, [Cinven Partner] 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* [✂]*: 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* [✂] *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* [✂] *on 4 and p28 but as* [✂] *on p31 (is the difference the fact that* [✂]'[1417] AMCo's Chief Financial Officer responded to each of these questions, stating that clarifications would be provided at the meeting and noting in particular that [Cinven Partner] 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* [✂] *and the balance captured under* [✂]'. AMCo's CFO 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.'*[1418]

(e) Following this process, the Investor Directors attended an AML board meeting at [✂].[1419]

6.234 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 [✂], exercised decisive influence over AML, and through AML

[1415] Document LIO0375, email between [Advanz Chief Financial Officer] and [Advanz CEO] dated 22 November 2013.
[1416] Document LIO0385, Concordia's '*Budget presentation workbook template - v1 2_Cinven.xlsx*' shows the ASP for Liothyronine Tablets increasing from £45.6 in March 2013 to £94.6 in January 2014 (Appendix 3).
[1417] Document LIO0755, email from [Cinven Partner] to [Advanz Chief Financial Officer] and [Advanz CEO] dated 25 November 2013.
[1418] Document LIO0755, email from [Cinven Partner] to [Advanz Chief Financial Officer] and [Advanz CEO] dated 25 November 2013.
[1419] Document LIO3899, minutes of AML board meeting dated 29 January 2014.

over the Mercury Pharma Companies.[1420] Not only would the AMCo group's 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.

6.235 [✂].[1421] [✂].[1422] [✂].

- *Investor Consent*

6.236 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.[1423]

6.237 [✂].

6.238 Cinven MGP exercised this right in practice. For example:

(a) [✂].[1424]

(b) [✂].[1425]

6.239 [✂].[1426] [✂].[1427]

iii. Cinven MGP exercised the Cinven Limited Partnerships' rights to obtain strategic and operational information about the AMCo group's performance

6.240 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

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[1420] Compare *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63 to 67. As explained in section 6.G.VI 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.
[1421] Document LIO6321, Cinven RSO, paragraph 12.24.
[1422] Document LIO6321, Cinven RSO, paragraph 12.37.
[1423] *Mylan v Commission*, T-682/14, EU:T:2018:907 paragraph 345 (currently on appeal to the Court of Justice: C-197/19 P) and the case law cited.
[1424] LIO3901, 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.*'
[1425] LIO3904, Investor Director Consent annexed to minutes of AML board meeting dated 15 October 2015.
[1426] LIO3897, minutes of AML board meeting dated 27 June 2013, item 6.
[1427] LIO3903, 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*'; LIO3904, minutes of AML board meeting dated 20 August 2015, item 2.

of control over the subsidiary's decisions. Such information and reports show organisational links between the parent and its subsidiary and allow the parent to monitor and control the activities of its subsidiary in order to take specific measures in relation to it.[1428]

6.241 [✂].

6.242 [✂]:

(a) [✂].[1429]

(b) [✂].[1430] [✂].

(c) [✂].[1431]

(d) [✂].[1432]

(e) [✂].[1433]

6.243 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.[1434] [✂].[1435]

6.244 [✂].[1436] [✂].

[1428] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 351 (currently on appeal to the Court of Justice: C-197/19P) and the case law cited.
[1429] LIO3897, 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 Partner] *also requested that* [✂] *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 (LIO3896, minutes of AML board meetings), at which [Cinven Partner] 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 Partner] and [Cinven Partner] both attended a meeting (LIO3898, 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.
[1430] LIO3907, minutes of AMCo investor meeting dated 28 May 2013; LIO3908, minutes of AMCo investor meeting dated 27 June 2013. See also LIO3909, LIO3910, minutes of AMCo investor meetings; LIO3911, minutes of Mercury Pharma Group Limited management meeting dated 19 December 2013.
[1431] Document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 6.2.
[1432] Document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 6.3.
[1433] Document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 6.4.
[1434] 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: *General Química v Commission*, C-90/09P, 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 *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89.
[1435] See, for example, LIO3905 and LIO3906, board minutes of Cinven MGP.
[1436] Document LIO6321, Cinven RSO, paragraphs 12.29.

6.245 [✂].[1437] [✂].[1438]

6.246 [✂].[1439] [✂].[1440] [✂].[1441] 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.[1442]

iv. Cinven MGP oversaw the AMCo group's commercial conduct and strategy

6.247 As explained at paragraph 6.28 above, decisive influence does not require influence on a subsidiary's commercial conduct: this is not the only factor that is relevant.[1443] However, where such influence can be demonstrated (whether indirectly, from the totality of the economic, legal and organisational links between the parent and subsidiary,[1444] or directly from positive evidence of a shared commercial strategy) that is strong evidence of decisive influence.[1445] In particular, influence over '*the company's commercial policy in the broadest sense*',[1446] and over strategic commercial decisions such as whether its business activities shall be expanded or down-sized, whether investments or acquisitions shall be made and whether it shall be sold and for what price, can be particularly important.[1447]

6.248 The contemporaneous evidence demonstrates that Cinven MGP exercised decisive influence over the AMCo group's commercial conduct and strategy (and therefore that of the Mercury Pharma Companies).

[1437] Document LIO6321, Cinven RSO, paragraphs 12.20-12.31.
[1438] Document LIO6321, Cinven RSO, paragraphs 12.34.
[1439] Cinven also noted that the AML Shareholders' Agreement also gave these information rights to [Waymade Director], as minority shareholder in AML (document LIO6321, Cinven RSO in Case 50395, paragraph 12.32). However, as a minority shareholder [Waymade Director] 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 Director] therefore conferred decisive influence on Cinven MGP but not on [Waymade Director].
[1440] Document LIO6321, Cinven RSO, paragraph 12.34(c) (emphasis added).
[1441] See, e.g., *Gigaset*, T-395/09, EU:T:2014:23.
[1442] *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 77, 94-95 and 100.
[1443] 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 *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89.
[1444] *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraph 347 (currently on appeal to the Court of Justice: C-197/19 P) and the cases cited.
[1445] *Durkan* [2011] CAT 6, paragraph 22; *Akzo Nobel*, C-97/08P, EU:C:2009:356, paragraphs 73-74, approving the Opinion of AG Kokott, EU:C:2009:262, paragraph 87. See also *Alliance One & Others v Commission*, T-24/05, EU:T:2010:453, paragraph 170; and *Holding Slovenske*, T-399/09, EU:T:2013:647, paragraph 32.
[1446] Opinion of AG Kokott in *Del Monte*, C-293/13, EU:C:2014:2439, paragraph 89 (followed by the Court of Justice).
[1447] *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*': *FLS Plast A/S v Commission*, T-64/06, EU:T:2012:102, paragraph 47; upheld in *FLS Plast A/S v Commission*, C-243/12P, EU:C:2014:2006.

6.249 The board of AML, which Cinven MGP controlled, set the strategic direction for its wholly-owned subsidiaries, including the Mercury Pharma Companies.[1448] As explained in section 6.D above, the AMCo group's executive management – including [Advanz CEO], [Advanz General Counsel and Secretary] and [Advanz Chief Strategy Officer] – 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.[1449]

6.250 As explained in section 6.G.I.a above, Cinven acquired the Mercury and Amdipharm groups in pursuit of a strategy to exploit the fact that [✂].[1450]

6.251 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 [✂] in September 2012, demonstrating [Cinven Partner]'s endorsement of that strategy outwardly towards the group's lenders. This presentation noted that [✂].[1451]

(b) Following correspondence between [Cinven Partner], [Advanz CEO], [Cinven Partner] and [Cinven Partner] on the scope of the non-compete obligation to apply to Waymade following the Amdipharm sale, [Cinven Partner] followed up: '*Btw If there is anything you want him* [Waymade Director] *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*'.[1452] [Cinven Partner] 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,

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[1448] 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*'.
[1449] See, eg, LIO3897, minutes of Amdipharm Mercury Limited board meeting dated 29 April 2013; LIO3898, minutes of Amdipharm Mercury Limited board meeting dated 30 October 2013; Document LIO3899, minutes of Amdipharm Mercury Limited board meeting dated 29 January 2014; LIO3901, minutes of Amdipharm Mercury Limited board meeting dated 31 July 2014; LIO3902, minutes of Amdipharm Mercury Limited board meeting dated 5 November 2014; LIO3902, minutes of Amdipharm Mercury Limited board meeting dated 27 January 2015; LIO3903, minutes of Amdipharm Mercury Limited board meeting dated 24 April 2015; LIO3904, minutes of Amdipharm Mercury Limited board meeting dated 22 July 2015.
[1450] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 3.
[1451] Document LIO0231, Project Glacier Lenders Presentation, slides 10, 11 and 27.
[1452] Document LIO12190, email from [Cinven Partner] to [Advanz CEO] and [Cinven Partner] dated 12 October 2012.

'[✂] *[*[Advanz CEO]*] /* [✂] *[*[Cinven Partner]*] to discuss media handling with PR company*'.[1453]

6.252 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.

6.253 In mid-2013, AMCo group management [✂]:

(a) [Advanz CEO] 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* [✂] *[*[✂], *Investor Director] today with no substance behind our plans will not be wise*'. Later that day, [Advanz CEO] stated: '*I have spoken to* [Cinven Partner] *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 [✂].[1454]

(b) [Advanz CEO] then emailed a set of slides to [Cinven Partner], saying: '[✂]*. If there is anything I can help to explain over the weekend feel free to ask*'.

(c) Later, [Advanz CEO] told colleagues, '*I have just had a call with* [Cinven Partner] *and there is a discussion to be had to do with the principals [sic] of what we do about* [✂]'. [Advanz CEO] considered [✂].[1455]

(d) In response, AMCo group staff put together detailed plans for [✂], including Liothyronine Tablets. When these were sent to [Advanz CEO], he noted that '*[o]ne of the big issues that our Cinven friends have is* [✂]*. They are considering whether we may want to accept* [✂]'.[1456]

(e) AMCo group senior management were of course aware [✂]. [✂], Amdipharm Managing Director, noted that [✂]. [Advanz CEO] replied: '*the point that you*

[1453] Document LIO0314, email between [Advanz General Counsel and Secretary], [Advanz Chief Strategy Officer], [Advanz Finance Director] and [Advanz CEO] dated 1 August 2013.
[1454] Document LIO0259, email between [Advanz CEO], [Advanz Head of Sales UK Brands and Generics] and [Advanz Finance Director] dated 24 May 2013 and document LIO0260, email between [Advanz CEO], [Advanz Head of Sales UK Brands and Generics] and [Advanz Finance Director] 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 *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraphs 344-361 (currently on appeal to the Court of Justice: C-197/19 P).
[1455] Document LIO0264, email from [Advanz CEO] to [Advanz Finance Director], [Advanz General Counsel and Secretary], [Advanz Head of Sales UK Brands and Generics], [Advanz Commercial Servies Director] and [Advanz Chief Operating Officer], dated 25 May 2013.
[1456] Document LIO0275, email from [Advanz Commercial Servies Director] to [Advanz CEO] dated 27 May 2013.

make in your first sentence is very valid. That will be the topic of conversation at today's investor meeting … [✂]'.[1457]

6.254 [✂]:

'[✂]'.

6.255 [✂].[1458]

6.256 The evidence therefore shows that the AMCo group's executive management, including its CEO, 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 Mercury Pharma Companies.

6.257 [✂].[1459] The CMA considers that this contemporaneous evidence from senior managers at AMCo, including its CEO, speaks for itself.

6.258 The decisive influence exercised via the Investor Directors therefore directly contributed to price increases such as those in the Infringement. As explained above, the AMCo group was an attractive investment for Cinven precisely because of its ability to exploit lack of competition and weak pricing regulation to increase the prices of drugs. When Cinven was considering the divestment of the AMCo group, a draft document was prepared '*to update the articulation of AMCo's business model and growth strategy as part of the preliminary preparation for future discussions with potential bidders*'. This process included conducting interviews with [Cinven Partner], [Cinven Partner] and [Cinven Partner]. One of the '*success stories*' identified in the document, showing the '*highly desirable pricing flexibility*' of generic drugs, was Liothyronine Tablets: '*20-50% p.a. price increase since 2010 with sable [sic] volumes. Further price upsides anticipated*'. There followed a case study on the AMCo group's having '*leveraged the favorable market dynamics to deliver 20-50% YOY price increase for Liothyronine Sodium in UK*'. *'The company was able to deliver continued price increases y-o-y (not just one-offs). Similar increase is planned for next year*'.[1460]

[1457] Document LIO0277, email from [Advanz CEO] to [Advanz Chief Operating Officer] dated 28 May 2013.
[1458] Document LIO0340, email between [Advanz CEO], [Advanz Head of Sales UK Brands and Generics] and [Advanz Commercial Servies Director] dated 22 September 2013; Document LIO0342, email between [Advanz CEO], [Advanz Head of Sales UK Brands and Generics] and [Advanz Commercial Servies Director] dated 22 September 2013; and Document LIO0348, email between [Advanz Head of Sales UK Brands and Generics], [Advanz General Counsel and Secretary] and [Advanz Commercial Servies Director] dated 23 September 2013.
[1459] Document LIO6321, Cinven RSO, paragraphs 12.35. 12.40 and 12.41.
[1460] Document LIO0468, '*Project Asclepius - Initial draft_Exec Sum and storyline_v3 12.pdf*', pages 2, 41 and 42.

6.259 The CMA therefore concludes, on the basis of the totality of organisational, legal and economic links between Cinven MGP and the Mercury Pharma Companies considered above (many of which in themselves would suffice), that Cinven MGP exercised decisive influence over the Mercury Pharma Companies during the Cinven Period.

V. Liability of Luxco 1

6.260 [✂].[1461] 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.

6.261 Cinven submitted that [✂].[1462]

6.262 The CMA does not consider that the evidence adduced by Cinven suffices to rebut the *Akzo* presumption.

6.263 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.[1463] 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.[1464]

(b) Similarly, in *Team Relocations*, an assertion that the subsidiary had managerial autonomy failed to rebut the *Akzo* presumption.[1465]

[1461] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, paragraph 9.11, and Document LIO3920, structure chart of the Fifth Cinven Fund.
[1462] Document LIO6321, Cinven RSO, paragraphs 12.42-12.43.
[1463] *Dow v Commission*, T-77/08, EU:T:2012:47, paragraph 77, upheld in *Dow v Commission*, C-179/12P, EU:C:2013:605. See also *Durkan* [2011] CAT 6, paragraph 22(b). See also *Evonik Degussa GmbH v Commission*, C-155/14P, EU:C:2016:446, paragraph 41, citing *Del Monte*, EU:C:2015:416, paragraphs 96 and 97.
[1464] *Stichting Gosselin*, C-440/11P, EU:C:2013:514, paragraphs 62-68.
[1465] *Team Relocations v Commission*, T-204/08, EU:T:2011:286, paragraph 152.

(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 include over Weichert's conduct on the relevant market*'.[1466]

6.264 Secondly, [✂].[1467] [✂].[1468]

6.265 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 Mercury Pharma Companies throughout the Cinven Period.

VI. Liability of Cinven Partners

6.266 The CMA also finds that Cinven Partners exercised decisive influence over the Mercury Pharma Companies during the Cinven Period, and that liability for the infringement committed by Advanz should be attributed to it. [✂].[1469]

6.267 Formally, [✂].[1470]

6.268 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.[1471]

6.269 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 Mercury Pharma Companies and formed an economic unit for the purpose of the Infringement with the Mercury Pharma Companies, Cinven MGP and Luxco 1, in particular through the personal links between those legal entities. 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.

[1466] *Del Monte v Commission*, C-293/13P, EU:C:2015:416, paragraph 88.
[1467] Document LIO6321, Cinven RSO, paragraphs 12.42-12.43.
[1468] Compare *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 63 to 67 and 73; *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraphs 345 and 350 (currently on appeal to the Court of Justice: C-197/19 P) and the case law cited; *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraph 114 (upheld in *Goldman Sachs v Commission,* C-595/18P, EU:C:2021:73) and case law cited.
[1469] [✂].
[1470] Document LIO3924, investment advisory agreement, clause 2.4.
[1471] [✂].

6.270 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.[1472]

6.271 As explained in paragraph 6.27 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 necessarily imply that they were in a position to do so*'.[1473] The test focuses on substance over form. For example, in *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'.[1474]

6.272 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*'.[1475]

6.273 The Court of Justice followed the Advocate General, holding that:

> 'the fact that a finding that the author of the inringement 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.'[1476]

6.274 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 Mercury Pharma Companies.[1477]

[1472] [✂].
[1473] *Alliance One and Others v Commission*, T-24/05, EU:T:2010:453, paragraphs 165 to 167, upheld in *Alliance One*, C-628/10P and C-14/11P, EU:C:2012:479. See also *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 95; and *EI du Pont de Nemours v Commission*, C-172/12P, EU:C:2013:601, paragraph 44; and *Sasol v Commission*, T-541/08, EU:T:2014:628, paragraph 43.
[1474] Opinion of AG Kokott, C-440/11P, EU:C:2012:763, paragraph 72.
[1475] Opinion of AG Kokott in *Stichting Gosselin*, C-440/11P, EU:C:2012:763, paragraphs 71 to 76.
[1476] *Stichting Gosselin*, C-440/11P, EU:C:2013:514, paragraphs 66 to 68. Compare *Toshiba*, C-623/15P, EC:C:2017:21, paragraph 46. See also *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, C-293/13 P and C-294/13 P, EU:C:2015:416, paragraph 76.
[1477] *Goldman Sachs v Commission*, T-419/14, EU:T:2018:445, paragraph 109, upheld in *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73.

6.275 As explained above (see section titled '*The presence of parent company representatives on the subsidiary's board*'), 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 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'.[1478]

6.276 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.[1479]

6.277 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*'.[1480] 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

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[1478] *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 184. See also *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraphs 354-355.

[1479] *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, 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*'. *Toshiba*, C-623/15P, EU:C:2017:21, paragraph 76. Compare *General Química v Commission*, C-90/09P, 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]*'.

[1480] *Toshiba*, C-623/15P, EC:C:2017:21, paragraph 15. As explained in the 'Legal Framework' section 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 *Toshiba v Commission*, T-104/13, 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.

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 pursues, in view of his or her links with another company, the interests of the latter. That may also be the case where 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.'[1481]

6.278 The principles established in these cases apply to the individuals appointed by Cinven MGP to AMCo group roles: the Investor Directors, [✂] and [✂], and the additional directors, [Cinven Partner] and [Cinven Partner] (see paragraphs 6.218 and 6.223 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.[1482]

6.279 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.'[1483]

6.280 This passage of the EU Jurisdictional Notice concerns the issue of whether an investment company acquires '*control*' for the purposes of the European

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[1481] *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 89 and 93-95.
[1482] [✂].
[1483] EU Jurisdictional Notice, paragraph 15.

merger control regime. This is a different issue from attributing liability for antitrust infringements.

6.281 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.[1484] 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 parties accepted that the EU Jurisdictional Notice was relevant to the question of decisive influence for attribution of liability.[1485] The CMA must therefore have regard to the EU Jurisdictional Notice by virtue of section 60A(3) of the Act.[1486]

6.282 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.'[1487]

6.283 [✂].[1488]

6.284 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:

[1484] Article 3(2) of Regulation 139/2004.
[1485] *Toshiba*, C-623/15P, EU: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*'.
[1486] [✂].
[1487] EU Jurisdictional Notice, paragraph 15.
[1488] 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 LIO3872, Cinven's response to the CMA's s.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.

(a) They were all members or employees of Cinven Partners [✂].[1489]

(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 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.

6.285 The decisive influence that Cinven MGP (and Luxco 1 through Cinven MGP) exercised over the Mercury Pharma Companies through those individuals is therefore equally attributable to Cinven Partners.

a. The Investor Directors and other key individuals appointed to AMCo group company boards were Cinven Partners staff

6.286 As explained in section 6.G.IV.b.i above, Cinven MGP [✂] appoint directors to key AMCo group company boards. In particular, Cinven MGP appointed:

(a) Two Investor Directors, [✂] and [✂], to the board of AML, the Mercury Pharma 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 its CEO [✂], did not sit on the AML board but reported to it;

(b) [Cinven Partner] and [Cinven Partner] to the boards of 13 and 21 other AMCo group companies respectively; and

(c) Two other senior individuals, [Cinven Partner] and [Cinven Partner], to the boards of Mercury Pharma Group Limited, the immediate 100% parent of the company that employed the AMCo group management including [✂], its CEO. [Cinven Partner] was also appointed to the boards of the three immediate 100% parents of Mercury Pharma Group Limited.

[1489] 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 s.26 notice dated 16 May 2018, paragraphs 1.2, 8.4 and 9.2.

6.287 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*':[1490]

(a) [✂] has been a Cinven Partner since July 2011 and is the leader of Cinven's healthcare sector team (as well as its business services sector team), having joined Cinven in 2004.[1491] [✂] took over the role of Cinven Limited in February 2012.[1492] He was an LLP Member of Cinven Partners until 31 May 2020, [✂].[1493]

(b) [✂] is now a Cinven Partner ([✂]). He is a member of Cinven's healthcare sector team, having joined Cinven in 2006. [✂] also leads Cinven's investment activities in the USA.[1494] During the Cinven Period, he was employed as a [✂].[1495] He was an LLP Member of Cinven Partners from January to August 2016.[1496]

(c) [✂] is Cinven's Managing Partner (a role to which he was appointed in September 2015, towards the end of the Cinven Period) and during the Cinven Period was a member of Cinven Partners' Executive Committee and Investment and Portfolio Review Committees. He joined Cinven in 1996 and is '*responsible for the execution of the firm's strategy and the day-to-day management of the firm*'.[1497] [✂].[1498] He was an LLP Designated Member of Cinven Partners from February 2012 until 31 May 2020, [✂] above he transferred to become an LLP Designated Member of Cinven Partnership LLP.[1499]

(d) [✂] is described as a 'Partner' on Cinven's website. [✂] was employed by Cinven Partners during the Cinven Period. [✂] joined Cinven in 2010 and is a member of its healthcare sector team.[1500]

[1490] Document LIO6537.310, Cinven's response to the CMA's s.26 notice dated 16 May 2018, paragraphs 1.2, 8.4 and 9.2.
[1491] Document PAD082, Cinven: [✂].
[1492] Document LIO6490.5, '[Cinven Partner] *partner letter dated 17 February 2012*'.
[1493] According to Companies House.
[1494] Document PAD076, Cinven: [✂].
[1495] Document LIO3872, Cinven's response to the CMA's s.26 notice dated 20 October 2016, footnote 20.
[1496] According to Companies House.
[1497] Document PAD058, Cinven: [✂].
[1498] Document PAD059, '*Cinven appoints* [✂] *as Executive Chairman,* [✂] *as Managing Partner*'.
[1499] According to Companies House.
[1500] Document PAD077, Cinven: [✂].

6.288 These individuals were seconded from Cinven Partners to their roles in the AMCo group [✂].[1501] [✂].[1502]

6.289 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.[1503] 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 employment.[1504] [✂];[1505] [✂].[1506] The actions of [Cinven Partner] and [Cinven Partner], 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 [✂] and [✂], as LLP members of Cinven Partners during the Cinven Period, are also attributable to Cinven Partners:

(i) [✂].[1507]

(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*'.[1508] Not only were both [✂] and [✂] LLP members of Cinven Partners; they were also 'Authorised Signatories' of Cinven Partners,[1509] with [✂].[1510] They (particularly [✂], as Cinven's Managing Partner towards the end of the

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[1501] [✂].
[1502] Document LIO6537.310, Cinven's response to the CMA's s.26 notice dated 16 May 2018, paragraphs 8.4 and 9.2.
[1503] *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*'.
[1504] See e.g. *Musique Diffusion v Commission*, 100/80 to 103/80, EU:C:1983:158, paragraphs 97-98; *Suiker Unie v Commission*, 40/73, EU:C:1975:78, paragraphs 539 and 542; *Slovenska sporitelna v Commission*, C-68/12, EU:C:2013:71, paragraph 25; *Dole v Commission*, T-588/08, EU:T:2013:130, paragraphs 581-582; *Marlines v Commission*, T-56/99, EU:T:2003:333, paragraph 60. See also the CMA's *Paroxetine* decision of 12 February 2016 (Case CE/9531-11), paragraph 9.19.
[1505] Document LIO6497.6, '*Initial employment contract of* [✂]', paragraph 4.1(e), as amended by the transfer of employees from Cinven Limited to Cinven Partners.
[1506] [✂].
[1507] Document LIO6497.1, '*Cinven Partners LLP Partnership Agreement dated 17 February 2012*', clause 13.1.2.
[1508] *Slovenská sporiteľňa*, C-68/12, EU:C:2013:71, paragraph 25; and *Musique Diffusion française and Others v Commission*, 100/80 to 103/80, EU:C:1983:158, paragraph 97 (see also *Dole v Commission*, T-588/08, 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.
[1509] Document LIO7764, Cinven's response to question 3 of the CMA's s.26 notice dated 6 November 2018.
[1510] [✂].

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*'.[1511]

(iii) Further, the members of an LLP such as Cinven Partners are deemed in law to be agents of the LLP.[1512] 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 principal's instructions and thus, like a commercial employee, forms an economic unit with his undertaking*'.[1513] The CMA finds, on the basis of the evidence set out in this section, that [Cinven Partner] and [Cinven Partner] were acting for Cinven Partners (as well as the AMCo group boards on which they sat) in administering the AMCo group investment.[1514]

b. Cinven Partners set the strategy for the AMCo group investment through those individuals

6.290 As explained in paragraph 6.45 above, the 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*'.[1515]

6.291 As explained in section 6.G.I.a 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.[1516] 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.

6.292 Cinven's strategy – and especially its implementation through a merged group under the management of [✂], Mercury Pharma's existing CEO with extensive experience of this business model – is attributable to Cinven

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[1511] *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraph 77. See also *Parker Pen v Commission*, T-77/92, EU:T:1994:85, paragraphs 78-82.
[1512] 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*'.
[1513] *Marlines v Commission*, T-56/99, EU:T:2003:333, paragraph 60 and case law cited; and *Suiker Unie v Commission*, 40/73, EU:C:1975:78, paragraph 480.
[1514] Compare *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 89 and 93-95.
[1515] *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 121, referring to the Opinion of AG Kokott in *Akzo Nobel*, C-97/08P, EU:C:2009:262, paragraph 73.
[1516] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', pages 3, 6 and 8.

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 6.140 to 6.142 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 [Advanz CEO] ('*it would be a synergistic combination with Mercury, and the levers* [Advanz CEO] *has pulled on pricing etc. would be applicable to Amdipharm*'), was authored by [four Cinven Partners] and two other individuals. It is dated 2 July 2012.[1517]

(b) The investment recommendation for Cinven's acquisition of the Amdipharm group, discussed at paragraph 6.143 above, which referred to '*our investment thesis for the combination of Mercury and Amdipharm*' and stated that '*The primary growth levers for Amdipharm* [✂]', was prepared by [four Cinven Partners] and three other individuals. It is dated 9 July 2012 and was prepared on Cinven Partners headed paper.[1518]

(c) The final recommendation for Cinven's acquisition of the Mercury Pharma and Amdipharm groups, discussed at paragraph 6.145 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* [Advanz CEO] *and the team have successfully executed at Mercury*'), was also authored by [four Cinven Partners] and three other individuals. It is dated 30 July 2012.[1519]

6.293 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 recommendation[1520]) before any of these individuals was appointed to roles on the boards of AML and other AMCo group

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[1517] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 2.
[1518] Document LIO6490.4, '*Annex 2.2 - memorandum to the IC titled 'Amdipharm - initial investment recommendation' dated 9 July 2012*'. Compare *Knauf Gips v Commission*, C-407/08P, 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).
[1519] Document LIO6491.1, '*Annex 2.3 - minutes of a meeting of the IC dated 30 July 2012*', pages 5 and 36.
[1520] [Cinven Partner] and [Cinven Partner] 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 Partner] in document LIO3940, Cinven's response to the CMA's s.26 notice dated 11 November 2016, paragraph 7.2(a).

companies. The work of those individuals in preparing the investment recommendations, and the strategy they set out, are therefore attributable to Cinven Partners.

6.294 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. [✂] – described as '*Partner at Cinven*'[1521] – 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.'[1522]

6.295 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'.[1523]

6.296 As explained above, [✂], which is not a Fifth Cinven Fund team. 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.

6.297 The recommendations for the two acquisitions were prepared and submitted to the Investment Committee of Cinven Partners. [✂].[1524] It was made up [✂], including [Cinven Partner].[1525] 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.

[1521] Compare the description of [✂] 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.
[1522] Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*'.
[1523] Document PAD066, Cinven: '*AMCo 8 September 2015 Cinven to sell AMCo to Concordia Healthcare Corp*' (emphasis added).
[1524] [✂].
[1525] Document LIO6537.310, Cinven's response to question 3 of the CMA's s.26 notice dated 16 May 2018.

6.298 On the basis of those recommendations, that committee agreed to recommend that the Fifth Cinven Fund make binding offers for the two groups.[1526] 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 forward. Cinven Partners determined the terms of those offers, including the maximum price to be paid. [✂].

c. Cinven Partners oversaw the implementation of that strategy through those individuals

6.299 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.

6.300 [Cinven Partner], [Cinven Partner], [✂] and [Cinven Partner] [✂].[1527] [✂].[1528]

6.301 As explained above (see paragraphs 6.275 to 6.277), 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.[1529] 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.

[1526] 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.
[1527] [✂].
[1528] Cinven submitted that: '*It is a significant stretch for the CMA to assert that a professional service company making available secondee 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 LIO7791, Cinven RSSO-2019, 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.
[1529] *Fuji Electric*, T-132/07, EU:T:2011:344, paragraph 184; *Toshiba v Commission*, T-104/13, EU:T:2015:610, paragraph 116, upheld in *Toshiba*, C-623/15P, EU:C:2017:21, paragraphs 15 and 76; *General Química v Commission*, C-90/09P, EU:C:2011:21, paragraph 106; *Goldman Sachs v Commission*, C-595/18P, EU:C:2021:73, paragraphs 89 and 93-95; *Mylan v Commission*, T-682/14, EU:T:2018:907, paragraphs 354-355.

6.302 As explained in section 6.G.VI.b above, as Partners ([✂] and [✂]), Principal ([✂]) and employee ([✂]) 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 6.G.VI.a above, the Investor Directors sat on the board of the ultimate 100% owner of all the Mercury Pharma 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) As [✂], [✂] 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 [✂], and a specialist in healthcare investments, having '*led several of Cinven's most successful transactions*' in this sector,[1530] [✂] 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.

6.303 [✂].

6.304 [✂]. 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.

[1530] See Document PAD091, '*Cinven Names* [✂]'.

6.305 Cinven submitted [✂].[1531]

6.306 The law on parental liability (like competition law in general) depends not on contractual or company law technicalities but on economic reality.[1532] 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.

6.307 [✂].[1533] 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.[1534] [✂].[1535]

6.308 The CMA finds that such a distinction is artificial in this case, particularly given that those interests were aligned. As explained in sections 6.G.I and II above, the interests of all the Cinven Entities, AML and the Mercury Pharma 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.[1536] 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.

6.309 The evidence shows that they did so in practice.

6.310 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 Review Committees.[1537] [✂]. This gave Cinven Partners, through the

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[1531] Document LIO6321, Cinven RSO, paragraphs 12.47-12.50.
[1532] *Stichting Gosselin*, C-440/11P, EU:C:2013:514, paragraphs 66-68. See also Opinion of AG Kokott, EU:C:2012:763, paragraphs 71-76: Compare *Toshiba*, C-623/15P, EU:C:2017:21, paragraph 46. See also *Fresh Del Monte Produce v Commission and Commission / Fresh Del Monte Produce*, C-293/13P and C-294/13P, EU:C:2015:416, paragraph 76.
[1533] Document LIO6321, Cinven RSO, paragraph 12.56.
[1534] 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*': *Holding Slovenske*, T-399/09, EU:T:2013:647, paragraphs 75-77.
[1535] Document LIO7791, Cinven RSSO-2019, paragraph 10.14(e) (emphasis in original).
[1536] [✂].
[1537] [✂].

individuals it seconded to the AMCo group, control over the pipeline of investments for the Fifth Fund and the AMCo group.[1538]

6.311 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 Partner] wrote to the Investment Committee to '*seek IC approval to proceed*' with the AMCo group's acquisition of [✂] on behalf of the '*Amco Team*'.[1539]

(b) In April 2014, [✂] sought approval from the Investment Committee and Portfolio Review Committee for the AMCo group to make an offer for [✂], stating: '*Please let me know if you are happy for us to proceed*'.[1540]

(c) [✂].[1541]

(d) An update for the Portfolio Review Committee on the acquisition of Focus Pharmaceuticals, on Cinven Partners headed paper, was prepared by [Cinven Partner], [Cinven Partner] and [Cinven Partner] 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*'.[1542] The final investment recommendation was also prepared by [four Cinven Partners] and two other individuals on Cinven Partners headed paper. It noted that Focus had [✂].[1543]

6.312 During the course of the Cinven Period, regular papers on the AMCo group investment were submitted to the Cinven Partners Portfolio Review Committee (see paragraph 6.242 above).[1544] These papers included updates on matters such as the integration of the Amdipharm and Mercury groups; AMCo management; acquisitions; financing; the AMCo group '*Strategy*

[1538] See, for example, Document LIO6496.10, 'M*inutes of the Cinven MGP quarterly Board Meeting dated 27 August 2015*', page 5: in relation to one potential investment, [✂]. The minutes of Cinven MGP board meetings on 22 November 2012 and 14 November 2013 stated that: [✂]: 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.
[1539] Document LIO6537.58, email from [Cinven Partner] to IC Members and PAs dated 1 February 2013.
[1540] Document LIO6537.135, email from [Cinven Partner] to [Cinven Partner] dated 30 April 2014.
[1541] Document LIO3901, AML board meeting minutes dated 27 June 2014, paragraph 4.2.
[1542] Document LIO6492.10, '*Focus Pharmaceuticals - AMCo bolt-on' dated 6 August 2014*'.
[1543] Document LIO6494.1, '*Focus Pharmaceuticals - Final Investment Recommendation' dated 17 September 2014*', page 3.
[1544] 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: *General Química v Commission*, C-90/09P, 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 *Unichem v Commission*, T-705/14, EU:T:2018:915, paragraphs 69-89.

agenda'; the budget (noting that [✂][1545] [✂][1546] and trading conditions.[1547] The Portfolio Review Committee papers also included a '*Strategy scorecard*' with a summary of risks and opportunities.

6.313 Once approved, investment recommendations were presented by Cinven Partners staff to the board of Cinven MGP. [✂].

6.314 [✂].[1548]

6.315 [✂].[1549]

6.316 [✂].

6.317 [✂].[1550]

6.318 [✂].[1551]

6.319 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.

6.320 Other key Cinven Partners staff also played a role. [✂] '*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 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.[1552]

[1545] Document LIO6492.7, '*Q4 PRC Paper on AMCo dated December 2013*', page 5.
[1546] 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)*'.
[1547] 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*'.
[1548] 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*'.
[1549] Document LIO3118, Minutes of Cinven MGP Board meeting dated 26 June 2014.
[1550] Document LIO3905, '*AMCo bolt-on M&A opportunities*' dated 1 April 2015, pages 12, 13.
[1551] Document LIO3905, Minutes of Cinven MGP board meeting dated 2 April 2015.
[1552] Document LIO6496.11, '*Minutes of the Cinven MGP quarterly Board Meeting dated 21 November 2013*'.

d. Cinven Partners drove the decision to divest the AMCo group through those individuals

6.321 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.

6.322 A recommendation for an AMCo group follow-on acquisition was prepared for the Cinven Partners Investment Committee in October 2013. It [✂]. The recommendation [✂] 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*'.[1553] 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.

6.323 The '*AMCo exit paper*' prepared in February 2015 and discussed in paragraphs 6.158 to 6.161 above was authored by [three Cinven Partners] and one other individual, on Cinven Partners headed paper. It was presented to the Cinven Partners Portfolio Review Committee.[1554] 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 [✂]. 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)*'. [✂].

6.324 In July 2015 [three Cinven Partners] 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, [✂]. Under '*Why 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*'.[1555] 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

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[1553] Document LIO6492.1, '*AMCo add-on acquisition recommendation dated 31 October 2013*', pages 2 and 3 (emphasis added).
[1554] Document LIO6494.3, '*AMCo Exit Paper' dated 27 February 2015*',
[1555] 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*'.

view that its strategy of increasing the prices of niche generic drugs had now reaped the [✂].

6.325 The recommendation for the sale of the AMCo group prepared in August 2015 was authored by [three Cinven Partners] and two other individuals, on Cinven Partners headed paper. It was presented to the Cinven Partners Portfolio Review Committee by [Cinven Partner] and [Cinven Partner] for unanimous approval before it was presented to Cinven MGP.[1556] [✂].[1557] [✂].

6.326 Cinven submitted [✂].[1558] However, this is not the right way to approach the evidence. As explained in paragraph 6.30 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*'.[1559] The CMA finds that the documentary evidence, taken together and as a whole, demonstrates the exercise of decisive influence by Cinven Partners.

H. Liability of Advanz Pharma Corp

6.327 The CMA attributes liability to Advanz Pharma Corp (formerly Advanz Pharma Corporation, Concordia International Corporation and Concordia Healthcare Corporation) for the Infringement, and for the resulting financial penalty, jointly and severally with the Mercury Pharma Companies from 21 October 2015 until the end of the Infringement Period. This is because the Mercury Pharma Companies were wholly-owned by Advanz Pharma Corp throughout that period.

6.328 On 21 October 2015, the AMCo group was acquired by Concordia Healthcare Corporation (now Advanz Pharma Corp. Limited)[1560] and from that date until the end of the Infringement Period, Mercury Pharmaceuticals Limited, Advanz

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[1556] Document LIO6537.293, email from [Cinven Partner] to PRC Members and others dated 26 August 2015; document LIO6537.295, email from [Cinven Partner] to PRC Members dated 26 August 2015.
[1557] Document LIO3119, minutes of Cinven MGP board meeting dated 27 August 2015.
[1558] Document LIO6321, Cinven RSO in Case 50395, paragraph 12.59.
[1559] *Knauf Gips v Commission*, C-407/08P, EU:C:2010:389, paragraph 65.
[1560] Document PAD068, Advanz: '*Completes AMCo acquisition*'. Concordia Healthcare Corporation announced its name change to Concordia International Corporation on 28 June 2016: document PAD069, Cision PR Newswire: '*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 Corporation on 29 November 2018: '*Concordia International Corp. Announces Name Change to ADVANZ PHARMA Corp.*' 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: '*2020 ANNUAL MANAGEMENT'S DISCUSSION AND ANALYSIS*', https://www.advanzpharma.com/media/uploads/advanz-pharma-corp.-limited-management-discussion-and-analysis-17-march-2021.pdf, page 7.

Pharma Services (UK) Limited and Mercury Pharma Group Limited were all indirectly wholly-owned by Advanz Pharma Corp.[1561]

6.329 Advanz Pharma Corp therefore had the ability to exercise decisive influence over the Mercury Pharma Companies during this period, and the CMA applies the *Akzo* presumption that it did actually exercise such influence.

6.330 The application of the *Akzo* presumption has not been disputed and the presumption has therefore not been rebutted.

[1561] Document LIO0875, '*Confidential Annex 5.1 - Corporate Structure Chart for the AMCo Group af....pdf*'; document LIO0876, '*Confidential Annex 5.2 - Current Corporate Structure Chart of the AMCo G....pdf*', attached to document LIO0870, Email from [✂] to [✂] dated 26 October 2016; document LIO3955, Advanz's response to question 1 of the CMA's s.26 notice dated 21 August 2017, and document LIO3954, '*Annex 2: Updated structure chart*'.

7. The CMA's actions

7.1 This chapter sets out the actions that the CMA is taking in connection with the Infringement and the CMA's reasons.

A. The CMA's decision

7.2 The CMA finds on the basis of the evidence set out in this Decision that:

(a) From at least 1 November 2007 to 31 July 2017, Advanz held a dominant position in the market for the supply of Liothyronine Tablets in the UK.

(b) Throughout the Infringement Period, Advanz abused that dominant position by imposing unfair selling prices for Liothyronine Tablets, thereby infringing the Chapter II prohibition.

7.3 The CMA finds on the basis of the evidence set out in this Decision that the following legal entities are liable for the Infringement in respect of the following periods:

(a) From at least 1 January 2009 to 29 December 2009, Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited and Mercury Pharma Group Limited;

(b) From 30 December 2009 to 30 August 2012, Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited, Mercury Pharma Group Limited and HgCapital LLP;

(c) From 31 August 2012 to 20 October 2015, Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited, Mercury Pharma Group Limited, Cinven Capital Management (V) General Partner Limited, Cinven (Luxco 1) S.A. and Cinven Partners LLP; and

(d) From 21 October 2015 to 31 July 2017, Mercury Pharmaceuticals Limited, Advanz Pharma Services (UK) Limited, Mercury Pharma Group Limited and Advanz Pharma Corp. Limited.

B. Directions

7.4 Section 33(1) of the Act provides that if the CMA has made a decision that conduct infringes the Chapter II prohibition, it may give to such person or persons as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.

7.5 The CMA has not made a finding that the Infringement is ongoing at the time of this Decision, and accordingly does not give directions to Advanz to require it to modify or cease its conduct or direct it not to engage in the same or similar conduct in the future.

C. Financial penalties

I. The CMA's power to impose penalties

7.6 Sections 36(2) and (3) of the Act provide that, if the CMA takes a decision that an undertaking's conduct infringes the Chapter II prohibition, it may require the undertaking concerned to pay a penalty in respect of the infringement if it is satisfied that the infringement has been committed intentionally or negligently.

II. Conduct of minor significance

7.7 Section 40 of the Act precludes the imposition of a penalty for an infringement of the Chapter II prohibition if the abuse is 'conduct of minor significance'. Section 40 applies where the infringing undertaking's applicable turnover '*for the business year ending in the calendar year preceding one during which the infringement occurred did not exceed £50 million*'.[1562] This condition is not met here: the Infringement occurred between the years 2009 and 2017. Advanz's turnover exceeded £50 million in each business year ending in the calendar years 2008 to 2016.[1563]

III. Intent and negligence

7.8 The CMA may impose a penalty on an undertaking which has infringed the Chapter II prohibition only if the CMA is satisfied that the infringement has been committed intentionally or negligently.[1564] However, the CMA is not

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[1562] See Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000, SI 2000/262, reg 4.
[1563] In 2008 and 2009, Goldshield Group plc (later Mercury Pharma Group Limited) had a turnover of £84.9 million and £98.4 million respectively (*Goldshield Group plc Annual Report 2009*, page 5, available at: https://find-and-update.company-information.service.gov.uk/company/02330913/filing-history). Between 30 December 2009 and 20 October 2015, during HgCapital and Cinven's respective ownership periods, both firms would have significantly exceeded the £50 million turnover threshold. Advanz Pharma Corp also comfortably exceeded this threshold with a turnover of $394 million (£257.7 million) in 2015 and $816 million (£602 million) in 2016 (*Advanz Pharma Corp Annual Financial Report 2016*, page 17, available at: https://www.advanzpharma.com/media/uploads/2016-Year-End-Report.pdf).
[1564] Competition Act 1998, s 36(3).

obliged to specify whether it considers the infringement to have been committed either intentionally or merely negligently.[1565]

a. Legal framework

7.9 The CAT has defined the terms 'intentionally' and 'negligently' as follows:

> '… an infringement is committed intentionally for the purpose 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 s 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition'.[1566]

7.10 Intent 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 legal characterisation*' of its conduct, '*but whether it was aware of its anti-competitive nature*'.[1567] In cases of exploitative abuse, by analogy, this means that the undertaking must have been aware of the exploitative nature of the conduct.

7.11 This is consistent with the approach taken by the Court of Justice, which has confirmed that:

> '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'.[1568]

7.12 The CAT recently confirmed in *Paroxetine* that the principles set out at paragraphs 7.9 to 7.11 above are the principles applicable for the purpose of section 36(3) of the Act, noting that the question is whether the relevant

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[1565] *Napp* [2002] CAT 1, paragraphs 453 to 455; see also *Argos and Littlewoods v OFT* [2005] CAT 13, paragraph 221.
[1566] *Argos* [2005] CAT 13, paragraph 221; see also *Napp*, paragraphs 456 to 457, and *Ping v CMA* [2020] EWCA Civ 13, paragraph 117.
[1567] *Royal Mail Plc v Ofcom* [2019] CAT 27, paragraph 782, citing *Lundbeck v Commission,* T-472/13, EU:T:2016:449, paragraph 762 ('*it is settled case-law that that condition is satisfied where the undertaking concerned cannot be unaware of the anticompetitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty*'). See also *Napp*, paragraph 456.
[1568] *Deutsche Telekom*, C-280/08P, EU:C:2010:603, paragraph 124, citing *IAZ v Commission*, 96/82, EU:C:1983:310, paragraph 45 and *NV Nederlandsche Banden-Industrie Michelin v Commission*, 322/81, EU:C:1983:313, paragraph 107.

undertakings '*knew or should have known*' that the agreements in question '*were anti-competitive in nature*'.[1569]

7.13 It follows that ignorance or mistake of law is no bar to a finding of an intentional (or negligent) infringement. This is the case even when such ignorance or mistake is based on independent legal advice.[1570]

7.14 An undertaking will be aware of the exploitative nature of its conduct where it is aware of the 'essential facts' underpinning the legal finding of abuse.[1571] 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 undertaking was in a dominant position, and (ii) the undertaking's price was excessive and unfair.[1572]

7.15 The CMA will assess the relevant evidence objectively and may draw reasonable inferences. In some cases, '*an undertaking's intention will be confirmed by internal documents*'. In other cases, '*in the absence of evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred*'.[1573]

7.16 Where a dominant undertaking pursues a certain policy which in fact has, or would foreseeably have, an anti-competitive (or, by analogy, an exploitative)

[1569] *Paroxetine II* [2021] CAT 9, paragraphs 117 and 121.
[1570] *Ping* [2020] EWCA Civ 13, paragraph 117, citing *Bundeswettbewerbsbehörde v Schenker & Co AG* ('***Schenker***'), C-871/11, 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*'.
[1571] This can be inferred from the case law, which states that awareness of the essential facts which form the basis of an infringement finding is sufficient for a finding of intentional or negligent conduct. See, e.g. *NV Nederlandsche Banden-Industrie Michelin v Commission,* 322/81, EU:C:1983:313, 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*', *Raiffeisen Zentralbank Österreich v Commission*, T-259 to 264/02 and T 271/02, EU:T:2006:396, 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*', *Intel v Commission,* T-286/09, 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 Mazak in *Deutsche Telecom*, C-280/08P, 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*'.
[1572] See *Phenytoin CoA* [2020] EWCA Civ 339, paragraph 97. *United Brands*, 27/76, EU:C:1978:22, paragraphs 249 and 250.
[1573] See *Napp* [2002] CAT 1, paragraph 456.

effect, it may be legitimate to infer that it is acting intentionally for the purposes of section 36(3) of the Act.[1574]

b. Application of the legal principles to the facts: Intentional or at the very least negligent conduct on the part of Advanz

7.17 Applying these principles to the facts of this case, the CMA finds that the Infringement was committed intentionally, or at the very least negligently since Advanz knew, or at the very least should have known, the essential facts underpinning the CMA's findings that throughout the Infringement Period (i) it was in a dominant position with regard to the supply of Liothyronine Tablets in the UK, and (ii) the prices it charged for Liothyronine Tablets in the UK were excessive and unfair.

7.18 The Parties made numerous representations challenging the CMA's conclusion that Advanz committed the Infringement intentionally or at the very least negligently. The CMA rejects these arguments. The Parties' representations, together with the CMA's response, are set out in Annex 7.

i. Advanz's awareness of the essential facts supporting the conclusion that it was dominant

7.19 As set out in paragraphs 4.33 ff above, Advanz's internal documents clearly indicate that Advanz knew or at the very least should have known that other treatments were not appropriate substitutes for, and did not constrain its pricing of, Liothyronine Tablets. This shows that Advanz knew or at the very least should have known that Liothyronine Tablets were not part of a wider relevant product market.

7.20 As set out below, Advanz also knew or at the very least should have known that:

(a) it was the sole MA holder and supplier of Liothyronine Tablets in the UK throughout the Infringement Period, giving it a 100% share of the market;

(b) it was not subject to any competitive pressure from existing competitors, or imminent competitive pressure from potential new entrants (due to the relatively high barriers to entry into the market);

(c) the NHS had no countervailing buyer power;[1575] and

[1574] See *Napp* [2002] CAT 1, paragraph 456.
[1575] See paragraphs 4.146 ff, in particular paragraphs 4.180 ff above and Annex 5.

(d) it was this position that enabled it to profitably sustain significant price increases without any material effect on volumes throughout the entire Infringement Period.[1576]

7.21 Advanz's internal documents confirm its understanding of its market power and the lack of competitive constraints in the UK market for Liothyronine Tablets with Advanz frequently referring to itself as the sole or exclusive UK supplier of Liothyronine Tablets and to the absence of competitive constraints. It also stressed that this gave it a strong market position and the ability to raise prices without losing sales volume:

(a) In a spreadsheet modelling future price rises emailed from [✂] (then Head of Marketing) to [✂] (then Chief Operating Officer) and [✂] (then UK Head of Pharmaceuticals) dated November 2008, Advanz commented: '*Goldshield is sole supplier. Price increase is possible. We have already increased price from £8.72 (Mar'08) to £20.80 (Jan'09)*'. It further stated that '*[i]n year 2008 Goldshield sales has not decreased inspite [sic] of price increase*'.[1577]

(b) In a budget preparation document dated March 2011 that was emailed to [✂] (then Chief Executive Officer), Liothyronine Tablets were listed as one of the products for which '*[p]rices have been increased on sole supply products which have been taken out of the PPRS scheme*'.[1578]

(c) A memorandum to investors dated September 2012 stated that '*Mercury Pharma has a strong market position as the only supplier of Liothyronine]tablets in the UK market … Through its position as sole market provider in the UK, Mercury Pharma has strong pricing power. Over the last 3 years, Mercury Pharma has doubled the price of Liothyronine. Continued stable growth in historical volumes demonstrates the inelasticity of demand to the price increases, with volumes growing from FY2010 to FY2012 at a CAGR of 2%*'.[1579]

(d) In a draft question and answer pack prepared for investors dated 12 November 2015, a slide on Liothyronine Tablets stated: '*No direct competitor*

[1576] See paragraphs 4.128-4.131 above.
[1577] Document LIO0043, *'Proposed - Price Increase Model 2009-10.xls*', page 3; attached to document LIO0042, Email from [Goldshield Head of Marketing Brands and Generics, India] to [Goldshield Founder and Group Board Director] dated 28 November 2008.
[1578] Document LIO0112, '*Budget 2011-2012_15_03_2011_version 2.docx*', page 5, attached to document LIO0111, Email from Advanz employee to [Advanz CEO] dated 18 March 2011.
[1579] Document LIO0740, *'Mercury Pharma Confidential Information Memorandum_vF.docx*', page 62; see also document LIO0221, *'Glacier Management Presentation_vFINAL.pdf*', page 30, and document LIO0250, '*Ampule Confidential Information Memorandum_Draft_v08.pdf*', page 47.

… Non-branded, therefore free pricing … Volumes have been stable historically, with consistent price increases achieved'.[1580]

ii. Advanz's awareness that it was exploiting its dominant market position in order to charge excessive and unfair prices for Liothyronine Tablets

7.22 The contemporaneous evidence shows that Advanz knew or at the very least should have known that it was exploiting the absence of competition in the UK market for Liothyronine Tablets in order to charge unfair prices for Liothyronine Tablets.

7.23 Liothyronine Tablets were part of Advanz's general price optimisation strategy, described in detail above,[1581] which consisted of applying '*price increases on products with limited competition and barriers to entry*'.[1582] Most of the products selected for price optimisation, including Liothyronine Tablets, were '*characterised by high demand inelasticity, hence even high price increases do not lead to significant volume drops*'.[1583] This meant that ASP increases to the detriment of the NHS and ultimately patients, could be sustained.[1584]

7.24 Advanz's price optimisation strategy was expressly designed to ensure that its numerous successive price increases went '*below the radar'* of both competitors and the NHS.[1585]

7.25 In September 2007, shortly before their de-branding, the ASP for Liothyronine Tablets had been the equivalent of £4.05.[1586] At this price, Liothyronine Tablets were Advanz's seventh most profitable product in its portfolio of 63 drugs.[1587,1588] Having de-branded the drug, in November 2007 Advanz introduced an ASP of £8.05 per pack. In November 2010, Liothyronine Tablets became listed under Part VIIIA of the Drug Tariff and Advanz increased the ASP to £30.34. A series of price changes followed until January

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[1580] Document LIO0601, '*Investor Q&A info pack - DRAFT 12Nov2015.pptx*', page 14.
[1581] See paragraphs 5.4 to 5.45 above.
[1582] Document LIO0588, '*Project Harmony_LEK CDD_v210815_vDraft.pdf*', page 9; see also document LIO0740, '*Mercury Pharma Confidential Information Memorandum_vF.docx*', pages 14-15 and 33; document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', pages 13 and 15.
[1583] Document LIO3814, '*20150808 AMCo's Pricing Expertise.pptm'*, page 2; see also document LIO0765, *'CCM Pharma Confidential Information Memorandum Addendum.pdf*', page 23.
[1584] Document LIO0356, *'FINAL Current Trading and Projections Report 20Jul2012.pdf*', pages 23 and 44; see also document LIO3822, '*Project Navy Financial Due Diligence Report.pdf*', page 48.
[1585] Document LIO0740, '*Mercury Pharma Confidential Information Memorandum.pdf*', pages 14-15; Document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', pages 65- 67; Document LIO0769, '*Project Armour CIM_v72.pdf*', pages 16-17. See also Document LIO0546, Email from [✂] (then Global Marketing Director) to [✂] (then Chief Financial Officer) dated 30 July 2015, page 4.
[1586] As noted at paragraph 3.22 above, Advanz reduced the number of tablets per pack from 100 to 28.
[1587] Document LIO0010, Advanz's '*UK Retail Brands Business Plan.doc*', page 2.
[1588] Document LIO0044, '*Consolidated PPA Rx data for 2003-07*', 'Rx data 2007' tab.

2017, when Advanz's ASP reached £247.87. This amounted to an increase of 1,110% during the Infringement Period and of 6,021% above the September 2007 ASP.

7.26 The sustained increases in the ASP of Liothyronine Tablets over the Infringement Period were not accompanied by any material increase in production costs; nor was there any other objective justification for them. On the contrary, Liothyronine Tablets were a very old drug, which was long off-patent, had been de-branded, and Advanz had made no material investments or innovations in relation to it. Advanz had also not added any additional benefits for patients beyond those already available since Glaxo first launched its Liothyronine Tablets product in the 1950s. Advanz must have been aware of this.[1589]

7.27 Indeed, Advanz's '*Branded Pharmaceuticals UK Business Plan*' indicated that Advanz adopted its de-branding strategy for Liothyronine Tablets, which dated back to 2007, to '*increase prices*'. Advanz had reduced the pack size of Liothyronine Tablets from 100 tablets to 28 tablets at the same time as de-branding the product to '*drive price increases*'.[1590] Its price increases were sustained '*y-o-y* [year-on-year] *(not just one-offs)*'.[1591]

7.28 Advanz highlighted Liothyronine Tablets as an example of the successful implementation of its price optimisation strategy, observing that '*stable historical volumes*' despite '*significant price increases*' show the '*market's acceptance*' of year-on-year price increases.[1592] Advanz gradually and consistently increased prices for Liothyronine Tablets with volumes remaining stable.

7.29 Advanz's pursuit of its pricing policy had a foreseeable and direct exploitative effect on the NHS and patients.[1593] In accordance with the principles set out in

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[1589] When the CMA asked Advanz, by way of a section 26 notice, what factors it took into account in determining the price of Liothyronine Tablets during the Infringement Period, Advanz responded that it took into account '*the following competitive and regulatory constraints in determining its price […]:*
(a) alternative treatments;
(b) threat of generic entry from other suppliers;
(c) MHRA requirements;
(d) PPRS until Liothyronine ceased to be available under a brand name; and
(e) DH control of pricing through direct intervention to ensure that prices are reasonable under Scheme M'. See Document LIO3061, Advanz's response to question 25 of the CMA's s.26 notice dated 25 January 2017.
[1590] Document LIO0010, '*UK Retail Brands Business Plan.doc*', page 3; see also document LIO0019, Email from Advanz employee to [Goldshield Head of pharmaceuticals UK] dated 20 December 2007; document LIO0070, '*MINUTES OF MEETING - 21 July 2010-1.DOC*', page 3; document LIO0223, Email discussion between [Advanz Finance Director], [Advanz CEO] and [Advanz Finance Director], dated 19 July 2012; and document LIO0008, '*UK Monthly Report January 07*', pages 6-7.
[1591] Document LIO3796, '*AMCo for MSDW.PDF*', page 7; document LIO0601, '*Investor Q&A info pack - DRAFT 12Nov2015.pptx*', page 14.
[1592] Document LIO0765, '*CCM Pharma Confidential Information Memorandum Addendum.pdf*', page 46; see also document LIO0493, '*Project Asclepius - Initial draft_Exec Sum and storyline_v6.5.pdf*', page 58.
[1593] See paragraphs 5.35 to 5.45 above.

Napp, the CMA therefore infers that Advanz was acting intentionally for the purposes of section 36(3) of the Act from its pursuit of the price optimisation strategy with regard to Liothyronine Tablets.[1594] In any event, the other evidence set out in paragraphs 7.23 to 7.28 above, as well as the evidence relating to Advanz's strategy more generally (see section 5.B above), also shows Advanz's intention to charge prices which were excessive and unfair, or at the very least, that it acted negligently in this regard.

7.30 Since HgCapital, Cinven and Advanz Pharma Corp each formed part of Advanz during their respective ownership periods (and the Mercury Pharma Companies formed part of Advanz throughout the Infringement Period), there is no need for the CMA to establish intent or negligence separately for any of these entities.[1595]

IV. The CMA's margin of appreciation in determining the appropriate amount of the penalty

7.31 The CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.[1596] It 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. Rather, it makes its assessment on a case-by-case basis,[1597] having regard to all relevant circumstances and the objectives of its policy on financial penalties.

7.32 In line with statutory requirements and the twin objectives of its policy on financial penalties, as reflected in its Penalty Guidance,[1598] in determining the appropriate amount of a penalty, the CMA will take into account the seriousness of the infringement and the need to ensure that the penalty imposed deters both the infringing undertakings and other undertakings from engaging in anti-competitive activities.[1599]

[1594] See *Napp* [2002] CAT 1, paragraph 456.
[1595] See s 36(3) of the Act, which states that 'the undertaking' (in this case the undertaking referred to as Advanz in its changing forms/compositions throughout the Infringement Period) must have acted intentionally or negligently.
[1596] Section 36(2) of the Act. Any penalty imposed by the CMA under the Act must be 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 CMA73 in accordance with section 38(8) of the Act. The CMA's margin of appreciation is referred to in, for example, *Argos and Littlewoods v OFT* [2005] CAT 13, paragraph 168, and *Umbro Holdings and Manchester United and JJB Sports and Allsports v OFT* [2005] CAT 22, paragraph 102.
[1597] See, for example, *Kier Group and Others v OFT* [2011] CAT 3, paragraph 116, where the CAT noted that *'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, where the CAT observed that '*[d]ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case*'. See also CMA73, paragraph 2.6.
[1598] The guidance currently in force is *CMA's guidance as to the appropriate amount of a penalty* (CMA73, April 2018) – the '*Penalty Guidance*'.
[1599] The Act, section 36(7A); *Penalty Guidance*, paragraph 1.3.

7.33 The CMA has concluded that, in the circumstances of this case, it is appropriate for it to exercise its discretion under section 36(2) of the Act to impose a substantial penalty in respect of the Infringement.

7.34 The Infringement was a very serious abuse, which led to the NHS being overcharged by a significant amount, causing direct harm to patients, whose access to the drug was restricted or withdrawn as a result, and diverting limited NHS resources. There was no objective justification for Advanz's sustained price increases, which were based on a systematic and carefully designed and monitored price optimisation strategy, aimed solely at exploiting the absence of competition in the supply of Liothyronine Tablets in the UK to Advanz's own financial advantage.

7.35 A substantial penalty is also appropriate in these circumstances from a general deterrence point of view: as the number of recent unfair pricing investigations conducted by the CMA and other competition authorities show, unfair pricing appears to be widespread, including in the pharmaceuticals sector. The CMA considers that there is a need to send a strong message to deter similar conduct both by the Parties and other undertakings in the future.

7.36 The Parties have argued that no penalty, or only a nominal penalty should be imposed in this case, including, they argue, because the CMA's case is '*novel*' and the legal framework applied uncertain.[1600] The CMA disagrees with the Parties' arguments, which are discussed in detail at paragraphs 7.33 ff of Annex 7.

7.37 Unfair pricing is a well-established and well-known competition law abuse, listed in the Chapter II prohibition (as well as Article 102 TFEU, which still applied throughout the Infringement Period). The prohibition has been the subject of several high-profile UK and EU cases and decisions, including in the UK and EU pharmaceuticals sector.[1601] Protecting customers against

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[1600] Document LIO7981, HgCapital RDPS, paragraphs 63 ff, document LIO7978, Cinven RDPS, paragraph 2.14, document LIO7973, Advanz RDPS, paragraphs 6.2 ff. The Parties argue that the novely of the case relates to
(i) the fact that throughout the Infringement Period, there had never been any infringement decisions at EU or UK level involving excessive pricing 'without more' (that is, not coupled with exclusionary conduct, or in circumstances where there were no insurmountable barriers to entry);
(ii) the 'novel' nature of the legal test applied in the SSO and
(iii) the fact that the legal test for excessive and unfair pricing itself is controversial and unsettled, and extremely difficult for undertakings to apply 'ex ante' at the time they are setting their prices, which is contrary to the principle of legal certainty.

[1601] See, for example, , *Napp and Phenytoin*, document PAD195, Italian Competition Authority (AGCM): '*A480 – Price increase of Aspen's drugs*', Measure No. 26185, the decision against the multinational pharmaceutical company Aspen of 29 September 2016 (appeal by Aspen dismissed by the Consiglio di Stato on 13 March 2020); document PAD196, European Commission: '*Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines*'; and document PAD197, Danish Competition and Consumer Authority (KFST): '*CD Pharma has abused its dominant position by increasing their price by 2,000 percent*', Case no. 14/08469, CD Pharma's pricing of Syntocinon.

exploitation is one of the core purposes of competition law and imposing unfair prices is an obvious example of such exploitation.

D. The CMA's penalty calculation

7.38 When setting the amount of a penalty in respect of an infringement of the Chapter I or the Chapter II prohibition, the CMA must have regard to the guidance on penalties in force at the time of setting the penalty.[1602] The Penalty Guidance sets out a six-step approach for calculating the penalty.

7.39 A summary of the CMA's penalty calculation in this case is set out in the table below.

Table 7.1: Summary of CMA's penalty calculation

Step	Description	Calculation			
1	Starting point as a percentage of relevant turnover	Relevant turnover	£35,419,521		
		Starting point percentage	30%		
	Penalty at the end of Step 1 (starting point)	**£10,625,856**			
2	Adjustment for duration	x 8.58			
	Penalty at the end of Step 2	**£91,169,846**			
3	Aggravating factor: Director involvement	+10%			
	Mitigating factor: Compliance discount	-5% (Advanz Pharma Group only – applied after the allocation of the fine by ownership period at the start of Step 4)			
	Penalty at the end of Step 3	**£100,286,831**			
4	**Allocation of total fine to ownership periods based on percentage of minimum direct financial benefit generated:**	**Period 1 (Mercury Pharma Companies (MPCs) Ownership period)**	**Period 2 (HgCapital Ownership period)**	**Period 3 (Cinven Entities Ownership period)**	**Period 4 (Advanz Pharma Corp Ownership period)**

[1602] Section 38(8) of the Act.

Step	Description	Calculation			
	Fine by ownership period after allocation	£50,324	£6,206,035	£37,074,343	£56,956,129
	Compliance discount for Advanz Pharma Corp and MCPs	-£2,290	N/A	N/A	-£2,591,504
	Penalty after compliance discount	£48,034	£6,206,035	£37,074,343	£54,364,625
	Step 4 adjustment for specific deterrence and proportionality				
	Adjustment for specific deterrence and proportionality	N/A	£8,600,000	£51,900,000	£65,200,000
	Penalty by ownership period at the end of Step 4	£48,034	£8,600,000	£51,900,000	£65,200,000
5	Adjustment to take account of the statutory cap	-£48,034	N/A	N/A	-£24,257,101
	Penalty at the end of Step 5	0	£8,600,000	51,900,000	£40,942,899
6	Leniency discount	N/A	N/A	N/A	N/A
	Settlement discount	N/A	N/A	N/A	N/A
	Liability for relevant portion of the total penalty at the end of Step 6	**MPCs**	**HgCapital**	**The Cinven Entities (jointly and severally)**	**Advanz Pharma Corp and the MPCs (jointly and severally)**
	Penalty payable	**0**	**£8,600,000**	**£51,900,000**	**£40,942,899**

Source: CMA analysis

I. Penalty calculation Step 1 – Starting point

7.40 The starting point in determining the level of financial penalty to be imposed is calculated having regard to (i) the relevant turnover of the undertaking and (ii) the seriousness of the infringement and the need for general deterrence.[1603]

a. Relevant turnover

7.41 The Penalty Guidance states that the 'relevant turnover' is the turnover of an undertaking in the relevant product market and relevant geographic market affected by the infringement in the undertaking's last business year, which for these purposes is the financial year preceding the date when the infringement ended.[1604] The principle underlying the identification of relevant turnover is that the level of penalty should reflect the undertaking's '*real economic situation at the time the infringement was committed*'.[1605]

7.42 In this case, the relevant product and geographic market affected by the Infringement was the UK market for the supply of Liothyronine Tablets. Advanz's turnover in this market in 2016, the last business year before the date when the Infringement ended, was £35,419,521 ('**Relevant Turnover**').[1606]

7.43 The Parties argue that the CMA should have departed from its '*standard approach*' of using an undertaking's last business year before the end of the Infringement as a reference period at Step 1, to avoid an improperly inflated

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[1603] *Penalty Guidance*, paragraphs 2.3–2.15.
[1604] *Penalty Guidance*, paragraph 2.11. Relevant turnover is calculated after the deduction of sales rebates, value added tax and other taxes directly related to turnover. Generally, the CMA will base relevant turnover on figures from an undertaking's audited accounts. However, in exceptional circumstances it may be appropriate to use a different figure as reflecting the true scale of an undertaking's activities in the relevant market. (Penalty Guidance, footnotes 25 and 26).
[1605] See *Kier Group plc and others v OFT* [2011] CAT 3, paragraphs 126, 132 and 138. See also *Balmoral v CMA* [2017] CAT 23, paragraph 141, in particular the CAT's reference to the need to reflect '*the infringer's position on the market*'. This position has been confirmed in EU case law: '*it is settled case-law that, in assessing the gravity of an infringement, regard must be had to the economic reality as revealed at the time when that infringement was committed. The aspects relevant in that assessment are, inter alia, the size and economic power of each undertaking and the scale of the infringement committed by each of them (Case T 334/94 Sarrió v Commission [1998] II 1439, paragraph 397 and the case-law cited therein). When those factors are being assessed, it is necessary to refer to the turnover achieved at the time in question (Case C 291/98 P Sarrió v Commission [2000] ECR I 9991, paragraph 86 and the case law cited). Whilst, admittedly, as the applicant points out, the calculation method employed in the matters leading to the judgments in Cases T 334/94 Sarrió v Commission and C 291/98 P Sarrió v Commission, cited in paragraph 91 above, was based on turnover achieved in the last full year of the infringement, that circumstance does not mean that the same choice should always be made. As is made clear in the same case-law, a method should be chosen that permits account to be taken of the size and economic power of each of the undertakings concerned, as well as of the scope of the infringement committed by each of them, in light of the economic reality as it appeared at the time the infringement was committed*.' - See *Trioplast*, T-40/06, EU:T:2010:388, paragraphs 91 and 92.
[1606] Source: CMA Cost Plus assessment, 'Sales volumes and direct costs' tab.

and materially erroneous starting point, and to ensure that the fine is specific to the offence and the offender.[1607]

7.44 They submit that instead, the CMA should have calculated the relevant turnover in this case by reference to the average annual turnover in the UK market for the supply of Liothyronine Tablets during the Infringement Period, or individually for each ownership period by reference to the turnover generated in the last business year of each of the different ownership periods. Both would have resulted in a lower relevant turnover than the '*standard*' approach as Adanz's turnover from the supply of Liothyronine Tablets increased over the Infringement Period, in line with its sustained price increases.

7.45 A summary of the Parties' representations and the CMA's responses are set out in paragraphs 7.48 ff of Annex 7.

7.46 The CMA concludes that in this case, it is appropriate to apply the '*standard approach*' to calculating the relevant turnover. It agrees that in exceptional circumstances, assuming there are adequate reasons, it is free to depart from the approach set out in its Penalty Guidance if the specific facts of a case justify (or require) it to reflect the true scale of an undertaking's activities in the relevant market.[1608]

7.47 This point was recently confirmed by the CAT in its *Pre-cast drainage products* judgment:

> 'The Penalty Guidance does not require the CMA to calculate the average of the turnovers over the period of an infringement which lasted more than one year. Accordingly, the normal position is that one does not take an average figure. […] it is clear that the CMA is entitled to depart from this aspect of the Penalty Guidance when it is appropriate to do so. It is not helpful to try to define the cases in which it would be appropriate to depart from the usual approach. […] All one can usefully say is that the Penalty Guidance is to be applied in the normal case so that there must be something out of the norm to justify departing from it and using an average of the turnovers for the whole period of the infringement (or some other approach).'[1609]

[1607] See document LIO7981, HgCapital RDPS, paragraphs 41 ff (in particular paragraph 44); document LIO7973, Advanz RDPS, paragraphs 7.5 ff; and document LIO7978, Cinven RDPS, paragraphs 3.6 ff.
[1608] *Penalty Guidance*, paragraph 2.12 and 2.13.
[1609] *FP McCann Limited v CMA*, [2020] CAT 28, paragraphs 178 and 179.

7.48 The CMA considers that in this case, there is no need for a departure from the Penalty Guidance. In particular, a departure is not necessary to ensure that the ultimate level of the penalty is proportionate, specific to the offence and the offender and reflects Advanz's real economic situation at the time the Infringement was committed, including specifically the different levels of direct financial benefit generated in each of the four ownership periods. Indeed, the CMA concludes that it is better able to take account of these factors by applying the standard approach at Step 1 and making any necessary adjustments in Step 4 of its assessment (see paragraphs 7.125 to 7.137 below).

7.49 As set out in detail at Step 4 below, in the CMA's view, one of the anchoring principles in this case is that for deterrence purposes, the financial penalty imposed on the Parties needs to exceed the direct financial benefit generated by Advanz in each individual ownership period by a material amount. The CMA considers that only this approach takes proper account of the '*impact of and the economic reality*' of the Infringement in its totality and during the different ownership periods.

7.50 Therefore, had the CMA decided to depart from the Penalty Guidance in Step 1 and chosen a different reference point or period to determine the 'relevant turnover', or used the average turnover over the Infringement Period as the relevant turnover in this case (both of which would have led to a lower starting point), it would have considered it necessary to apply a significantly higher deterrence uplift at Step 4 than under its 'standard' approach to take into account the level of minimum direct financial benefit generated by the Parties.[1610]

7.51 The Relevant Turnover for the determination of the starting point is therefore £35,419,521.

[1610] For example, had the CMA established a separate starting point for each individual ownership period in Step 1, this would have led to a relevant turnover of £2,953,195 for Period 1, £4,014,786 for Period 2, £13,999,373 for Period 3 and £35,419,521 for Period 4. Had the CMA taken this approach, it would have applied multipliers for duration of 0.99, 2.67, 3.14 and 1.78 respectively for Periods 1, 2, 3 and 4 in Step 2, leading to a penalty of £878,677, £3,214,029, £13,174,752 and £18,893,646 respectively for Periods 1, 2, 3 and 4 at the end of Step 2. After application of a 10% uplift at Step 3 (and a compliance discount for the Advanz Pharma Group), the CMA, in Step 4, would have then applied a reduction for Period 1, and the necessary uplifts in Periods 2, 3 and 4 to ensure that the ultimate penalty for each liable undertaking not only meets, but exceeds by a material amount, the financial benefit generated in each relevant ownership period.
Similar reasoning was set out in the CMA's *Balmoral* decision where the CMA noted that it would have been open to it to take a different approach to the determination of the 'relevant turnover' but that had it done so it would have considered it appropriate to include a significant uplift at Step 4: '*If a turnover figure of £19,200 for the period from April 2011 to July 2012 had been used, resulting in a penalty at the end of step 3 of £3,110, the CMA would have considered a significant uplift for deterrence to be appropriate at step 4.*' (*Balmoral decision*, paragraph 5.21). The CAT upheld the CMA's decision to depart from the Guidance - *Balmoral judgment* [2017] CAT 23, paragraph 141. The CAT noted that, '*the starting point is aimed simply at identifying what turnover the infringer has earned on the relevant market, however it has earned it.*'

b. Starting point percentage

7.52 The CMA will apply a percentage rate of up to 30% to the relevant turnover.

i. Legal principles: Assessment of seriousness

7.53 The starting point percentage is largely determined by the seriousness of an infringement and ultimately the extent and likelihood of actual or potential harm to competition and consumers. In determining the starting point percentage, the CMA will also reflect the need to deter the infringing undertaking and other undertakings generally from engaging in that type of infringement in the future.[1611]

7.54 In making this case-specific assessment, the CMA will take into account how likely it is that the type of infringement at issue will, by its nature, cause harm to competition and consumers. As set out in the Penalty Guidance, the CMA will generally use a starting point between 21% and 30% of relevant turnover for the most serious types of infringement, that is, those likely by their very nature to harm competition and consumers. In relation to infringements of the Chapter II prohibition, this will typically include conduct which is inherently likely to have a particularly serious exploitative or exclusionary effect, such as excessive and predatory pricing. A starting point between 10% and 20% is more likely to be appropriate for infringements of the Chapter II prohibition involving conduct which is less likely to be inherently harmful.[1612]

7.55 The CMA will also consider whether it is appropriate to adjust the starting point upwards or downwards to take account of specific circumstances of the case that might be relevant to the extent and likelihood of harm to competition and ultimately to consumers.[1613] These may include, for example, the nature of the product, including the nature and extent of demand for that product, the structure of the market, including market shares of the undertaking/s involved in the infringement, market concentration and barriers to entry and the actual or potential harm caused to consumers whether directly or indirectly.

7.56 Finally, the CMA will consider whether the starting point for a particular infringement is sufficient for the purpose of general deterrence. In particular, the CMA will consider the need to deter other undertakings, whether in the same market or more broadly, from engaging in the same or similar conduct.[1614]

[1611] *Penalty Guidance*, paragraph 2.4.
[1612] *Penalty Guidance*, paragraph 2.6.
[1613] *Penalty Guidance*, paragraph 2.8.
[1614] *Penalty Guidance*, paragraph 2.9.

ii. Application in this case

7.57 The CMA concludes that, in the circumstances of this case, a starting point percentage of 30% is appropriate. The Parties disagree; their detailed arguments and the CMA's response to them are set out in paragraphs 7.59 ff of Annex 7.

7.58 In reaching its conclusion that a 30% starting point percentage is appropriate, the CMA has taken into account the following factors:

- *The likelihood of excessive and unfair pricing, by its nature, to have a particularly serious exploitative effect*

7.59 The Infringement involves unfair (excessive) pricing, which the CMA considers to be one of the most serious forms of abuse of a dominant position, especially in a case like this, where it caused direct and considerable harm to the NHS and to patients. This position is also reflected in the CMA's Penalty Guidance, which refers to excessive pricing as an example of conduct which is inherently likely to have a particularly serious exploitative effect and which will therefore generally attract a starting point between 21% and 30%.[1615] It is also consistent with the approach taken by the CAT, which has previously confirmed that excessive pricing is a serious abuse.[1616]

7.60 Protecting customers against exploitation is one of the core aims of competition law. Unfair pricing, therefore, by its very nature, goes to the heart of one of the key harms that competition law is designed to prevent – namely, customers being exploited by companies charging artificially/excessively high prices. While other forms of abuse of dominance (e.g. exclusionary conduct such as predatory pricing) and cartels typically seek to restrict competition with a view to the infringing parties being subsequently able to charge artificially/excessively high prices, companies involved in unfair pricing directly exploit the absence of (effective) competition to impose such prices.

7.61 The prices (and consequently the direct financial benefit) resulting from excessive and unfair pricing are typically considerably higher, and more certain to be achieved, than those which might ordinarily be expected from exclusionary conduct or the cartelisation of a market.[1617]

[1615] *Penalty Guidance*, paragraph 2.6, first bullet point.
[1616] *Napp* [2002] CAT 1, paragraph 531.
[1617] The minimum level of financial benefit set out in paragraph 7.76 below amounts to more than 78% of the total revenues over the Infringement Period. This can be contrasted to literature on typical overcharges in cartels. See, for example, paragraph 143 of the European Commission's Practical Guide 'Qu*antifying harm in actions for damages based on breaches of Article 101 or 102 of the TFEU*' in which the average observed cartel overcharge was around 20%.

7.62 Where the structure of a market allows for excessive and unfair pricing, the harmful effects of this abuse may, absent intervention, also be more sustainable and persist for longer than other forms of serious anti-competitive conduct such as cartelisation. At the same time, excessive and unfair pricing does not usually entail the same risks and costs typically associated with such other forms of anti-competitive conduct (for example, the risk that one of the cartelists may apply for leniency, triggering an investigation and leaving other cartelists exposed, and the costs of monitoring compliance with the cartel).

7.63 Consequently, the CMA considers that the harm to consumers which results from excessive and unfair pricing is among the most serious types of harm caused by any form of anti-competitive conduct and that therefore excessive pricing constitutes one of the most serious abuses of a dominant position.[1618]

7.64 The following factors also support a starting point percentage at the top end of the range (i.e. 30%) in this case:

- *Nature of the product (including nature and extent of demand)*

7.65 Liothyronine Tablets are used to treat some of the more severe conditions in which the thyroid does not produce enough thyroxine and to balance the effect of medicines used to treat an overactive thyroid.[1619] They are an essential medicine for a small number of patients for whom switching to alternative drugs is not recommended.

7.66 Liothyronine Tablets are a very old product and were long off-patent before the start of the Infringement Period. Advanz made no material investment in R&D for, or improvements to, the product during the Infringement Period.[1620]

- *Market share, structure of the market and entry conditions*

7.67 Advanz held a market share of 100% throughout the Infringement Period reflecting the fact that it was the sole supplier of Liothyronine Tablets in the UK. This meant that it was not subject to any competitive pressure and was able to exploit this position to pursue its price optimisation strategy for Liothyronine Tablets. There were no restrictions on its ability to increase prices for Liothyronine Tablets by 1,110% during the Infringement Period and by 6,021% compared to the September 2007 price equivalent (just before the

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[1618] A 30% starting point can be justified where a type of conduct is among the most serious abuses. The Penalty Guidance does not require that an undertaking's abusive conduct must be ***the*** most serious abusive conduct possible.
[1619] See document PAD071, Mercury Pharma: '*Liothyronine Sodium BP 20micrograms Tablets*'.
[1620] See, e.g., paragraphs 4.49 and 5.364 above.

de-branding of Tertroxin),[1621] despite costs increasing only slightly in absolute terms.[1622]

7.68 As set out in paragraphs 4.140 ff above, costs of entry into the UK market for Liothyronine Tablets are high relative to the overall market size, and entry typically takes several years, meaning that, even after Advanz's prices had reached a level that incentivised entry attempts by third parties, Advanz did not have to fear any competition in the short term.

- *Actual effect of the Infringement on end customers and patients*

7.69 The end customer in this case is principally the NHS. Where Advanz's high prices led to prescriptions being withdrawn, more patients became customers in their own right, via private prescriptions.[1623]

7.70 The NHS budget is finite and legitimate demands for healthcare will always exceed capacity. Accordingly, financial resources need to be prioritised. In this respect, in the period 2010 to 2015, the NHS Efficiency Policy was introduced, tasking the NHS with making £20 billion of efficiency savings in order to make more funds available to treat patients.[1624]

7.71 Advanz's prices resulted in the NHS paying significantly more for Liothyronine Tablets than it was paying prior to the de-branding of Liothyronine Tablets in October 2007 and significantly more than it would have paid absent the Infringement. In 2006, the last full year prior to the de-branding of Liothyronine Tablets, the NHS's annual spend on Liothyronine Tablets was approximately £604,000. During the Infringement Period, the NHS's annual spend on Liothyronine Tablets increased to over £30 million in 2016 despite sales volumes having stayed largely the same as before.[1625]

7.72 As a result of the increased costs, CCGs would have had to divert money to continue to fund the supply of Liothyronine Tablets to patients. This inevitably reduced the money available to CCGs for other healthcare services.[1626] Therefore, the harm caused by the Infringement also extended to patients requiring treatments other than the supply of Liothyronine Tablets.

[1621] See Section 1.II.
[1622] See, e.g., Table 5.4 above.
[1623] See paragraphs 5.41 ff.
[1624] Document PAD074, NHS: '*Efficiency*', page 2.
[1625] See paragraph 5.365 above. See also: document LIO12042, Julie Lizbeth Wood's witness statement, paragraphs 15-16, and document LIO11979, Linda Mary Mynott's witness statement, paragraph 23.
[1626] Document LIO12042, Julie Lizbeth Wood's witness statement, paragraphs 30-33. The CAT has also recognised the importance of preventing harm suffered by patients denied funds diverted to purchasing products whose prices are excessive and unfair. See *(1) Flynn Pharma Limited (2) Flynn Pharma (Holdings) Limited v CMA* [2017] CAT 1, paragraph 99.

7.73 The effect of Advanz's conduct has continued beyond the end of the Infringement Period, as prices have reduced only slowly following new entry, contaminated as they are by the Infringement. Accordingly, evidence of the actual effect of the Infringement dating both from the Infringement Period and following the Infringement Period is relevant.

7.74 The impact of the Infringement on patients requiring Liothyronine Tablets was equally severe. In October 2018, The Times reported that '*doctors [had] stopped prescribing [Liothyronine] after the price rose from 16p to £9.22 per tablet*'. The Times article provided details of a patient who had credited '*the thyroid medication liothyronine with giving her a life*', who had her '*prescription stopped in July 2018*' with alternative treatments having had a major adverse impact on her health including being hospitalised with violent illness and headache.[1627] The high price of Liothyronine Tablets and the adverse consequences for patients of its limited availability were raised in written questions in Parliament on numerous occasions. The Secretary of State for Health told the House of Commons in 2016 that '*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*'.[1628]

7.75 The CMA has also received correspondence from members of the public, who are having to source liothyronine and pay for it themselves. Those patients who are able to source it overseas appear to be paying less than those who source it in the UK. For example:

(a) One patient told the CMA: '*I pay £30 for 100 x 20 mcg tablets of Liothyronine [in Germany]. The equivalent amount of product in the UK would cost approx £900*'.[1629]

(b) Another patient stated: '*I have autoimmune problems and I am having to purchase meds and now I have to forkout on the state pension for the thyroid hormones t3*'.[1630]

(c) A third patient commented: '*I […] have chosen to purchase my annual supply in France, for now. My annual cost of the drug equates what it would cost the NHS for just about one month!*'.[1631]

[1627] Document PAD203, The Times: '*Failure to halt rip-off drug deals costs the NHS £200m*', October 2018.
[1628] Document PAD035, Debate - Health Service Medical Supplies (Costs) Bill, page 10.
[1629] Document LIO5535, Email from [name withheld] to Ronan Flanagan dated 6 December 2017.
[1630] Document LIO5921, Email to the CMA from [name withheld].
[1631] Document LIO5358, Email to the CMA from [name withheld].

(d) The father of a patient told his MP that his daughter '*is faced with a monthly bill of approx £600 to restore her life to a tolerable level*'.[1632]

(e) Linda Mynott, Chief Executive of Thyroid UK and patient, told the CMA that she '*had no choice but to start purchasing liothyronine online from overseas*'. It cost her '*about £46 (including postage and prescription fees) for three months' treatment, so around £185 per year*'.[1633]

(f) In a debate in the House of Lords in 2018, Lord Hunt of Kings Heath observed that '*[s]ome clinicians are helping patients by giving them private prescriptions, but these are expensive. The Brighton and Sussex University Hospitals NHS Trust is informing patients that their only option is to obtain the drug privately*'. He referred to another patient '*who is looking for a price to purchase T3 privately. She contacted Pharmacy2U and asked for a price for 56 T3 tablets. From four suppliers, only one could supply and that price was £774. That was for 56 tablets, one a day*'.[1634]

7.76 As set out in paragraph 7.134 below, the minimum direct financial benefit (or minimum overcharge paid by the NHS) caused by the Infringement was at least £92,368,282.

7.77 The significant adverse impact of Advanz's price increases on the NHS and on patients is set out in further detail in section 5.B.V above (*Significant adverse impact of Advanz's strategy on the NHS and patients*).

- *The need to deter other undertakings from engaging in the same or similar conduct.*

7.78 The imposition of unfair (excessive) selling prices, by definition, tends to create significant excess profits for undertakings which engage in such conduct. Since the potential gains from such conduct are often considerable and certain of being achieved where no suitable alternatives are available for customers reliant on a particular product, the CMA considers that the maximum starting point is appropriate in order to ensure that other dominant firms with captive customers are deterred from engaging in the same or similar conduct in the future.

7.79 The Infringement is unlikely to be an isolated example of such conduct within the pharmaceutical sector in the UK and more broadly in other industries, and

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[1632] Document LIO7777, Letter from Julia Lopez MP (Hornchurch & Upminster) to Andrea Coscelli dated 2 January 2019.
[1633] Document LIO11979, Linda Mary Mynott's witness statement, paragraph 26.
[1634] Document PAD178, UK Parliament: *'Motion to Regret moved by Lord Hunt of Kings Heath on 20 June 2018*', Volume 791, Column 2066 (text only), page 4.

similar cases have been, and are still being, investigated in both the UK and EU Member States.[1635]

c. Calculation at the end of Step 1

7.80 Based on the above, the starting point for determining the level of financial penalty to be imposed in relation to the Infringement is therefore £10,625,856 (i.e. 30% of £35,419,521).

II. Penalty calculation Step 2 – Adjustment for duration

7.81 The CMA may adjust the starting point reached at the end of Step 1 to take into account the duration of the infringement. Where the total duration of an infringement is more than one year, the CMA will (in most cases) round up part years to the nearest quarter year, although the CMA may in exceptional cases decide to round up the part year to a full year.[1636]

a. Duration in this case

7.82 The duration of the Infringement was from at least 1 January 2009 to 31 July 2017, a period of eight years and seven months (or 8.58 years).

7.83 In this case, the CMA has decided to reflect the exact duration of the Infringement in the duration coefficient rather than rounding up to the nearest quarter year. It has therefore multiplied the penalty at the end of Step 1 by a duration coefficient of 8.58.

b. Calculation at the end of Step 2

7.84 At the end of Step 2, the penalty for the Infringement is therefore £91,169,846.

[1635] See, for example, document PAD195, Italian Competition Authority (AGCM): '*A480 – Price increase of Aspen's drugs*', Measure No. 26185, the decision against the multinational pharmaceutical company Aspen of 29 September 2016 (appeal by Aspen dismissed by the Consiglio di Stato on 13 March 2020); document PAD196, European Commission: '*Antitrust: Commission opens formal investigation into Aspen Pharma's pricing practices for cancer medicines*'; and document PAD197, Danish Competition and Consumer Authority (KFST): '*CD Pharma has abused its dominant position by increasing their price by 2,000 percent*', Case no. 14/08469, CD Pharma's pricing of Syntocinon. See also: the CMA's decision of 15 July 2021 relating to excessive and unfair pricing and anti-competitive agreements relating to Hydrocortisone tablets (case 50277).
[1636] *Penalty Guidance*, paragraph 2.16.

III. Penalty calculation Step 3 – Adjustment for aggravating and mitigating factors

7.85 The CMA may, at Step 3, increase a penalty where there are aggravating factors, and/or decrease it where there are mitigating factors. A non-exhaustive list of aggravating and mitigating factors is set out in the Penalty Guidance.[1637]

a. Aggravating factors – Involvement of directors or senior management

7.86 The CMA concludes that the involvement of Advanz's directors and senior management should be taken into account as an aggravating factor at Step 3 and justifies an uplift in Advanz's penalty of 10%. The Parties have argued that a 10% uplift for director involvement in this case is inappropriate. A detailed summary of the Parties' representations and the CMA's responses is set out in paragraphs 7.75 ff of Annex 7.

7.87 Directors and senior management within Advanz were actively involved in the design, implementation and continuation of Advanz's price optimisation strategy in relation to Liothyronine Tablets, which formed the basis of the Infringement. Accordingly, the intention to exploit the absence of competition in order to charge unfair prices for Liothyronine Tablets extended to the highest levels of the undertaking.

7.88 The table below provides examples of director involvement or awareness of the conduct in relation to Liothyronine Tablets pricing across each of the four ownership periods. This list is illustrative and not intended to be exhaustive.

Table 7.2: Examples of director involvement or awareness of the infringing conduct

Ownership Period	Director/senior manager involvement	Example of involvement
Period 1 (January-December 2009)	[✂] (Head of marketing brands and generics India)	*'As advised by you [*[Goldshield Founder and Group Board Director]*], during my recent visit to UK, I am enclosing herewith a proposed price increase model for the year 2009-10 [including Lio] contributing a gross profit of £2,736,668.'* Document LIO0042, Email from [Goldshield Head of Marketing Brands and Generics, India] to [Goldshield Founder and Group Board Director], cc [Goldshield Head of Pharmaceuticals UK], dated 28 November 2008.
	[✂] (founder and Group Board Director)[1638]	
	[✂] (Head of Pharmaceuticals UK)	

[1637] *Penalty Guidance*, paragraphs 2.14 and 2.15.
[1638] From August 2009 until May 2010.

Ownership Period	Director/senior manager involvement	Example of involvement
Period 2 (December 2009-August 2012)	[✂] (CEO)[1639]	Liothyronine Tablets are '*easy for them [IMS Consulting Group] to forecast'* as *'[t]hey just need to apply some price increases to them'*. Document LIO0180, Email from [Advanz CEO] to [Advanz Chief Strategy Officer], [Advanz Finance Director] and [Advanz Finance Director] dated 15 March 2012.
	[✂] (Finance director)[1640]	
Period 3 (August 2012-October 2015)	[✂] (CEO)	*'[I]f we move the price of Liothyronine up by 30% now does it prevent us from seeing similar growth from that product for future years*.' Document LIO0264, Email from [Advanz CEO] to [Advanz Finance Director], [Advanz General Counsel and Secretary], [Advanz Head of Sales UK Brands and Generics], [Advanz Commercial Servies Director] and [Advanz Chief Operating Officer] dated 25 May 2013. *'Below is the potential price increase [including Lio] options of GBP 10 million with comments and risk involved while increasing the price.'* Document LIO0275, Email from [Advanz Commercial Servies Director] to [Advanz CEO] dated 27 May 2013.
	[✂] (Commercial Services Director)[1641]	
Period 4 (October 2015-July 2017)	[✂] (CEO)	'*A 30% price increase of Lio in March would provide a £10.4 headroom which I think is needed to cover the risk. Again this is a commercial decision that you are best suited to make*.' Document LIO0611, Email from [Advanz Chief Financial Officer] to [Advanz CEO] dated 19 January 2016.
	[✂] (CFO)[1642]	

Source: CMA analysis of Advanz internal documents

7.89 The CMA concludes that the director-level involvement in the Infringement in this case was reprehensible and should therefore be treated as a factor which 'aggravates' the Infringement:[1643]

(a) The Infringement to which Advanz's director-level and other senior staff contributed was based on a deliberate strategy[1644] and committed intentionally, or at the very least negligently (see paragraphs 7.8 to 7.30 above). Advanz's senior management understood that it had successfully identified a loophole in the existing regulatory scheme (under which the NHS relied on competition to keep prices low), and that this loophole was likely to

[1639] From June 2010.
[1640] From January 2011 to October 2012.
[1641] From December 2012 to November 2014.
[1642] From September 2013 to January 2016: document PAD198, Cision PR Newswire: *'Concordia Healthcare Provides Corporate Update'*.
[1643] The CAT stated in *Ping* that in cases concerning public (as opposed to secret) infringing conduct, director-level knowledge alone should not be treated as an aggravating factor as an uplift would otherwise become meaningless. Instead, an uplift should be reserved for more reprehensible behaviour (*Ping* [2018] CAT 13, paragraph 247).
[1644] In *Ping* the CAT made clear that it would have treated the relevant director's involvement in the infringement as an aggravating factor had it found the infringement to be intentional (*Ping* [2018] CAT 13, paragraph 248).

remain open and ripe for exploitation.[1645] Internal documents show that Advanz did in fact exploit this loophole in a deliberate and calculated manner (e.g. price increases were made incrementally in order to '*fall below the reimbursement radar*').[1646]

(b) Furthermore, the Infringement had a significant adverse impact on the NHS (with its finite resources) and on patients (some of whom suffered physically as a result of the de-prescribing of Liothyronine Tablets): see Section 5.E.III.e ('*Advanz's price increases have had a significant adverse impact on the NHS and patients*') above.

7.90 Even if Advanz's conduct in this case had been merely negligent, the CMA concludes that in the absence of any legitimate aim, an uplift for director-level involvement would still be justified.[1647]

7.91 In the light of the above, the CMA concludes that an uplift to reflect the involvement of Advanz's directors and/or senior management in the Infringement is appropriate. As for the appropriate level of the uplift, the CMA concludes that an uplift of 10% is justified. 10% is below the uplifts imposed in some other cases (up to 20%),[1648] yet reflects the active role which directors and senior management played in consciously designing, maintaining and supporting Advanz's exploitative conduct, despite the serious harm it caused to patients and the NHS.

b. Mitigating factors

7.92 The CMA concludes that the only relevant mitigating factor to be taken into account in this case is a 5% compliance discount for the Advanz Pharma Group.[1649] For practical reasons, this is applied in a preliminary step at the start of Step 4 – see paragraphs 7.138 and 7.139 below.

[1645] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 8: [✂].
[1646] Document LIO6490.3, '*Annex 2.1 - Minutes of a meeting of IC dated 2 July 2012*', page 3.
[1647] In *Ping* the CAT specifically left open the possibility that even in cases of 'mere' negligence, an uplift for director involvement might be appropriate (*Ping* [2018] CAT 13, paragraph 248).
[1648] See, for example, (1) CMA infringement decision regarding the supply of groundworks products to the construction industry (case 50415), paragraph 6.52, available at https://assets.publishing.service.gov.uk/media/604633538fa8f577c7dc58f8/Case_50415_-_CMA_Decision.pdf; (2) CMA infringement decision regarding the supply of precast concrete drainage products (case 50299), paragraph 6.44, available at https://assets.publishing.service.gov.uk/media/5dfb98e7ed915d54a62419a6/Non-confidential_decision_201219_----.pdf; the CAT did not address the uplift in its decision on FP McCann's appeal dated 22 December 2020 in *FP McCann v CMA* [2020] CAT 28; (3) both CMA infringement decisions relating to Nortriptyline tablets (case 50507.2), (a) market sharing, paragraph 7.61, available at https://assets.publishing.service.gov.uk/media/5f115b4dd3bf7f5baab7a5e4/Market_Sharing_Decision.pdf; (b) information exchange, paragraph 7.61, available at https://assets.publishing.service.gov.uk/media/5ef469bcd3bf7f7142efc039/Information_Exchange_Decision.pdf; Lexon appealed the decision but not the 15% uplift relating to director involvement, *Lexon (UK) Limited v CMA* [2021] CAT 5.
[1649] Advanz Pharma Corp and the Mercury Pharma Companies.

7.93 All three Parties argue that a penalty reduction at Step 3 is appropriate on a number of bases:

(a) All three Parties argue that there was **genuine uncertainty** as to whether Advanz's conduct was unlawful.[1650]

(b) The Cinven Entities and Advanz further contend that a reduction was appropriate owing to the **actions (or inaction) of the DHSC**.[1651]

(c) Advanz argues that the Infringement was **not intentional** and that this merits a reduction at Step 3.[1652]

(d) HgCapital submits that it has **fully cooperated** with the CMA and its investigation and should be granted a discount for this reason.[1653]

(e) Finally, all three Parties contend that they have taken adequate steps with a view to ensuring and promoting competition law compliance.[1654]

7.94 The CMA does not accept that the Parties' representations justify a discount (with the exception of a 5% compliance discount for the Advanz Pharma Group) for the reasons set out below:

i. Uncertainty regarding the law

7.95 The CMA concludes that there cannot have been any genuine uncertainty on the part of Advanz at any point during the Infringement Period as to whether its pricing conduct in relation to Liothyronine Tablets constituted an infringement of competition law: Advanz's pricing conduct saw the ASP for Liothyronine Tablets rise by around 1,110% since the start of the Infringement Period and by 6,021% since September 2007 without any material increase in production costs, any material investment in R&D or any other objective justification. The legal advice which Advanz seeks to rely on does not change this assessment (see paragraphs 7.8 ff of Annex 7).

7.96 It was clear throughout the Infringement Period that excessive and unfair pricing on the part of a dominant undertaking constitutes an infringement of

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[1650] Document LIO7981, HgCapital RDPS, paragraphs 53 to 55. Document LIO7978, Cinven RDPS, paragraph 3.71-3.72. Document LIO7973, Advanz RDPS, paragraphs 7.60-7.62.
[1651] Document LIO7978, Cinven RDPS, paragraph 3.73-3.74;. document LIO7973, Advanz RDPS, paragraphs 7.68 to 7.69.
[1652] Document LIO7973, Advanz RDPS, paragraphs 7.63-7.67.
[1653] Document LIO7981, HgCapital RDPS, paragraph 61.
[1654] Document LIO7981, HgCapital RDPS, paragraphs 56-60, document LIO7978, Cinven RDPS, paragraph 3.75-3.77, and document LIO7973, Advanz RDPS, paragraphs 7.51-7.59. See also: document LIO12217, Advanz's response to the CMA's request dated 30 March 2021, document LIO12227, Cinven's response to CMA's request dated 30 March 2021 and document LIO12245, HgCapital's response to the CMA's request dated 30 March 2021.

the Chapter II Prohibition and/or (at the time) Article 102 TFEU. Excessive pricing is not a 'novel' legal concept or type of abuse. The judgment of the Court of Justice in *United Brands,* the seminal case which set out the legal test for excessive and unfair pricing, was issued in 1978.[1655]

7.97 Protecting customers against exploitation is one of the core purposes of competition law and the imposition of unfair (excessive) selling prices (with or without exclusionary conduct) is an obvious example of such exploitation.

7.98 The Parties argue that the need for supplementary SOs in this case evidences the legal uncertainty regarding the legal test to be applied in excessive pricing cases. The CMA disagrees. The supplementary SOs in this case were issued in response to the clarification of certain aspects of the *United Brands* test in the CAT and the Court of Appeal's judgments in *Phenytoin*. Neither of these judgments created any uncertainty during the Infringement Period with regard to the fact that exploiting a dominant position in order to impose unfair selling prices constitutes an infringement of competition law. The gradual clarification of a legal concept by the courts[1656] does not mean that an undertaking adopting certain conduct[1657] which is clearly within the remit of a prohibition based on earlier case law,[1658] could not reasonably have foreseen that this prohibition was applicable to its conduct in principle.[1659]

7.99 In any event, the judgments in *Phenytoin* were only issued after the end of the Infringement Period and could not, therefore, possibly have led to any uncertainty about the legal test to be applied in excessive pricing cases during the Infringement Period. Finally, not only did Advanz's pricing conduct with regard to Liothyronine Tablets constitute an abuse within the meaning of the Chapter II prohibition under the *United Brands* test as applied during the Infringement Period and following the Court of Appeal's clarification of the law, but the CMA also provisionally found in the 2019 SSO that it would have constituted an abuse following the CAT's judgment. In these circumstances, there can be no scope to grant a discount for uncertainty regarding the law.

ii. Action/inaction on the part of the DHSC/NHS

7.100 In previous cases, discounts have sometimes been granted where a public authority was actively involved in setting or approving an undertaking's anti-

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[1655] See on the issue of uncertainty and novelty also paragraphs 7.18 ff of Annex 7.
[1656] Here: the application in practice of certain elements of the *United Brands* test.
[1657] Here: a dominant undertaking taking advantage of its market power to impose ever-increasing prices without any corresponding increase in costs or other objective justification.
[1658] Here: the prohibition on imposing excessive and unfair prices.
[1659] See, to the same effect, *AC-Treuhand v Commission,* T-99/04, EU:T:2008:256, paragraphs 143 to 150.

competitive/exploitative conduct.[1660] However, the present case is very different from those cases. As set out in Annex 6.2 ('*The Unfair Limb: Economic Value - willingness to pay*'): (i) the NHS/DHSC did not 'approve' or 'acquiesce' to Advanz's price increases; and (ii) the NHS/DHSC's conduct could not create a legitimate expectation on Advanz's part that its pricing strategy with regard to Liothyronine Tablets was legal.

iii. No intent

7.101 The CMA has concluded that Advanz committed the Infringement intentionally, or at the very least negligently (see paragraphs 7.17 ff above). A discount for negligence would be at odds with this finding. In any event, and as a matter of principle, the CMA does not consider it appropriate to grant discounts for negligence. Instead, where appropriate, it imposes uplifts for infringements which are committed intentionally rather than negligently.[1661] The fact that the CMA has not applied such an uplift in this case does not mean that a discount would be warranted instead.

iv. Full cooperation

7.102 HgCapital has argued that its cooperation merits a discount.[1662]

7.103 The CMA disagrees. HgCapital did not provide cooperation which enabled the CMA's investigation to be concluded more effectively and/or speedily.[1663] It co-operated with the CMA broadly to the extent that the CMA would expect, but not in a way that would warrant a discount at Step 3. HgCapital complied with the CMA's deadlines but did not provide any particular additional assistance to the CMA beyond responding to statutory requests for information and submitting written and oral representations to the CMA, either in response to the CMA's provisional case or on an ad hoc basis.

7.104 Although this point was not expressly raised by either of the other Parties, the CMA does not consider that the Cinven Entities or Advanz Pharma Corp are entitled to a cooperation discount either, as neither provided cooperation

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[1660] See *Deutsche Telekom*, C-280/08P, EU:C:2010:212, paragraphs 278 to 279 and *National Grid* [2009] CAT 14, paragraphs 111 to 115. In *Deutsche Telekom* the General Court and the Court of Justice found that a 10% discount was appropriate to account for the fact that in that case the relevant regulator had actively approved Deutsche Telekom's prices. A larger discount was awarded by the Court of Appeal in *National Grid* but this was in the context of the public authority that had been involved in the ex ante process that led to the relevant agreements then taking the ex post decision to penalise National Grid.
[1661] See *Penalty Guidance*, paragraph 2.18. Uplifts for intentional infringements were, e.g., recently applied in (1) CMA infringement decision regarding the electronic drum sector (case 50565-5), paragraph 5.42; and (2) CMA infringement decision relating to the supply of precast concrete drainage products (case 50299), paragraph 6.41.
[1662] Document LIO7981, HgCapital RDPS, paragraph 61.
[1663] See paragraph 2.19 of the *Penalty Guidance*.

which enabled the CMA's investigation to be concluded more effectively and/or speedily.

v. Compliance activities

7.105 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. In this context, the:

> 'CMA will consider carefully whether evidence presented of an undertaking's compliance activities in a particular case merits a discount from the penalty of up to 10%. The mere existence of compliance activities will not be treated as a mitigating factor. Compliance activities are likely to be treated as a mitigating factor where an undertaking demonstrates 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 throughout the undertaking (from the top down).
>
> This will be expected to include appropriate steps relating to competition law risk identification, risk assessment, risk mitigation and review activities, including making a public statement regarding a commitment to compliance on the undertaking's relevant website(s) and conducting periodic review of its compliance activities, and reporting that to the CMA. The undertaking will also need 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. The CMA will expect compliance activities and the steps taken to be appropriate to the size of the undertaking.'[1664]

- *HgCapital*

7.106 Having carefully considered the evidence presented of HgCapital's compliance activities, the CMA concludes that no discount to the part of the penalty for which HgCapital is liable is warranted.

[1664] *Penalty Guidance*, footnote 33.

7.107 [✂].[1665] [✂].[1666] [✂].[1667]

7.108 [✂].

7.109 In the light of the above, the CMA considers that HgCapital has not demonstrated that adequate steps have been taken to achieve a clear and unambiguous commitment to compliance throughout the undertaking, from the top down, such as to merit a reduction in its penalty.

- *The Cinven Entities*

7.110 Having carefully considered the evidence presented of the Cinven Entities' compliance activities, the CMA concludes that no discount to the part of the penalty for which the Cinven Entities are liable is warranted.

7.111 [✂].[1668] [✂].[1669] [✂].

7.112 [✂].

7.113 [✂].

7.114 [✂].

7.115 In the light of all of the above, the CMA considers that Cinven has not demonstrated that adequate steps have been taken to achieve a clear and unambiguous commitment to compliance throughout the undertaking, from the top down, such as to merit a reduction in its penalty.

- *Advanz Pharma Corp*

7.116 Having carefully considered the evidence presented of Advanz Pharma Corp's compliance activities, the CMA concludes that a compliance discount of 5% to the parts of the penalty for which Advanz Pharma Corp, or any members of the Advanz group as it currently exists[1670] are liable, is warranted.

7.117 Submissions from Advanz show that, since 2017, it has:

[1665] [✂].
[1666] See, for example, documents LIO7992, LIO8008, LIO8009, LIO8010, LIO8001, LIO8003, LIO8004, LIO8006, LIO12258 and LIO12259.
[1667] In an email to HgCapital of 30 March 2021, [✂] (See document LIO12245, request for information from the CMA dated 30 March 2021). [✂].
[1668] [✂].
[1669] Document LIO12227, Cinven response to the CMA's request for information dated 30 March 2021, paragraph 21. [✂].
[1670] Including the Mercury Pharma Companies.

(a) [✂]:

(i) [✂];[1671]

(ii) [✂];[1672]

(iii) [✂];[1673]

(b) [✂];[1674]

(c) Made a clear public commitment to compliance with competition law on its website;[1675] and

(d) [✂].[1676]

7.118 [✂].[1677]

7.119 [✂].[1678]

7.120 Taking these considerations in the round, the CMA concludes that Advanz has provided sufficient evidence of compliance activities to warrant a reduction in penalty of 5%.

c. Calculation at the end of Step 3

7.121 Based on the above, at the end of Step 3, the penalty for the Infringement is £100,286,831. A reduction of 5% is to be applied to the parts of the penalty for which Advanz Pharma Corp and the Mercury Pharma Companies respectively are liable. This discount will be applied after the allocation of the overall penalty to the different ownership periods at the start of Step 4 (see paragraphs 7.125 to 7.137 below), but prior to any adjustments for specific deterrence and proportionality (see paragraphs 7.138 ff).

[1671] Document LIO12217, Advanz response to the CMA's request for information dated 30 March 2021, paragraph 2.6; and document LIO12222, '*Annex 6 – NAVEX Global AntiTrust and Competition Law Advanced*'. See also, document LIO8044, [Advanz General Counsel and Secretary] witness statement, paragraph 12; and documents LIO8045, LIO8046, LIO8027, LIO8028 and LIO8029.
[1672] Documents LIO12223 and LIO12224.
[1673] [✂],
[1674] Document LIO12217, Advanz response to the CMA's request for information dated 30 March 2021; paragraph 2.6.
[1675] Document LIO12220, '*Advanz code of conduct published 11 August 2020';* also available at https://www.advanzpharma.com/media/uploads/2020_08_11_Code-of-Conduct.doc.pdf.
[1676] Document LIO12220, '*Advanz code of conduct dated 11 August 2020*', paragraph 6.3.
[1677] [✂].
[1678] As set out in paragraph 2.19 and footnote 33 of the *Penalty 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*'.

IV. Penalty calculation Step 4 – Adjustment for specific deterrence and proportionality

7.122 According to the Penalty Guidance, the CMA may adjust the penalty at Step 4 for specific deterrence (that is, to ensure that the penalty imposed on the infringing undertaking/s will deter it/them from engaging in anti-competitive practices in the future) and/or proportionality, having regard to appropriate indicators of the size and financial position of the relevant undertaking, as well as any other relevant circumstances of the case. The assessment of the need to adjust the penalty will be made on a case-by-case basis.[1679] Adjustments at Step 4 may result in either an increase or a decrease to the penalty.

7.123 Specific deterrence (as distinct from general deterrence) should ensure that the penalty is specific to the offence and the offender.[1680]

7.124 The objective of pursuing a specific deterrent effect through a financial penalty '*is essentially to control, in the future, the conduct of the economic entit[ies] to which the 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.*'[1681]

a. Step 4 preliminary steps (apportionment of the penalty between undertakings and application of the 5% compliance discount)

7.125 At the time of this Decision, some of the economic entities to which it is addressed are no longer part of the undertaking referred to as Advanz (which committed the Infringement) but are part of separate undertakings.

7.126 As explained in section 6 above, the undertaking that committed the Infringement (Advanz) included different legal entities over time, as successive parent companies joined and left it during the Infringement Period.

(a) From 1 January 2009 until 29 December 2009 (Period 1), Advanz consisted of the Mercury Pharma Companies (Mercury Pharmaceuticals Limited, Advanz

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[1679] *Penalty Guidance*, paragraphs 2.20 and 2.21.
[1680] *Areva v Commission*, C-247/11P and C-253/11P, EU:C:2014:257, paragraphs 127 and 131.
[1681] *YKK v Commission*, C-408/12, EU:C:2014:2153, paragraph 91. 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 of the judgment). '*[T]he fact that [the parent companies, post-acquisition] are not held jointly and severally liable for the infringement committed by [the subsidiary] for the period prior to [the acquisition] has no bearing on the determination of a deterrence multiplier*' (paragraph 87 of the judgment). See also *Alliance One*, C-628/10P and C-14/11P, EU:C:2013:606, paragraph 64; and *Total and Elf Aquitaine v Commission*, T-190/06, EU:T:2011:378.

Pharma Services (UK) Limited and Mercury Pharma Group Limited), with Mercury Pharma Group Limited as the ultimate parent company;

(b) From 30 December 2009 until 30 August 2012 (Period 2), Advanz consisted of the Mercury Pharma Companies and HgCapital, their ultimate parent company at the time;

(c) From 31 August 2012 until 20 October 2015 (Period 3), Advanz consisted of the Mercury Pharma Companies and the Cinven Entities, their ultimate parent companies at the time; and

(d) From 21 October 2015 until 31 July 2017 (Period 4), Advanz consisted of the Mercury Pharma Companies and Advanz Pharma Corp, their ultimate parent company at the time. The Mercury Pharma Companies and Advanz Pharma Corp still form part of Advanz at the date of this Decision.

7.127 According to settled case law, where an infringing subsidiary is owned by successive parents during the infringement period, each parent is jointly and severally liable with that subsidiary only for the penalty in relation to its ownership period and cannot be jointly and severally liable with the other parent companies for the totality of the penalty.[1682]

7.128 As HgCapital and the Cinven Entities no longer form part of Advanz at the time of this Decision, three undertakings[1683] will be liable to pay the penalty imposed in different proportions, and a separate Step 4 assessment is carried out separately for each of these liable undertakings:

(a) The Mercury Pharma Companies and Advanz Pharma Corp, which still form a single undertaking (the '**Advanz Pharma Group**'). Absent any adjustments in Steps 4 and 5 (see below), within the Advanz Pharma Group:

(i) The Mercury Pharma Companies would be jointly and severally liable *inter se* for the entire penalty imposed in relation to the Infringement; and

(ii) Advanz Pharma Corp would be jointly and severally liable with the Mercury Pharma Companies for the portion of the penalty that relates to its ownership period (Period 4).

(b) Absent any adjustments in Steps 4 and 5 (see below), **HgCapital** would be jointly and severally liable with the Mercury Pharma Companies for the portion of the penalty that relates to its ownership period (Period 2); and

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[1682] *Areva v Commission*, C-247/11P and C-253/11P, EU:C:2014:257, paragraphs 126 to 142.
[1683] That is, each of the separate undertaking/s of which the liable entities form part at the time of this Decision.

(c) Absent any adjustments in Steps 4 and 5 (see below), the **Cinven Entities** would be jointly and severally liable with the Mercury Pharma Companies for the portion of the penalty that relates to their ownership period (Period 3).

7.129 Although it is not for the CMA to specify the proportions that each of two or more legal entities jointly and severally liable for a particular amount should pay, it is necessary that every legal entity knows the total amount for which it is jointly and severally liable.

7.130 It is therefore necessary to apportion the penalty figure reached at the end of Step 3 between the three undertakings liable to pay it, and to assess whether, once apportioned, the individual penalties will provide an effective deterrent on the three undertakings, without being disproportionate or excessive.

i. Allocation of the penalty between the different ownership periods

7.131 Consistent with these principles, the CMA has first allocated the penalty at the end of Step 3 between the different ownership periods. In this case, the CMA does not consider it appropriate to apportion the penalty at the end of Step 3 simply by reference to the duration of the different ownership periods since this would disregard the significant differences in ASPs during the different ownership periods.

7.132 Instead, in this case, the CMA has decided to allocate the penalty at the end of Step 3 by reference to the proportion of the overall minimum direct financial benefit gained during each of the different ownership periods. The CMA considers this allocation to be fair, equitable and objective.

7.133 The minimum direct financial benefit (and consequently the harm caused) in each ownership period may be calculated in a straightforward manner in this case given that the volumes of Liothyronine Tablets sold and the prices charged can be mapped accurately across the successive ownership periods.

7.134 To calculate the minimum direct financial benefit for each ownership period, the CMA has calculated the difference between its 'enforcement price' of (£20.48), that is the lowest price charged for Liothyronine Tablets during the Infringement Period that has been found to be excessive and unfair[1684] and Advanz's actual selling prices during each of the different ownership periods of the Infringement. The resulting figures are then multiplied by the volumes sold in each ownership period.[1685] This results in a conservative estimate

[1684] This is the price charged at the start of Period 1, in January 2009. Prices below this level may have also been excessive and unfair.
[1685] Source: CMA Cost Plus assessment, 'Sales volumes and direct costs' tab.

since profits based on prices that were lower than £20.48 could also be unlawful; the calculation also does not take into account any potential excess profits based on prices charged following the end of the Infringement Period.[1686] The total minimum direct financial benefit generated throughout the Infringement Period was £92,368,282. The shares of this generated in each ownership period were as follows:

[1686] As set out in footnote 2 above, the CMA has decided for reasons of administrative priority not to pursue its investigation into Advanz's pricing conduct during the period from 1 November 2007 to 31 December 2008, and following 31 July 2017. It has not reached a conclusion on whether Liothyronine Tablet prices were excessive and unfair in those periods. The CMA concludes that prices following 31 July 2017 are contaminated by Advanz's pricing conduct during the Infringement Period, and notes that the minimum direct financial benefit does not take account of any excess profits which may have arisen from this contamination.

Table 7.3: Minimum direct financial benefit per ownership period

Ownership Period	Legal entities jointly and severally liable for the Infringement	Differential above January 2009 ASP *(minimum direct financial benefit)*	% of minimum total direct financial benefit attributable to each period
Period 1	Mercury Pharmaceuticals Limited Advanz Pharma Services (UK) Limited Mercury Pharma Group Limited	£46,351	0.05%
Period 2	Mercury Pharmaceuticals Limited Advanz Pharma Services (UK) Limited Mercury Pharma Group Limited HgCapital LLP	£5,716,012	6.19%
Period 3	Mercury Pharmaceuticals Limited Advanz Pharma Services (UK) Limited Mercury Pharma Group Limited Cinven Capital Management (V) General Partner Limited Cinven (Luxco 1) S.A. Cinven Partners LLP	£34,146,989	36.97%
Period 4	Mercury Pharmaceuticals Limited Advanz Pharma Services (UK) Limited Mercury Pharma Group Limited Advanz Pharma Corp. Limited	£52,458,930	56.79%
Total minimum direct financial benefit		**£92,368,282**	**100%**

Source: CMA analysis

7.135 The CMA has then allocated the penalty at the end of Step 3 (£100,286,831) to the different ownership periods in accordance with the percentage of minimum direct financial benefit accrued in each ownership period:

Table 7.4: Allocation of the penalty to the different ownership periods in accordance with % of minimum direct financial benefit generated in each ownership period

Ownership Period	% of minimum total direct financial benefit attributable to ownership period	Fine adjusted to reflect % of minimum total direct financial benefit attributable to period
Period 1	0.05%	£50,324
Period 2	6.19%	£6,206,035
Period 3	36.97%	£37,074,343
Period 4	56.79%	£56,956,129
Total	**100%**	**£100,286,831**

Source: CMA analysis

7.136 This approach allows the penalty to be apportioned in a way that reflects the scale of the Infringement during each ownership period.[1687, 1688]

7.137 Having allocated the fine to the different ownership periods, the CMA has then considered whether any adjustments to the resulting fines for each liable undertaking are required.

ii. Application of (the equivalent of) a 5% compliance discount for the Advanz Pharma Group

7.138 The first necessary adjustment is the application of the equivalent[1689] of a 5% discount for compliance activities at Step 3 to the part of the penalty for which the Advanz Pharma Group is liable (see paragraphs 7.116 ff above).

7.139 Having applied this discount, at this point in the penalty calculation (before any further adjustments):

(a) The Advanz Pharma Group would be liable as follows:

[1687] *Areva v Commission*, C-247/11P and C-253/11P, EU:C:2014:257, paragraphs 127 and 131.
[1688] Advanz made no representations on this aspect of the CMA's draft penalty calculation, while HgCapital states that it '*acknowledges that the CMA's method for allocation of the overall penalty between the respective ownership periods at Step 4 is proportionate*'. See HgCapital's representations on the DPS, paragraph 4(c). See also paragraph 31: '*Hg acknowledges that the CMA's allocation of the penalty is proportionate*'.
[1689] Although a compliance discount is ordinarily applied at Step 3, in this case, it could only be applied at this point in the calculation, due to the need to first allocate the overall penalty at the end of Step 3 to the different undertakings liable to pay it. The reduction applied at this point to achieve the equivalent of a 5% discount for compliance activities at Step 3 is a discount of 4.55%. The reason why the discount applied is lower than 5% is that, had it been applied in Step 3, it would have been set off against the 10% uplift for senior management/ director involvement, resulting in a net uplift of 5%. In this case, the full 10% uplift for senior management/director involvement has already been applied at this point in the calculation. Therefore, without any adjustment, the application of a 5% compliance discount at this point would have resulted in a higher discount in absolute terms than the application of a 5% compliance discount in Step 3.

(i) The Mercury Pharma Companies would be jointly and severally liable *inter se* for the full amount of the penalty of (**£100,286,831**) minus a 5% compliance discount, resulting in a total liability of **£95,723,780**. Of this, they would be solely liable for the portion of the total penalty relating to Period 1 (**£48,034**)[1690] and jointly and severally liable with their successive parent companies for the portions of the total penalty relating to Periods 2, 3 and 4 as set out below.

(ii) Advanz Pharma Corp would be jointly and severally liable with the Mercury Pharma Companies for the portion of the total penalty relating to Period 4 minus a 5% compliance discount, i.e. a total amount of **£54,364,625**;

(b) HgCapital would be liable for **£6,206,035** (the portion of the penalty relating to Period 2), with the Mercury Pharma Companies being jointly and severally liable for **£5,923,660**;[1691] and

(c) The Cinven Entities would be liable for **£37,074,343** (the portion of the penalty relating to Period 3), with the Mercury Pharma Companies being jointly and severally liable for **£35,387,460**.[1692]

b. Adjustments for specific deterrence and proportionality

7.140 Having allocated the penalty to the different ownership periods, and applied a compliance discount of 5% to the part of the penalty for which the Advanz Pharma Group is liable, the CMA has next considered whether there were any factors which indicated that an uplift for specific deterrence or any downward adjustments for proportionality were appropriate and required. The Penalty Guidance sets out a number of factors that the CMA will have regard to in this assessment:

(a) The penalty figure reached after Steps 1 to 3 may be increased to ensure that the penalty to be imposed will deter the undertaking/s from breaching competition law in the future, given its/their specific size and financial position and any other relevant circumstances of the case.[1693]

(b) An increase for specific deterrence may in particular be appropriate where the undertaking has a significant proportion of its turnover outside the relevant market, where the undertaking has made or is likely to make an economic or financial benefit from the infringement that exceeds the level of penalty reached at the end of Step 3 or to ensure that a penalty accurately reflects the

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[1690] Penalty relating to Period 1 minus a 5% compliance discount.
[1691] Penalty relating to Period 2 minus a 5% compliance discount.
[1692] Penalty relating to Period 3 minus a 5% compliance discount.
[1693] *Penalty Guidance*, paragraph 2.21.

scale of an undertaking's involvement in the infringement and/or the likely harm caused.[1694]

7.141 Applying these principles to this case, the CMA concludes that the penalty reached at this point in the assessment should be increased for each of the three liable undertakings.

7.142 In reaching this conclusion, the CMA has taken into account, in particular, the minimum direct financial benefit for each of the liable undertakings from the Infringement and assessed whether the penalty should be increased above this level to ensure that each liable undertaking is deterred from breaching competition law in the future by reference to its overall size and financial position at the time of this Decision. It has also taken into account the considerable actual harm caused by the Infringement.

i. Specific deterrence

- *Uplift to ensure penalty materially exceeds financial benefit*

7.143 In order to have a sufficient deterrent effect, the penalty for each of the liable undertakings needs to not only meet, but exceed by a material amount, the minimum direct financial benefit accrued by Advanz in each relevant ownership period from its strategy of exploiting the absence of effective competition and regulation to impose unfair selling prices for the supply of Liothyronine Tablets in the UK, at the expense of the NHS and ultimately patients.

7.144 It is an important part of effective deterrence that an undertaking should not be in a position to earn a profit from infringing competition law even after paying a penalty in respect of that infringement.[1695] Nor is it sufficient for any penalty to only neutralise an infringing undertaking's direct financial gains resulting from an infringement. If the penalty imposed on an undertaking for a competition law infringement only neutralises the gains made (i.e. puts the undertaking in the same position as it would have been absent the infringement) there is little economic incentive for the undertaking not to infringe competition law again: at most, it would risk losing its gains if it was caught and sanctioned.

7.145 The need for any penalty imposed in relation to an infringement to exceed the direct financial gains from the Infringement by a material amount is particularly

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[1694] *Penalty Guidance*, paragraphs 2.21 and 2.22.
[1695] As acknowledged by the CAT in *Napp* [2002] CAT 1, paragraph 510, a penalty that understates the real commercial gain of the infringer risk being ineffective.

relevant for infringements involving the imposition of unfair selling prices where the gains are accrued as a direct result of the infringing conduct (i.e. charging excessive and unfair prices). The CMA considers that simply asking a company to repay the minimum level of its unlawful direct gains (or a small percentage more) would not be sufficient to deter the company from taking the risk of engaging in the same or similar breaches of competition law again in future, in the pharmaceutical sector or in any sector of the economy. This is particularly the case given the possibility that future unlawful conduct may not be detected or subject to enforcement.

7.146 The General Court has confirmed the validity of this approach, holding that in the interests of effective deterrence, a fine may be increased so that the final amount exceeds the level of the financial benefit obtained. The level of financial benefit generated by an infringing party does not constitute a 'ceiling' above which a penalty cannot be imposed.[1696] Indeed, this is clear from the fact that it is perfectly legitimate for a penalty to be imposed where an infringement has generated no financial benefit at all for the infringing party.

7.147 Against this background, the CMA has compared the minimum direct financial benefit generated in each ownership period with the apportioned penalty for that period:[1697]

Table 7.5: Relative size of the penalty by reference to the minimum direct financial benefit in each ownership period

Ownership Period	Differential above January 2009 ASP *(minimum direct financial benefit)*	Penalty by ownership period at this point in the assessment	Difference
Period 1	£46,351	£48,034	£1,683
Period 2	£5,716,012	£6,206,035	£490,023
Period 3	£34,146,989	£37,074,343	£2,927,354
Period 4	£52,458,930	£54,364,625	£1,905,695
Total	**£92,368,282**	**£97,693,037**	**£5,324,755**

[1696] *Evonik Degussa v Commission*, T-391/09, EU:T:2014:22, paragraphs 239-242: in the interests of deterrence, a fine may be imposed irrespective of whether the parties have obtained any financial benefit from an infringement. The level of any financial benefit obtained may, however, justify increasing the fine so that the final amount exceeds the level of benefit obtained. The CMA therefore rejects the Cinven Entities' argument that applying an uplift to ensure the penalty materially exceeds the gains from the Infringement is unjustified (document LIO7978, Cinven RDPS, paragraph 1.19).

[1697] Penalty after the application of the 5% compliance discount for the Advanz Pharma Group, which is reflected in the table below in Periods 1 and 4 but not in Periods 2 and 3 as it does not affect the level of the penalties for which HgCapital (Period 2) and the Cinven Entities (Period 3) as former parent companies of the Mercury Pharma Companies are liable at this point in the calculation.

7.148 As can be seen from the table above, at this stage in the calculation, the total penalty (£97,693,037) is only £5,324,755 (or 5.8%) above the total minimum direct financial benefit of £92,368,282. Equally, the penalties by ownership period are only 8.6% (in Periods 2 and 3), and 3.6% (in Periods 1 and 4) above the minimum direct financial benefit accrued during that ownership period.

7.149 Given that the minimum direct financial benefit from the Infringement has been calculated based on conservative assumptions, it is likely that the true economic or financial benefit from the Infringement was in fact above the level of the unadjusted penalty set out above.

7.150 An uplift at Step 4 for each of the liable undertakings is therefore required to ensure a clear deterrent effect beyond equivalence with the direct financial benefit derived by the liable undertakings. It is further appropriate in the light of the significant level of actual harm caused by the Infringement to the NHS and ultimately patients in each ownership period. The extent of the uplift to be applied for specific deterrence should reflect the need to ensure that the penalty materially exceeds the minimum direct financial benefit. It should also take account of the overall size and financial position of each liable undertaking and other relevant circumstances as discussed below.

- *Size and financial position of the parties*

7.151 All of the liable undertakings are of considerable size. The table below sets out the relative size of the penalty for each of the liable undertakings at this point in the assessment by reference to a number of financial indicators.

Table 7.6: Relative size of the apportioned penalty at the end of Step 3[1698] for each liable undertaking by reference to its respective financial indicators

Financial Indicators	Advanz Pharma Corp[1699]		Cinven Entities[1700]		HgCapital[1701]	
	£m	Relative size of the penalty (Period 4 only) before adjustments (in %)	£m	Relative size of the penalty before adjustments (in %)	£m	Relative size of the penalty before adjustments (in %)
Worldwide turnover (last financial year)	409.4	13.3	[✂]	[✂]	[✂]	[✂]
Average worldwide turnover (last three years)	403.3	13.5	[✂]	[✂]	[✂]	[✂]
Operating profit / adjusted EBITDA (last financial year)	232.6	30.0	[✂]	[✂]	[✂]	[✂]
Average operating profit / adjusted EBITDA (last three years)	238.8	29.6	[✂]	[✂]	[✂]	[✂]
Profit after tax (last financial year)	-58.3	-93.2	[✂]	[✂]	[✂]	[✂]
Average profit after tax (last three years)	295.7	18.4	[✂]	-[✂]	[✂]	[✂]
Net cashflow from operating activities (last financial year)	129.5	42.0	[✂]	[✂]	[✂]	[✂]
Net assets (last financial year)	5.6	978.2	[✂]	[✂]	[✂]	[✂]

[1698] After application of a compliance discount for the Advanz Group.
[1699] The financial metrics used for Advanz Pharma Corp was based on information reported in Advanz's publicly available information, comprising of the 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 report, dated 25 March 2020; and Advanz's 2020 Annual Management's Discussion and Analysis, dated 17 March 2021. Figures have been converted US Dollars into Sterling Pounds using the Bank of England's annual average and year end spot exchange rates over the period. Averages have been calculated over a three year period ending 31 December 2020.
[1700] Document LIO6539.2, Annex 1 of Cinven response to CMA s.26 notice dated 15 May 2018; document LIO12205, Annex 1 of Cinven response to s.26 notice dated 14 April 2021; document LIO12206, Annex 2 of Cinven response to the CMA's s.26 notice dated 14 April 2021.
[1701] Document LIO6502, HgCapital response to the CMA's s.26 notice dated 15 May 2018; document LIO7980, HgCapital response to the CMA's s.26 notice dated 13 September 2019; and document LIO12208, HgCapital response to the CMA's s.26 notice dated 14 April 2021.

Source: CMA analysis of information provided by the Parties

7.152 While the unadjusted fines for each ownership period at this point in the calculation already account for a relatively large proportion of Advanz Pharma Corp's worldwide turnover, they are small relative to HgCapital and the Cinven Entities' worldwide turnover, indicating that the penalties reached at this point in the calculation should be increased for HgCapital and the Cinven Entities to ensure that the penalty imposed on each of them will deter them from breaching competition law in the future.

- *Turnover outside the relevant market*

7.153 According to the Penalty Guidance, an uplift for specific deterrence may also be appropriate where an undertaking has a significant proportion of its turnover outside the relevant market.[1702]

7.154 Sales of Liothyronine Tablets during HgCapital and Cinven's respective ownership periods accounted for less than [✂] of their worldwide revenues.[1703]

7.155 The Advanz Pharma Group also had a very significant proportion of its turnover outside the relevant market. In fact, more than 94% of the Advanz Pharma Group's total revenue in the last full business year of the Infringement came from products other than Liothyronine Tablets.[1704]

7.156 This, too, indicates that the penalty figures reached at this point in the calculation should be increased to ensure that the penalty imposed on each of the three liable undertakings will deter them from breaching competition law in the future.

- *Conclusion on the need for adjustments*

7.157 The CMA finds that, in the light of all of the factors above, the unadjusted penalties are not sufficient to effectively deter the liable undertakings from breaching competition law in the future, including by engaging in unfair pricing.

[1702] Penalty Guidance, paragraph 2.21.
[1703] In 2011 (the last full year of HgCapital's participation in the Infringement), Liothyronine Tablet revenues were £5,725,071. This is less than [✂] of HgCapital's 2019/2020 worldwide turnover of [✂]. In 2014 (the last full year of Cinven's participation in the Infringement), Liothyronine Tablet revenues were £13,999,373. This is less than [✂] of Cinven's 2019 worldwide turnover of [✂].
[1704] Document LIO6284.56, '*FTI Report Evidence Item-13 - Concordia 2016 Annual Report*', page 18, shows total revenues of $816,159,000 (£604,551,800) in 2016. This compares to Liothyronine revenues of £35,419,521 in the same year.

- *HgCapital*

7.158 Given the relatively small size of the apportioned penalty for which HgCapital is liable at this point in the calculation[1705] by reference to its considerable size and financial position,[1706] the CMA considers that a significant uplift is required in order to achieve a sufficient deterrent effect. Having assessed all relevant circumstances in the round, including the serious harm the Infringement caused to the NHS and ultimately patients, the CMA concludes that a penalty which exceeds the minimum direct financial benefit generated in the HgCapital ownership period by approximately £2.9 million (just over 50%) and therefore, in accordance with the principles set out in 7.143 ff, by a material amount, is appropriate. This leads to a penalty of **£8.6 million** (equating to approx. [✂] of HgCapital's average worldwide turnover in the last three years).[1707]

- *Cinven Entities*

7.159 Given the relatively small size of the apportioned penalty for which the Cinven Entities are liable at this point in the calculation[1708] by reference to their considerable size and financial position,[1709] the CMA considers that a significant uplift is required in order to achieve a sufficient deterrent effect. Having assessed all relevant circumstances in the round, including the serious harm the Infringement caused to the NHS and ultimately patients, the CMA concludes that a penalty which exceeds the minimum direct financial benefit generated in the Cinven ownership period by approximately £17.8 million (just over 50%) and therefore, in accordance with the principles set out in 7.143 ff, by a material amount, is appropriate. This leads to a penalty of **£51.9 million** (equating to approx. [✂] of the Cinven Entities' average worldwide turnover in the last three years).

- *Advanz Pharma Corp*

7.160 Although the apportioned penalty for which Advanz Pharma Corp is liable at this point in the calculation[1710] is somewhat higher relative to its overall size

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[1705] Penalty for HgCapital ownership period - Period 2
[1706] See Table 7.6 above.
[1707] As set out in footnote 1610, had the CMA taken a different approach in Step 1 and established a separate starting point for each individual ownership period, this would have led to a very similar penalty at this point in the calculation: in that case, to reflect the need to exceed, by a material amount, the level of direct financial benefit generated in HgCapital's ownership period, the CMA would have considered it necessary to apply a significantly higher deterrence uplift in Step 4 to get to the same or a very similar penalty as under its chosen approach. The same is true for the penalties that relate to Periods 3 and 4.
[1708] Penalty for Cinven ownership period - Period 3
[1709] See Table 7.6 above.
[1710] Penalty for Advanz ownership period - Period 4

and financial position, [1711] the CMA considers that an uplift is still required to ensure that Advanz Pharma Corp's penalty exceeds the minimum direct financial benefit generated in its ownership period by a material amount.

7.161 As set out in paragraphs 7.143 to 7.146 above, the CMA considers that it would be unacceptable from a specific deterrence point of view to impose a penalty on Advanz Pharma Corp which is below the level of the minimum direct financial benefit generated during its ownership period (£52,458,930). Indeed, in the CMA's view, merely requiring Advanz Pharma Corp to re-pay the amount of its gains or slightly more would also be inappropriate for the reasons given at paragraph 7.150 above.

7.162 Having carefully assessed all the relevant factors in the round, including the serious harm the Infringement caused to the NHS and ultimately patients, the CMA has decided that a significant uplift is required in order to achieve a sufficient deterrent effect. It concludes that a penalty which exceeds the minimum direct financial benefit generated in the Cinven ownership period by approximately £12.8 million (just over 24%) and therefore, in accordance with the principles set out in 7.143 ff, by a material amount, is appropriate. This leads to a penalty of **£65.2 million** (equating to approx. 16.2% of Advanz Pharma Corp's average worldwide turnover in the last three years).

ii. Proportionality

7.163 The CMA has concluded that the resulting penalty for each of the three liable undertakings at this point in the assessment is not disproportionate or excessive having regard to each undertaking's size and financial position and the nature and impact of the Infringement: [1712]

- *HgCapital*

7.164 A penalty of **£8.6 million** for HgCapital represents:

(a) [✂] of HgCapital's worldwide turnover for the financial year ending 31 March 2020; and [✂] of its average annual worldwide turnover over the last three financial years;

(b) [✂] of HgCapital's operational profit for the financial year ending 31 March 2020; and [✂] of its average operational profit for the last three years.

[1711] See Table 7.6 above.
[1712] *Penalty Guidance*, paragraph 2.23.

(c) [✂] of HgCapital's profit after tax for the financial year ending 31 March 2020; and [✂] of its average annual profit after tax for the last three years; and

(d) [✂] of HgCapital's net assets for the financial year ending 31 March 2020.

7.165 This is not disproportionate or excessive by reference to HgCapital's worldwide turnover, operational profit or net assets, including with regard to the very serious nature of the Infringement and its considerable impact on the NHS and patients. The fact that HgCapital's average annual profit after tax for the last three years [✂]. The CMA considers that for private equity firms, turnover is a more meaningful indicator of the entity's size and financial position than profit after tax, which may be impacted by non-relevant factors such as the choice of capital structure for firms in the portfolio and associated financing costs.[1713]

- *Cinven Entities*

7.166 A penalty of **£51.9 million** for the Cinven Entities represents:

(a) [✂] of the Cinven Entities' worldwide turnover for the financial year ending 31 December 2019; and [✂] of its average annual worldwide turnover over the last three years.

(b) [✂] of the Cinven Entities' operational profit for the financial year ending 31 December 2019; and [✂] of its average operational profit for the last three years.

(c) [✂] of the Cinven Entities' profit after tax for the financial year ending 31 December 2019; and [✂] of its average annual profit after tax for the last three years; and

(d) [✂] of the Cinven Entities' net assets for the financial year ending 31 December 2019.

7.167 This is not disproportionate or excessive by reference to the Cinven Entities' worldwide turnover, operational profit or net assets, including with regard to the very serious nature of the Infringement and its considerable impact on the NHS and patients. The fact that the Cinven Entities' average annual profit after tax for the last three years [✂]. The CMA considers that for private equity firms, turnover is a more meaningful indicator of the entity's size and

[1713] Private equity firms seek to generate returns for their investors by increasing the gearing levels of companies within their portfolio in order to reduce the required level of equity investment in firms. This, in turn, results in higher finance costs which distorts their profit after tax. In general, private equity firms do not look to make returns via the payment of dividends but rather by the realisation of significant capital gains on disposal of the businesses in which they invest.

financial position than profit after tax, which may be impacted by non-relevant factors such as the choice of capital structure for firms in the portfolio and associated financing costs.[1714]

- *Advanz Pharma Corp*

7.168 A penalty of **£65.2 million** for Advanz Pharma Corp (Period 4)[1715] represents:

(a) 15.86% of Advanz Pharma Corp's worldwide turnover for the financial year ending 31 December 2020; and 16.17% of its average annual worldwide turnover over the last three financial years.

(b) 35.84% of Advanz Pharma Corp's adjusted EBITDA for the financial year ending 31 December 2020; and 35.31% of its average annual adjusted EBITA for the last three financial years.

(c) 50.15% of Advanz Pharma Corp's net cashflows generated from operating activities for the financial year ending 31 December 2020;

(d) -111.34% of Advanz Pharma Corp's profit after tax for the financial year ending 31 December 2020; and 21.95% of its average annual profit after tax for the last three years; and

(e) 1,168.24% of Advanz Pharma Corp's net assets for the financial year ending 31 December 2020.

7.169 While a penalty of £65.2 million is relatively high by reference to Advanz Pharma Corp's worldwide turnover and adjusted EBITDA, the CMA does not consider that it is disproportionate or excessive, including with regard to the very serious nature of the Infringement and its considerable impact on the NHS and patients.[1716]

7.170 More specifically, the CMA concludes that, taken in the round, a fine of **£65.2 million** strikes an appropriate balance between the need for specific

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[1714] See footnote 1713 above.
[1715] Absent any adjustments at Steps 4 and 5, the Mercury Pharma Companies, which form part of an undertaking with Advanz Pharma Corp at the time of this Decision, would in addition also be liable for the part of the overall penalty relating to Period 1 and parts of the penalty relating to periods 2 and 3. However, for the reasons set out in footnote 1718 below (and in the light of the fact that the application of the statutory cap in Step 5 ultimately prevents the Mercury Pharma Companies from being liable for any amount beyond the reduced amount of the penalty relating to Period 4), the CMA has concluded that it was not necessary to carry out a separate specific deterrence and proportionality assessment for the Mercury Pharma Companies beyond that relating to the part of the penalty for which Advanz Pharma Corp and the Mercury Pharma Companies are jointly and severally liable (Period 4).
[1716] As recently confirmed by the CAT in Case [2020] CAT 28 - *FP McCann v CMA*, paragraph 354, as a matter of principle, it is open to the CMA to conclude in Step 4 of its penalty assessment that the appropriate penalty, when expressed as a percentage of the turnover of the last year before the decision, should be greater than 10% of an undertaking's worldwide turnover, that is above the level of the statutory cap which applies in Step 5.

deterrence (which requires a penalty that exceeds the level of relevant direct financial benefit by a material amount) and proportionality.[1717] It is lower than the Advanz Pharma Group's cash flow generated from operations (£110.3 million) in its last business year. It is affordable and could be met from cash flow without recourse to any of the Advanz Pharma Group's assets.[1718]

7.171 The relative size of the penalty by reference to financial metrics such as Advanz Pharma Corp's profit after tax and net assets does not change the CMA's conclusion that the penalty for which Advanz Pharma Corp is liable after the uplift for specific deterrence is proportionate.[1719]

7.172 **Profit after tax**: Advanz reported losses of £153.5 million and £58.3 million respectively in 2019 and 2020 but reported a very high profit after tax of £1.1 billion in 2018. In the CMA's view, the profit after tax metric is not a useful indicator to assess the proportionality of a fine as it takes into account non-operational costs such as: finance costs; non-cash costs such as amortisation charges that relate to the value of intangible assets acquired by Advanz; and one-off and exceptional items such as the $1.9 billion (£1.4 billion) gain on debt settlement when the company underwent a restructuring in 2018.[1720] These costs do not reflect the operational profitability of the business nor its underlying health and financial position. The CMA considers that a more appropriate and relevant measure by which to assess profitability in this case is the adjusted EBITDA profit that Advanz reports to its shareholders in its

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[1717] The uplift applied at Step 4 results in a penalty which exceeds the direct financial benefit generated in Advanz Pharma Corp's ownership period by £10,835,375 (the difference between £65.2 million and Advanz's minimum direct financial benefit in Period 4 of £54,364,625). This amounts to 2.7% of Advanz Pharma Corp's average worldwide turnover for the last three years; and 5.9% of Advanz Pharma Corp's average adjusted EBITDA for the last three years.

[1718] As explained in footnote 1715 above, the Mercury Pharma Companies form part of an undertaking with Advanz Pharma Corp at the date of this Decision but were previously part of an undertaking with HgCapital and Cinven. Therefore, the CMA would ordinarily carry out an assessment of the appropriateness (both in terms of specific deterrence and proportionality) of the overall penalty (penalty for Periods 1-4) for which the Mercury Pharma Companies are liable at this point in the calculation by reference to the size and financial indicators of Advanz Pharma Corp. See *YKK v Commission*, C-408/12, EU:C:2014:2153, paragraph 86: '*in order to impose a fine of an amount capable of deterring the undertakings concerned from infringing, in the future, European Union rules of competition, account must be taken of the size and overall resources of those undertakings at the time when the contested decision is adopted. Consequently, that fact that the size and overall resources of those undertakings may be smaller at an earlier stage of the infringement has no bearing on the determination of a deterrence multiplier (the judgment in Alliance One International v Commission, C 668/11 P, EU:C:2013:614, paragraph 64)*' – See also paragraphs 84 and 85. However, the CMA has decided that, based on the financial indicators of Advanz Pharma Corp, a penalty exceeding **£65.2 million** would risk being disproportionate or excessive. Based on this, the CMA concludes that it is not necessary to carry out a separate Step 4 assessment for the additional part of the overall penalty for which the Mercury Pharma Companies would otherwise be liable: in the CMA's view, it would not be appropriate/proportionate to hold the Mercury Pharma Companies liable for a penalty in excess of that considered appropriate/proportionate for the Advanz Pharma Group as a whole. Furthermore, as set out in Step 5 below, the application of the statutory cap in this case means that the Mercury Pharma Companies cannot be held liable for any amount beyond the reduced amount of the penalty relating to Period 4, meaning that a proportionality assessment for any amount exceeding £65.2 million would be meaningless .

[1719] Nor does the fact that Advanz did not pay any dividends since 2016 change the CMA's assessment. Document LIO7973, Advanz RDPS, paragraph 7.85 ff.

[1720] Document PAD199, Advanz: '*ADVANZ PHARMA Corp. Announces Fourth Quarter and Fiscal 2018 Results*', page 2.

annual report. As a result, the CMA has used the adjusted EBITDA measure to analyse Advanz's profitability rather than the profit after tax measure which is distorted by non-relevant costs and gains.

7.173 **Net assets**: The CMA concludes that, in the circumstances of this case, the net assets reported in Advanz's financial statements are not relevant to the assessment of proportionality, as they are directly related to the profit after tax measure described above. The book value of net assets is not therefore a reliable indicator of the enterprise value and financial position of Advanz Pharma Corp. In the CMA's assessment, a more reliable and relevant indicator of the value of Advanz Pharma Corp's business is Nordic Capital's 2021 acquisition price of $846 million for the entire share capital of the company.[1721]

- [✂]

7.174 [✂].[1722]

7.175 [✂].[1723]

7.176 [✂].[1724] [✂].[1725]

7.177 [✂].

7.178 [✂].

c. Calculation at the end of Step 4

7.179 Taking a step back and assessing the penalties for each of the liable undertakings in the round, the CMA concludes that they are appropriate in the light of all the relevant factors and circumstances, including the size and financial position of the liable undertakings, the serious nature of the Infringement, the significant level of harm caused and the level of direct financial benefit resulting from the Infringement.

[1721] See Advanz Pharma press release, 1 June 2021, available at: https://www.advanzpharma.com/news/2021/nordic-capital-acquires-specialty-pharmaceutical-company-advanz-pharma-in-deal-worth-846-million
[1722] Document LIO7973, Advanz RDPS, paragraph 7.96.
[1723] *Penalty Guidance*, paragraph 2.33.
[1724] As set out in paragraph 7.170 above, the Advanz Pharma Group's cash flow generated from operations was £110.3 million in its last business year.
[1725] Advanz's consolidated annual financial statements for the financial year ending 31 December 2020, Note 4, available at: https://www.advanzpharma.com/media/uploads/ADVZ-Financials-Annual-with-Audit-opinion-2020-FINAL-17032021.pdf.

7.180 At the end of Step 4, the total penalty in respect of the Infringement is **£125.7 million**. Absent any adjustments in Step 5, of that total sum the three liable undertakings would be liable for the following fines:

(a) **Advanz Pharma Corp** and its subsidiaries, the Mercury Pharma Companies, would be liable for **£65.2 million**;[1726]

(b) **HgCapital** would be liable for **£8.6 million**; and

(c) The **Cinven Entities** would be liable for **£51.9 million**.

V. Penalty calculation Step 5 – Adjustment to prevent maximum penalty from being exceeded and to avoid double jeopardy

a. Adjustments to prevent maximum penalty from being exceeded (statutory cap)

7.181 No penalty fixed by the CMA may exceed 10% of the worldwide turnover of an undertaking in its last business year.[1727] The relevant business year for these purposes is 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.[1728]

b. Adjustments to avoid double jeopardy

7.182 In addition, the CMA must, when setting the amount of a penalty for a particular agreement or conduct, take into account any penalty or fine that has been imposed by the European Commission, or by a court or other body in another Member State in respect of the same agreement or conduct.[1729]

c. Adjustments made at this step

i. Double jeopardy

7.183 No adjustments to the level of the penalty for which any of the Parties is liable at the end of Step 4 are required in order to avoid double jeopardy.

[1726] See footnote 1718 above.
[1727] Calculated in accordance with the Turnover Order; see section 36(8) of the Act and the *Penalty Guidance*, paragraphs 1.12 and 2.21.
[1728] *Penalty Guidance*, paragraph 2.25.
[1729] *Penalty Guidance*, paragraph 2.28.

ii. Statutory cap (maximum penalty)

7.184 No adjustments to the level of the penalty for which HgCapital and the Cinven Entities are liable at the end of Step 4 are required in order to prevent the maximum penalty (statutory cap) from being exceeded. However, certain adjustments (described below) are required in order to prevent the maximum penalty from being exceeded in relation to Advanz Pharma Corp and the Mercury Pharma Companies.

- *HgCapital*

7.185 HgCapital's global turnover (including the turnover of the portfolio companies over which it exercises decisive influence) was [✂] in the financial year 2019-20 (which ended 31 March 2020).[1730] The maximum penalty that can be imposed on HgCapital is therefore around [✂].

7.186 Accordingly, the CMA has not made any adjustments to the part of the penalty for which HgCapital is liable (penalty of **£8,600,000** relating to Period 2).

- *The Cinven Entities*

7.187 The Cinven Entities' global turnover (including the portfolio companies over which they exercise decisive influence) in their 2019 financial year[1731] (which ended 31 December 2019) was approximately [✂].[1732] The maximum penalty that can be imposed on the Cinven Entities is therefore [✂].

7.188 Accordingly, the CMA has not made any adjustments to the part of the penalty for which the Cinven Entities are liable (penalty of **£51,900,000** relating to Period 3).

- *Advanz Pharma Group*

7.189 The Advanz Pharma Group's global turnover in the financial year ending 31 December 2020 was $525,584,000 (£409,428,994).[1733] This includes the turnover of Advanz Pharma Corp and the Mercury Pharma Companies, with the turnover of the Mercury Pharma Companies amounting to [£250-300

[1730] Document LIO12208, HgCapital's response question 1 of the CMA's s.26 notice dated 14 April 2021.
[1731] The financial information relating to Cinven's financial year ending 31 December 2020 was not available at the time of writing; document LIO12204, Cinven response to CMA's s.26 notice dated 14 April 2021, paragraph 1.1.
[1732] Document LIO12205; Annex 1 to Cinven's response to the CMA's s.26 notice dated 14 April 2021.
[1733] '*Consolidated Financial Statements of ADVANZ PHARMA Corp. Limited*', 31 December 2020, page 13, available at: https://www.advanzpharma.com/media/uploads/ADVZ-Financials-Annual-with-Audit-opinion-2020-FINAL-17032021.pdf

million].[1734] The maximum penalty that can be imposed on the Advanz Pharma Group (including Advanz Pharma Corp and the Mercury Pharma Companies) is therefore £40,942,899.[1735]

7.190 The CMA has therefore reduced the part of the penalty relating to Period 4 (for which Advanz Pharma Corp and the Mercury Pharma Companies are jointly and severally liable) from £65,200,000 to £40,942,899.

7.191 No amount in addition to this (for Periods 1-4) can be recovered by the CMA from the Mercury Pharma Companies or Advanz Pharma Corp.

7.192 The application of the statutory cap to the Advanz Pharma Group results in HgCapital and the Cinven Entities being solely responsible for the parts of the penalty imposed in relation to their respective ownership periods (Periods 2 and 3).

7.193 Both the Cinven Entities and HgCapital have argued that the CMA's approach to the application of the statutory cap in this case is wrong and should be revised.[1736] The CMA disagrees. A detailed summary of the Parties' arguments and the CMA's rejection of these is set out in paragraphs 7.125 ff of Annex 7.

7.194 Based on the above, at the end of Step 5, of the total penalty of £101,442,899 imposed in relation to the Infringement:

(a) HgCapital is (solely) liable for £8,600,000;

(b) The Cinven Entities are jointly and severally liable (*inter se*) for £51,900,000; and

(c) Advanz Pharma Corp and the Mercury Pharma Companies are jointly and severally liable (*inter se*) for £40,942,899.

[1734] Documents LIO12195, Advanz response to the CMA's s.26 notice dated 8 April 2021.
[1735] This is 10% of the GBP total based on the average BoE exchange rates for 2020. A separate statutory cap for the Mercury Pharma Companies for the part of the penalty for which they do not share liability with Advanz Pharma Corp (Periods 1 to 3) would be GBP [25-30 million] (10% of the Mercury Pharma Companies' total worldwide turnover in the last financial year (2020) of GBP [250-300 million] – see LIO12195). However, such a separate statutory cap is of no practical relevance in this case. This is because the penalty in respect of Period 4, for which Advanz Pharma Corp and the Mercury Pharma Companies are jointly and severally liable, already exceeds the 10% statutory cap for the Advanz Pharma Group as a whole (including both Advanz Pharma Corp and the Mercury Pharma Companies).
[1736] Document LIO7981, HgCapital RDPS, paragraphs 7ff and document LIO7978, Cinven RDPS, paragraphs 3.119ff.

VI. Penalty calculation Step 6 – Application of reductions for leniency and settlement

7.195 The CMA will reduce an undertaking's penalty at Step 6 where the undertaking has a leniency agreement with the CMA and/or agrees to settle with the CMA.[1737]

7.196 None of the Parties has entered into a leniency or settlement agreement with the CMA. Therefore, the CMA has not made any adjustments at Step 6.

E. Financial penalties

7.197 The CMA requires the Parties to pay a total penalty of £101,442,899 in relation to the Infringement, with each of the liable undertakings individually being liable for the following amount:

(a) Advanz Pharma Corp and its subsidiaries the Mercury Pharma Companies are liable for a penalty of **£40,942,899**. Each of these legal entities is jointly and severally liable to pay this sum in its entirety.

(b) HgCapital is liable for a penalty of **£8,600,000**.

(c) The Cinven Entities are liable for a penalty of **£51,900,000**. Each of the Cinven Entities is jointly and severally liable to pay this sum in its entirety.

7.198 Each of the above penalties will become due to the CMA in its entirety and must be paid to the CMA by close of banking business, on 30 September 2021. If that date has passed and (a) the period during which an appeal against the imposition, or amount, of that penalty may be made has expired without an appeal having been made, or (b) such an appeal has been made and determined, the CMA may commence proceedings to recover from the undertaking in question, as a civil debt due to the CMA, any amount payable which remains outstanding.[1738]

[1737] *Penalty Guidance*, paragraphs 2.25-2.26.
[1738] Section 37(1) of the Act.

Signed by the following who are members of, and together constitute, the Case Decision Group:

[✂]

Martin Coleman, Non-Executive Director of the CMA Board, Panel Chair and Panel Inquiry Chair, for and on behalf of the CMA

[✂]

Stuart McIntosh, Inquiry Chair, for and on behalf of the CMA

[✂]

Julie Bon, Deputy Chief Economic Adviser, for and on behalf of the CMA