ANNEX A

The Investigations

1. This annex summarises the main steps and key events in the CMA's Investigations.

I. Scope and beginning of the Investigations

2. In March 2016, the CMA opened an investigation into a suspected abuse of dominance by Auden/Actavis by charging excessive and unfair prices in relation to the supply of 10mg and 20mg hydrocortisone tablets in the UK ('Case 50277-1').

3. In April 2016, the CMA opened an investigation into suspected anti-competitive agreements and/or concerted practices involving AMCo and Auden/Actavis relating to 10mg hydrocortisone tablets ('Case 50277-2').

4. In October 2017, the CMA opened an investigation under the Act into suspected anti-competitive agreements and/or concerted practices involving Waymade and Auden/Actavis relating to 10mg and 20mg hydrocortisone tablets and into a suspected abuse of dominance by Auden/Actavis by buying off Waymade's independent entry with its own 10mg and 20mg hydrocortisone tablets ('Case 50277-3').

II. Evidence gathering and engagement before the issuance of the Statements of Objections and the Letters of Facts

5. In this section, the CMA provides details of key procedural steps taken in Cases 50277-1, 50277-2 and 50277-3 in relation to evidence gathering and engagement with the case parties and third parties. The steps described here were taken before the issuance of the second Letter of Facts in Case 50277-1 and the Statements of Objections in Cases 50277-2 and 50277-3, respectively.

a. Evidence gathering in Case 50277-1

i. Auden

Evidence gathering

<u>Section 27 inspection</u>

6. On 8 March 2016, the CMA conducted a site visit without notice at the premises of Auden, requiring the preservation and production of documents

pursuant to its notice under section 27 of the Act. Auden produced a number of documents at the site visit.

7. In April 2016, following the site visit, the CMA conducted a review of the evidence preserved relating to hydrocortisone tablets at the CMA's premises, with consent from Auden, and with its legal representatives present. The CMA obtained additional documents to the documents produced at the 8 March 2016 site visit in this process.

Section 26 notices

8. Further information and/or documents were requested from Auden/Actavis under section 26 of the Act on 18 March 2016, 30 March 2016, 23 May 2016, 23 June 2016, 24 August 2016 and 8 September 2016, 18 October 2016, 11 November 2016, 29 August 2017 and 10 November 2017.

9. On 3 May 2017, 15 June 2017, 10 October 2017, 20 December 2017, 2 February 2018 and 28 February 2018, the CMA requested information and/or documents from Intas and Accord under section 26 of the Act.

10. On 10 November 2017, the CMA requested information and documents from Allergan under section 26 of the Act.

Section 26A interviews

11. The CMA conducted compulsory interviews under section 26A of the Act with the following former Auden employees:

    a. [Auden Senior Employee 1], on 26 July 2016; and

    b. [Auden Senior Employee 2], on 21 September 2016.

Voluntary submissions

12. Allergan provided a voluntary submission to the CMA on 5 December 2016.

13. On 2 June 2017 and 1 August 2017, Intas and Accord provided voluntary submissions to the CMA.

State of play meetings and telephone conferences

14. The CMA held State of Play meetings with Auden/Actavis on 12 May 2016 and 7 September 2016 and held a State of Play telephone conference with Auden/Actavis on 18 October 2016 and 15 December 2017. The CMA also held a State of Play telephone conference with Allergan on 17 November 2016 and 14 December 2017.

15. The CMA met with Intas and Accord on 23 February 2017 and held a State of Play meeting with those companies on 8 May 2017. The CMA also held State of Play telephone conferences with those companies on 26 July 2017 and 6 February 2018.

ii. Other sources of information

16. During the course of its investigation, the CMA requested information under section 26 of the Act from a number of third parties.

Category	Entity
Actual/Potential competitors	Alissa Healthcare Research Limited ('**Alissa**'), Bristol Laboratories Limited ('**Bristol Laboratories**'),[1] Advanz, Genesis Pharmaceuticals, Novelgenix Therapeutics Limited, Teva UK Limited, Resolution Chemicals Limited ('**Resolution Chemicals**'), Waymade
Brand owner (former)	Merck Sharpe & Dohme Limited
Contract Manufacturing Organisations	Aesica Queenborough Limited, Tiofarma BV
Product Developers	YJBPort Limited
GP Software providers	Computer Sciences Corporation, EMIS Health,[2] In Practice Systems (INPS) Limited, Microtest Limited, The Phoenix Partnership (TPP) Limited
Government Departments	Department of Health, Medicines and Healthcare products Regulatory Agency, NHS Business Services Authority, NHS Clinical Commissioners, NHS Gloucestershire CCG, NHS South Devon and Torbay CCG, NHS Coastal West Sussex CCG
Orphan Designation Holder	The Shire Group, including Shire Services BVLA and Shire Pharmaceuticals Limited
Pharmacies	Asda Stores Limited, Boots UK Limited, Day Lewis Plc, Lloyds Pharmacy Limited, Wm Morrisons Supermarkets Plc, L Rowland & Co (Retail) Ltd, Sainsbury's Supermarkets Limited, Superdrug Stores Plc, Tesco Stores Limited, Well Pharmacy[3]
Specialists	Royal College of Physicians, Society for Endocrinology
Wholesalers	AAH Pharmaceuticals Limited, Alliance Healthcare (Distribution) Limited, DE Group, Mylan N.V. and Sigma Pharmaceuticals plc.
Other third parties	First Databank

[1] The CMA sent an informal information request to Bristol Laboratories on 29 June 2016 and also engaged in a telephone conference on 8 September 2016.
[2] EMS Health is a trading name used by members of the EMS Group of companies which includes Egton Medical Information Systems Limited.
[3] Well Pharmacy is part of the Bestway Group which is the trading name for Bestway Panacea Healthcare Limited, Bestway National Chemists Limited and Bestway Belfast Chemists Limited.

17. The CMA also conducted a voluntary witness interview with [Alissa Senior Employee] on 2 August 2016.

b. Evidence gathering in Case 50277-2

i. Auden

Evidence gathering

Section 26 notices

18. Information and/or documents were requested from Auden under section 26 of the Act on 18 March 2016, 23 May 2016, 23 June 2016 and 24 August 2016.

19. The CMA also requested information and/or documents under section 26 of the Act from [Auden Senior Employee 1] on 23 June 2016 and from [Auden Senior Employee 1] on 21 September 2016.

Section 26A interviews

20. The CMA conducted compulsory interviews under section 26A of the Act with former Auden employees:[4]

    a. [Auden Senior Employee 1], on 26 July 2016; and

    b. [Auden Senior Employee 2], on 21 September 2016.

Voluntary submissions

21. Allergan provided a voluntary submission to the CMA on 5 December 2016.

State of play meetings and telephone conferences

22. The CMA held State of Play meetings with Auden/Actavis on 12 May 2016 and 7 September 2016. The CMA held a State of Play telephone conference with Auden/Actavis on 18 October 2016.

23. The CMA held a State of Play telephone conference with Allergan on 17 November 2016.

[4] These are the same interviews as those mentioned in paragraph 11 above. The interviews were conducted for both case 50277-1 and 50277-2.

ii. AMCo

Evidence gathering

Section 26 notices

24. Information and/or documents were requested from AMCo under section 26 of the Act on 8 March 2016 (amended on 13 April 2016), 20 April 2016, 23 August 2016 and 21 September 2016.

25. Information and/or documents were requested from the Cinven Entities under section 26 of the Act on 20 October 2016 and 11 November 2016.

Section 26A interviews

26. The CMA conducted a compulsory interview under section 26A of the Act with [Amdipharm Senior Employee] on 4 August 2016.

Voluntary submissions

27. Voluntary submissions were provided by AMCo to the CMA on 10 June 2016 and 14 October 2016. Following AMCo's October 2016 submission, the CMA reviewed the evidence underlying that submission at the premises of AMCo's legal advisers on 17 January 2017, during which the CMA decided to take six documents made available by AMCo and place these on the case file.

28. In relation to the October 2016 voluntary submission, AMCo also submitted a number of documents containing internal and external legal advice relating to hydrocortisone tablets in support of its submission in mid-February. This followed an exchange of correspondence between the CMA and AMCo in which AMCo confirmed that its submission of legal advice would include the contemporaneous external competition law advice and the contemporaneous regulatory advice as to orphan drug status that AMCo received in respect of its agreements with Auden relative to hydrocortisone, and the contemporaneous legal advice that formed the basis upon which Amdipharm proceeded with the Second Written Agreement. AMCo confirmed that this would not involve 'cherry-picking'. This led to the CMA placing 19 further documents onto its file on 15 February 2017.

State of play meetings and telephone conferences

29. The CMA held State of Play meetings with AMCo on 18 May 2016 and 20 September 2016.

30. The CMA held a State of Play telephone conference with the Cinven Entities on 16 November 2016.

iii. Other sources of information

31. During the course of its investigation, the CMA requested information under section 26 of the Act from a number of third parties.

Category	Entity
Actual/Potential competitors	Alissa, Bristol Laboratories, Resolution Chemicals, Waymade
Brand owner (former)	Merck Sharpe & Dohme Limited
Contract Manufacturing Organisations	Aesica Queenborough Limited, Tiofarma BV
Orphan Designation Holder	The Shire Group, including Shire Services BVBA and Shire Pharmaceuticals Limited
Pharmacies	Asda Stores Limited, Boots UK Limited, Day Lewis Plc, Lloyds Pharmacy Limited, Wm Morrisons Supermarkets Plc, L Rowland & Co (Retail) Ltd, Sainsbury's Supermarkets Limited, Superdrug Stores Plc, Tesco Stores Limited, Well Pharmacy
Pre-wholesaler of AMCo	Alloga UK Limited
Specialists	Royal College of Physicians, Society for Endocrinology

32. The CMA also conducted a voluntary interview with [Alissa Senior Employee] on 2 August 2016.

c. Evidence gathering in Case 50277-3

i. Auden

Evidence gathering

Section 26 notices

33. On 4 May 2018, the CMA required [Auden Senior Employee 1] to provide documents and information under section 26 of the Act.

Section 26A interviews

34. The CMA conducted compulsory interviews under section 26A of the Act with former Auden employees:

    a. [Auden Senior Employee 1], on 23 May 2018; and

b. [Auden Senior Employee 2], also on 23 May 2018.

State of play meetings

35. The CMA held State of Play meetings with Accord-UK on 22 January 2018 and 17 January 2019.

ii. Waymade

Evidence gathering

Section 27 inspection

36. On 18 October 2017, the CMA conducted a site visit without notice at the premises of Waymade under section 27 of the Act.

37. On 22 March 2018, the CMA conducted a site visit with notice at the premises of Atnahs under section 27 of the Act.

Section 26 notices

38. On 8 October 2018 and 12 February 2019, the CMA required Waymade to provide information and/or documents under section 26 of the Act.

39. On 10 May 2018, the CMA required [Waymade Senior Employee 3] to provide information and documents under section 26 of the Act.

Section 26A interviews

40. The CMA conducted compulsory interviews with current Waymade employees under section 26A of the Act:

a. [Waymade Senior Employee 4], on 28 March 2018;

b. [Waymade Senior Employee 2], [✂], on 28 March 2018; and

c. [Waymade Senior Employee 1], on 27 June 2018.

41. The CMA conducted compulsory interviews with former Waymade employees under section 26A of the Act:

a. [Waymade Senior Employee 3], on 27 March 2018;

b. [Amdipharm Senior Employee], on 7 June 2018;

c. [Waymade Employee], on 12 November 2018;

d. [Waymade Employee], on 23 November 2018; and

e. [Waymade Employee], on 13 December 2018.

State of play meetings

42. The CMA held a State of Play meeting with Waymade on 24 January 2019.

iii. Third party evidence

43. On 20 March 2018, the CMA held a telephone call with [✂].

44. The CMA conducted voluntary witness interviews with former employees of Aesica:

a. [Aesica Employee], on 30 October 2018; and

b. [Aesica Employee], on 31 October 2018.

45. On 12 February 2019, the CMA required Aesica to provide information and/or documents under section 26 of the Act.

iv. Anonymous submission

46. In October 2016, the CMA received an anonymous submission. The anonymous submission, which was accompanied by contemporaneous documentary evidence, stated in relation to hydrocortisone tablets:

> *'HYDROCORTISONE TABLETS*
>
> *[Auden Senior Employee 1] and [Auden Senior Employee 5], [✂], had surpressed [sic] the entry on Waymade/Soveriegn's [sic] Generic Hydrocortisone tabs 20mg by paying them a monthly 'marketing' fee. This was to ensure that whilst [Waymade Senior Employee 1] and [Waymade Employee] got their share of the profits, prices for Hydrocrtisone [sic] tablets remained high at the expense of the NHS and Tax Payer.*
>
> *[Auden Senior Employee 1] and [Auden Senior Employee 5], [✂] also had a similar arrangement with Waymade/Soveriegn* [sic] *AND then AMCO regarding the Hydrocortisone tabs 10mg. By supplying a limited amount of stock to AMCO, prices were kept very high at the expense of the NHS and Tax Payer.'*[5]

[5] Document 201140, the Anonymous Submission received in October 2016.

III. The Statements of Objections and Letters of Facts

47. The CMA issued its provisional findings for Case 50277-1 as follows:

    a. On 16 December 2016, the CMA issued a Statement of Objections to Actavis UK and Allergan (the '**December 2016 SO**').

    b. On 5 April 2017, the CMA reissued the December 2016 SO to include AM Pharma and Auden Mckenzie Holdings Limited as addressees (the '**April 2017 SO**').

    c. On 9 August 2017, the CMA reissued the April 2017 SO but updated the data used therein to include Intas and Accord as new addressees in light of the fact that they had acquired Actavis UK in January 2017 and in light of the CMA's provisional view that the infringements alleged in the December 2016 SO were ongoing when that SO was issued (the '**August 2017 SO**').

    d. On 9 August 2017, the CMA issued a letter of facts to Actavis UK Limited, AM Pharma, Auden Mckenzie Holdings Limited and Allergan (the '**August 2017 LoF**') informing it of the new evidence included in the August 2017 SO.

    e. On 9 March 2018, the CMA issued a further letter of facts to Actavis UK, AM Pharma, Auden Mckenzie Holdings Limited, Allergan, Intas and Accord (the '**March 2018 LoF**').

48. The CMA issued a Statement of Objections in Case 50277-2 to Actavis UK, AM Pharma, Auden Mckenzie Holdings Limited, Allergan, Concordia (now Advanz) and the Cinven Entities on 3 March 2017 (the '**March 2017 SO**').

49. The CMA issued a Statement of Objections in Case 50277-3 to Accord UK, AM Pharma, Auden Mckenzie Holdings Limited and Waymade on 28 February 2019 (the '**February 2019 SO**').

a. Representations on the Statements of Objections and the Letters of Facts

50. The CMA invited each of the addressees of the Statements of Objections and the Letters of Facts to respond in writing, by submitting written representations on the CMA's provisional findings.

51. The CMA also offered the case parties to Cases 50277-1 and 50277-2 the opportunity to attend an oral hearing to discuss the matters set out in the

Statements of Objections. The CMA did not hold oral hearings in Case 50277-3 for reasons that are further explained below.

i. Case 50277-1

52. Actavis UK submitted written representations on 24 March 2017.

53. On 3 May 2017, AM Pharma and Auden Mckenzie Holdings Limited (together referred to hereafter as the Auden Companies) informed the CMA that they adopted Actavis UK's written representations with respect to the April 2017 SO and provided no further written representations.

54. On 16 May 2017, an oral hearing was held with Actavis UK and the Auden Companies. Allergan chose not to attend an oral hearing.

55. On 2 June 2017, Actavis UK and the Auden Companies together provided a response to follow-up questions following their oral hearing.

56. Actavis UK and the Auden Companies submitted written representations on the August 2017 LoF on 11 October 2017. Allergan chose not to provide written representations on the August 2017 LoF.

57. Intas, Accord and Actavis UK submitted written representations on the August 2017 SO on 18 October 2017.

58. On 15 December 2017, an oral hearing was held with Intas, Accord and Actavis UK to discuss the matters set out in the August 2017 SO.

59. On 5 April 2018, Allergan submitted written representations on the March 2018 LoF. On 10 April 2018, the Auden Companies, Intas, Accord and Actavis UK also submitted written representations on the March 2018 LoF.

ii. Case 50277-2

60. The following written representations were received:

    a. From Actavis UK and the Auden Companies on 26 May 2017.

    b. From the Cinven Entities on 26 May 2017.

    c. From Amdipharm Limited, Concordia International Rx (UK) Limited, Concordia International (Jersey) Limited and Concordia International Corporation on 26 May 2017.

61. Allergan chose not to submit written representations.

62. The following oral hearings were held:

    a. With Amdipharm Limited, Concordia International Rx (UK) Limited, Concordia International (Jersey) Limited and Concordia International Corporation on 20 July 2017.

    b. With the Cinven Entities on 24 July 2017.

    c. With Actavis UK and the Auden Companies on 25 July 2017.

63. Allergan chose not to attend an oral hearing.

iii. Case 50277-3

64. On 16 May 2019, the CMA informed the case parties to Case 50277-3 that the CDG had proposed to join Cases 50277-2 and 50277-3 on account of the cases' common factual basis and had instructed the case team to prepare an SSO. The CMA also explained that further evidence had been gathered in Case 50277-2 since the issuance of SOs in both Cases.

65. As a result, the case team offered the case parties to Case 50277-3 the opportunity to defer submitting written representations and attending an oral hearing on the SO issued in Case 50277-3 until they were granted access to the Case 50277-2 file. All of the case parties decided to defer their representations.

IV. Case Decision Groups

66. On 25 January 2017, the CMA appointed Andrea Coscelli, Ann Lambert and Philip Marsden as members of the Case Decision Group ('**CDG**') for Case 50277-1.

67. On 3 March 2017, the CMA appointed the same CDG for Case 50277-2.

68. On 26 April 2019, following the departure of Philip Marsden and Ann Lambert from the CMA, Geoff Steadman and Stephen Blake were appointed as members of the CDG for Cases 50277-1 and 50277-2. The CMA also appointed the same CDG for Case 50277-3.

69. On 20 June 2019, following correspondence from some of the parties, the CMA decided to replace Geoff Steadman with Paul Hughes (Panel Member) as a member of the CDG. The other CDG members remained the same.

V. Draft Penalty Statements in Case 50277-1

70. On 21 December 2017, the CMA issued a Draft Penalty Statement ('**December 2017 DPS**') to Allergan and Actavis UK in respect of the December 2016 and April 2017 Statements of Objections issued in Case 50277-1 and specifically the period up to the acquisition of Actavis UK by Accord and Intas.

71. Allergan and Actavis UK submitted written representations to the December 2017 DPS on 31 January 2018.

72. On 14 February 2018, the CMA issued a DPS ('**February 2018 DPS**') to Accord-UK, Intas and Accord in respect to the August 2017 Statement of objections issued in Case 50277-1 and specifically the period for which Intas and Accord were proposed to be held jointly and severally liable with Accord-UK.

73. Accord-UK, Intas and Accord submitted written representations to the February 2018 DPS on 29 March 2018.

74. The CMA held an oral hearing on the DPS with Allergan on 26 February 2018 and with Actavis UK on 26 March 2018. The CMA also held an oral hearing with Accord-UK, Intas and Accord on 16 April 2018.

VI. The *Phenytoin* appeal and Case 50277-1

75. On 7 June 2018, the CAT issued its judgment in the *Phenytoin* appeal.[6] The CAT disagreed with the CMA's application of the legal test for excessive and unfair pricing and remitted the case back to the CMA.

76. On 3 July 2018, the CMA wrote to Accord-UK, Allergan, Intas and Accord to inform that it was seeking permission to appeal the CAT's judgment and that the outcome of the appeal could impact the CMA's substantive assessment of the conduct in Case 50277-1. The CMA explained that if it proposed to take further steps in relation to Case 50277-1 other than investigative steps to gather evidence, the CMA would organise a State of Play meeting with the case parties before taking any such step.

[6] *Flynn Pharma Limited and Flynn Pharma (Holdings Limited) and Pfizer Inc and Pfizer Limited v Competition and Markets Authority* [2018] CAT 11 (on appeal to the Court of Appeal).

VII. Further evidence gathering following the issue of the Statements of Objections and the Letters of Facts

a. Further evidence gathering in relation to Case 50277-1

77. Following the March 2018 LoF, the CMA carried out the following further investigative steps.

78. On 22 July 2019, the CMA conducted further compulsory interviews under section 26A of the Act with the following Accord-UK employees in relation to Case 50277-1:

    a. [Actavis Senior Employee 1], [✂];

    b. [Actavis Senior Employee 2], [✂]; and

    c. [Actavis Senior Employee 3], [✂].

79. On 27 August 2019, the CMA requested further information and/or documents from Intas, Accord and Actavis UK under section 26 of the Act.

80. The CMA also requested further documents and/or information be provided by the following third parties:

Category	Entity
Actual/Potential competitors	Alissa, Bristol Laboratories, Concordia International Rx (UK) Limited, Flynn Pharma Limited, Genesis Pharmaceuticals, Renata (UK) Limited, Resolution Chemicals, Teva UK Limited, Waymade Plc
Pharmacies	Asda Stores Limited, Boots UK Limited, Day Lewis Plc, Lloyds Pharmacy Limited, Wm Morrisons Supermarkets Plc, L Rowland & Co (Retail) Ltd, Superdrug Stores Plc, Tesco Stores Limited, Well Pharmacy
Wholesalers	AAH Pharmaceuticals Limited, Alliance Healthcare (Distribution) Limited, Cambrian Alliance Limited, Mawdsley-Brooks & Company Limited, Phoenix Medical Supplies Limited, Sigma Pharmaceuticals Plc and WR Evans Healthcare Ltd

81. The CMA also continued to receive updated data from suppliers of hydrocortisone tablets on their volumes and prices. As of the date of this Decision, the CMA has obtained sales data up to the end of April 2021.

b. Further evidence gathering in relation to Case 50277-2

82. Following the March 2017 SO, the CMA carried out the following further investigative steps.

i. Section 28 and Section 28A Inspections and the Concordia warrant application

83. After issuing the March 2017 SO, the CMA received further information of relevance to the Investigation.[7] As a result of this information, the CMA suspected that certain evidence had not been submitted by AMCo in response to the section 26 notices addressed to it in cases 50277-1 and 50277-2 and that if the CMA were to request such evidence again, AMCo would conceal or destroy it rather than submit it to the CMA. The CMA also suspected that further evidence may be held by [Auden Senior Employee 1] and [AMCo Senior Employee 1] and that, if the CMA were to request such evidence from them, they would conceal or destroy it rather than submit it to the CMA. Accordingly, on 6 October 2017 the CMA obtained warrants from the High Court under sections 28 and 28A of the Act to inspect the premises of:

a. AMCo (then named Concordia);

b. [Auden Senior Employee 1], [✂];

c. and [AMCo Senior Employee 1], [✂].

84. These warrants were executed between 10 and 13 October 2017.

85. On 10 October 2017, Concordia applied to have the warrant in respect of its premises set aside. Pending determination of that challenge, the CMA refrained from reviewing the evidence obtained under that warrant.

86. Following a series of hearings in the High Court and the Court of Appeal, the warrant was ultimately upheld by the High Court on 16 January 2019.[8]

87. Following the conclusion of Concordia's unsuccessful challenge to the warrant, in April 2019, further to the filtering of the evidence and correspondence with AMCo's legal advisers, the CMA initiated the process of reviewing the Concordia evidence obtained under that warrant, including a

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

[8] *The Competition And Markets Authority v Concordia International Rx (UK) Ltd*, [2019] WLR(D) 20, [2019] Bus LR 1000, [2019] EWHC 47 (Ch) (16 January 2019) (see www.bailii.org/ew/cases/EWHC/Ch/2019/47.html). In his judgment, Marcus Smith J held that '*there were certainly reasonable grounds for suspecting that*' Advanz's methodology for replying to previous section 26 notices issued by the CMA was '*framed with a view to ensuring that certain types of document and certain custodians were excluded from the search*' and that there were reasonable grounds for the CMA to suspect that those personnel at Advanz who managed the responses to the CMA's previous section 26 notices ought to have known that those responses were incomplete. Marcus Smith J therefore upheld the warrant, finding that there were reasonable grounds to suspect that if the CMA were to require the missing documents under section 26, they would not be produced but would be concealed, removed, tampered with or destroyed (see paragraphs 33 and 34).

significant volume of emails, hardcopy documents and mobile device materials. The CMA's reviews produced new evidence relevant to the Investigations.

88. The majority of the CMA's review of the email evidence was conducted between 3 April 2019 and 17 May 2019 at the CMA's offices, with Concordia's legal advisers present, shadowing the CMA's review to check for both potentially legally privileged material and relevance to the matters being investigated.

89. In June 2019, the CMA reviewed the mobile devices it had obtained from the warrant in relation to Concordia's premises. However, the majority of the material contained on those devices postdated the events relevant to the Infringements because those devices had been upgraded and the older devices had not been retained. In addition, the CMA did not manage to extract data from passcode-protected mobile devices belonging to [Auden Senior Employee 1] and [AMCo Senior Employee 1] as they could not recall their passcodes. As a result, the CMA has not been able to obtain mobile material within the relevant periods.

90. The CMA was not able to review either the email or hardcopy materials obtained in relation to [AMCo Senior Employee 8] [✂] until a separate review was conducted by Independent Counsel to determine issues of legal professional privilege. The CMA's review of those materials started in July 2019 and finished on 10 February 2020. The majority of the non-legally privileged materials were reviewed by the CMA between 1 October 2019 and 20 November 2019.

ii. Other further evidence gathering in Case 50277-2

91. Further information and/or documents were requested under section 26 of the Act from the following case parties:

    a. the Cinven Entities, on 10 August 2017.

    b. Advanz, on 21 August 2017; and

    c. the Auden Companies and Actavis UK on 29 August 2017.

92. Further information and/or documents were requested under section 26 of the Act from the following former employees of the case parties:

    a. [AMCo Senior Employee 4], [✂], on 10 April 2018;

    b. [AMCo Senior Employee 2], [✂], on 10 April 2018; and

c. [Auden Senior Employee 1], on 4 May 2018 and on 24 May 2018 (reissue of the section 26 notice).

93. The CMA conducted further compulsory interviews under section 26A of the Act with former Auden employees:[9]

a. [Auden Senior Employee 1], on 23 May 2018; and

b. [Auden Senior Employee 2], also on 23 May 2018.

94. The CMA conducted further compulsory interviews under section 26A of the Act with [Actavis Senior Employee 1], [Actavis Senior Employee 2] and [Actavis Senior Employee 3], Accord-UK employees, on 22 July 2019.

95. The CMA conducted further compulsory interviews under section 26A of the Act with former employees of AMCo and/or Concordia:

a. [AMCo Senior Employee 2], [✂], on 12 October 2017;

b. [AMCo Senior Employee 1], [✂], on 20 October 2017 and 7 June 2018;

c. [AMCo Senior Employee 4], on 23 October 2017; and

d. [Amdipharm Senior Employee], on 7 June 2018.[10]

96. The CMA conducted further compulsory interviews under section 26A of the Act with current employees of AMCo, Concordia and/or Advanz:

a. [AMCo Senior Employee 7], [✂], on 13 October 2017;

b. [AMCo Employee], [✂], on 18 October 2017;

c. [AMCo Senior Employee 3], [✂], on 18 October 2017;

d. [AMCo Senior Employee 5], [✂], on 13 October 2017; and

e. [AMCo Employee], [✂], on 8 July 2019.

97. Additionally, the CMA conducted a voluntary interview with [AMCo Employee], [✂], on 25 June 2019.

98. The CMA also requested further documents and/or information be provided by the following third parties:

[9] These are the same interviews as those mentioned in paragraph 34 above.
[10] This is the same interview as the one mentioned in paragraph 41(b) above.

Category	Entity
Actual/Potential competitors	Alissa, Bristol Laboratories, Resolution Chemicals, Teva UK Limited, Waymade Plc,
GP Software providers	EMIS Group Plc, In Practice Systems (INPS) Limited, Microtest Limited, The Phoenix Partnership (TPP) Limited
Government Departments	NHS Business Services Authority
Pharmacies	Asda Stores Limited, Boots UK Limited, Lloyds Pharmacy Limited, Wm Morrisons Supermarkets Plc, L Rowland & Co (Retail) Ltd, Sainsbury's Supermarkets Limited, Superdrug Stores Plc, Tesco Stores Limited, Well Pharmacy
Wholesalers	AAH Pharmaceuticals Limited, Alliance Healthcare (Distribution) Limited, DE Group and Sigma Pharmaceuticals plc
Other third parties	First Databank

99. The CMA conducted a compulsory interview under section 26A of the Act with [Waymade Senior Employee 1, [✂], on 27 June 2018.[11]

100. The CMA conducted a voluntary interview with the following third parties:[12]

a. [Aesica Employee], [✂], on 30 October 2018; and

b. [Aesica Employee], [✂], on 31 October 2018.

iii. Update letters and further State of Play meetings

101. On 20 June 2019, the CMA sent an update letter to the case parties to Cases 50277-1, 50277-2 and 50277-3 to inform them that the CMA would progress the three cases on a joint basis and that the CDG had instructed the case team to prepare an SSO.

102. Further to the update letter, CMA held further State of Play calls with the following parties:

a. The Auden Companies and Actavis UK Limited, on 2 September 2019.

b. Intas and Accord, on 2 September 2019.

c. The Cinven Entities, on 5 September 2019.

d. Allergan, on 9 September 2019.

[11] This is the same interview as the one mentioned in paragraph 40(c) above.
[12] These are the same interviews as those mentioned in paragraph 43 above.

e. Advanz, on 16 September 2019.

f. Waymade, on 16 September 2019.

VIII. Other events and developments relevant to Cases 50277-1, 50277-2 and/or 50277-3

a. The CAT's judgment in the *Phenytoin* appeal

103. As mentioned above, in June 2018 the CAT issued its judgment in the *Phenytoin* appeal.[13] The CAT disagreed with the CMA's application of the legal test for excessive and unfair pricing and remitted the case back to the CMA. The CMA appealed the CAT's *Phenytoin* judgment to the Court of Appeal.

b. The CMA's Supplementary Statement of Objections in Case 50395

104. On 30 January 2019, the CMA issued a Supplementary Statement of Objections to AMCo and Cinven Entities in case 50395 (relating to alleged excessive and unfair pricing of liothyronine tablets), to reflect the CAT's judgment on the law of excessive and unfair pricing in the *Phenytoin* case. That Supplementary Statement of Objections also developed the case on the liability of the Cinven Entities, in light of further evidence obtained in that case, which was then transferred to case 50277-2.

c. [✂]

105. [✂].

106. [✂].

107. [✂].

108. [✂].[14] [✂].

109. [✂].[15]

IX. The Supplementary Statement of Objections

110. The CMA issued a Supplementary Statement of Objections in Case 50277 to Accord-UK, AM Pharma,[16] Allergan, Accord, Intas, Waymade plc, the

[13] *Flynn Pharma Limited and Flynn Pharma (Holdings Limited) and Pfizer Inc and Pfizer Limited v Competition and Markets Authority* [2018] CAT 11 (on appeal to the Court of Appeal).
[14] [✂].
[15] [✂].
[16] Auden Mckenzie Holdings Limited was also an addressee of the SSO.

Amdipharm Companies, the Cinven Entities and Advanz on 12 February 2020 (the '**SSO**').

111. On 7 May 2020, the CMA informed the addressees party to the Unfair Pricing Abuses that it considered it appropriate to revise Section 5 of the SSO ('*The Unfair Pricing Abuses'*) following the Court of Appeal's judgement in *Phenytoin*.

112. On 16 June 2020, the CMA issued a revised version of section 5 of the SSO to the addressees party to the Unfair Pricing Abuses.

a. Representations on the Supplementary Statement of Objections

113. The CMA invited each of the addressees of the Supplementary Statement of Objections to respond in writing, by submitting written representations on the CMA's provisional findings.

114. The CMA also offered the case parties to Case 50277 the opportunity to attend an oral hearing to discuss the matters set out in the Supplementary Statement of Objections.

115. The following written representations on the SSO were received:

a. From Advanz on 26 May 2020.

b. From Waymade on 26 May 2020.

c. From the Cinven Entities on 2 June 2020.

116. The following written representations on revised version of Section 5 of the SSO were received:

a. From Auden/Actavis on 28 July 2020.

b. From Intas, Accord and Accord-UK on 28 July 2020.

c. From Allergan on 28 July 2020.

117. The following oral hearings were held:

a. With Allergan on 8 September 2020.

b. With the Cinven Entities on 9 September 2020.

c. With Advanz on 10 September 2020.

d. With Auden/Accord on 15 September 2020.

e. With Intas/Accord on 15 September 2020.

118. Waymade chose not to attend an oral hearing.

119. Intas/Accord submitted further written representations in response to questions raised by the CMA during the oral hearing on 30 October 2020.

X. Draft Penalty Statements

120. On 27 October 2020, the CMA issued Draft Penalty Statements ('**2020 DPSs**') to:

a. Accord-UK Limited, Accord Healthcare Limited, Allergan plc and Intas Pharmaceuticals Limited in respect of the alleged Chapter I and Chapter II infringements in relation to 10mg and 20mg hydrocortisone tablets outlined in the SSO.

b. Amdipharm UK Limited, Amdipharm Limited, Advanz Pharma Services (UK) Limited, Cinven Capital Management (V) General Partner Limited, Cinven (Luxco 1) S.A., Cinven Partners LLP and Advanz Pharma Corp. Limited in respect of the alleged Chapter I infringement in relation to 10mg hydrocortisone tablets outlined in the SSO.

c. Waymade plc in respect of the alleged Chapter I infringements in relation to 10mg and 20mg hydrocortisone tablets outlined in the SSO.

a. Representations on the Draft Penalty Statements

121. The CMA invited each of the addressees of the 2020 DPSs to submit written representations on the CMA's provisional penalty calculations.

122. The CMA also offered the addressees of the 2020 DPSs the opportunity to attend an oral hearing to discuss the matters set out in the 2020 DPSs.

123. The following written representations on the 2020 DPSs were received:

a. From Allergan on 20 November 2020.

b. From Auden/Actavis on 23 November 2020.

c. From Intas/Accord-UK on 23 November 2020.

d. From Cinven on 23 November 2020.

e. From Advanz on 23 November 2020.

f. From Waymade on 23 November 2020.

124. The following oral hearings were held:

a. With Cinven on 30 November 2020.

b. With Advanz on 1 December 2020.

c. With Allergan on 2 December 2020.

d. With Accord-UK on 7 December 2020.

125. Waymade and Intas/Accord-UK chose not to attend an oral hearing.

126. Advanz submitted further written representations in response to questions raised by the CMA during the oral hearing on 22 December 2020.

XI. Further evidence gathering following the issue of the Supplementary Statement of Objections

127. Further information and/or documents were obtained from a number third parties following the issue of the SSO:

Category	Entity
Actual/Potential competitors	Alissa and Resolution Chemicals
CMO	Recipharm (Aesica)
Government Departments	NHSEI and the MHRA
Pharmacies	Boots UK Limited and Day Lewis
Wholesalers	DE Group, Mawdsley-Brooks and Sigma Pharmaceuticals plc
Other third parties	Colonis Pharma, [Aesica Employee], Shire, Zentiva Pharma

XII. Letter of Facts

128. Following the post-SSO further evidence gathering, the CMA issued a letter of facts to Auden/Actavis, Allergan, AMCo, Cinven, Intas/Accord and Waymade on 6 May 2021 (the '**2021 LoF**').

a. Representations on the 2021 LoF

129. The following written representations on the 2021 LoF were received:

a. From Auden/Actavis on 28 May 2021.

b. From AMCo on 28 May 2021.

c. From the Cinven Entities on 28 May 2021.

d. From Intas/Accord on 2 June 2021.

e. From Waymade on 21 May 2021.

ANNEX B

Representations on DHSC/NHS countervailing buyer power

1. Auden/Actavis submitted that it did not hold a dominant position because the DHSC/NHS was '*a near monopsony purchaser of pharmaceuticals in the UK and over the relevant period was capable of exercising substantial countervailing buyer power, such as to constrain any market power of Auden.*'[17]

2. Auden/Actavis submitted that the DHSC/NHS was capable of exerting this buyer power through:

    a. its statutory powers in the NHS Act 2006;

    b. informal 'intervention' such as its discussion with Teva in relation to phenytoin tablets in 2007, discussed by the CAT in the *Phenytoin* case; and/or

    c. issuing guidance to encourage changes in prescribing practices so that hydrocortisone tablets were not the main treatment for adrenal insufficiency, and/or encouraging new entry from parallel importers or skinny label suppliers.[18]

3. The CMA rejects these arguments for the reasons explained in section 4.C.II.d of the Decision.

4. As explained in that section, the NHS is not a '*near monopsony purchaser*'. It is a fragmented and diffuse collection of entities with separate roles and responsibilities. There is no monolithic 'NHS'.

5. Auden/Actavis submitted that the CMA could not rely on the Court of Appeal's findings in *Phenytoin* discussed in section 4.C.II.d of the Decision because Pfizer and Flynn were PPRS members, such that the Reserve Power was (on the CMA's case) unavailable; whereas in this case AM Pharma was not a member of any voluntary scheme.[19] However, the CAT and Court of Appeal's explanation of the legal test for countervailing buyer

[17] Document 205217, Auden/Actavis's RSSO, paragraphs 3.42, 3.79.2 and 1.6.2. See also Document 205813, Accord-UK's RDPS, paragraphs 1.4.2 to1.4.3, 1.14.2, 4.11 and 9.2.
[18] Document 205217, Auden/Actavis's RSSO, paragraphs 3.47 to3.54, 3.57-3.61, 3.64 to 3.66 and 3.72 to 3.74; and Annex 1. Document 205813, Accord-UK's RDPS, paragraphs 3.9-3.12 and 6.21. See also Document 01454, Auden/Actavis's RSO1, paragraph 1.5 to 1.6, 2.5 to 2.43 and 3.30; Document 01998.C, Auden/Actavis's representations on the CMA's first letter of facts, paragraphs 5.8 to 5.45, especially 5.9. Intas/Accord-UK argued that the existence of the DHSC's powers meant that the DHSC, and not the CMA, would be the appropriate 'regulator' of Auden/Actavis's prices (Document 02001.B, Intas/Accord-UK's RSO1, section 5.3; Document 205212, Intas/Accord-UK's RSSO, paragraphs 101-102).
[19] Document 205217, Auden/Actavis's RSSO, paragraphs 3.50 to 3.52.

power was not specific to the factual circumstances of that case but was focussed (consistently with the caselaw on countervailing buyer power) on the question of whether there was evidence of an effective constraint in reality, notwithstanding the theoretical position. That principle is equally applicable here.

6. Auden/Actavis's representations focused entirely on the theoretical position. It provided no evidence to support its claim that it was constrained by DHSC/NHS countervailing buyer power.[20] That the DHSC had powers on paper to intervene; had a discussion with another supplier about another drug a year before the Unfair Pricing Abuses even began (of which Auden/Actavis apparently only became aware because of litigation in the CAT over a decade later);[21] or could in theory have issued guidance cannot be considered an effective and meaningful constraint on Auden/Actavis's behaviour in relation to hydrocortisone tablets. Fundamentally, these submissions ignore the point that Auden/Actavis imposed a more than 1,300% price increase for a drug during a period when it was the sole supplier, without losing volumes. It was manifestly not constrained in practice by the prospect of DHSC/NHS intervention.

7. For completeness, and since the DHSC's powers formed the majority of Auden/Actavis's submissions in response to the CMA's provisional findings on dominance, the CMA explains below the scope of the powers during the Unfair Pricing Abuses. The position changed over time as the legal entity selling hydrocortisone tablets changed and the regime was subject to

[20] Instead it referred to '*a generally accepted principle that collective purchasing bodies*' possess buyer power, and a statement by HM Treasury about '*the Government's collective buying power*' (Document 205217, Auden/Actavis's RSSO, paragraph 3.66). Elsewhere it referred to academic articles. Its submissions were not grounded in reality. This is most clearly illustrated by its claim that the potential for the NHS and/or the DHSC to issue guidance recommending the prescribing of other medicines for the treatment of adrenal insufficiency '*was a clear constraint on Auden and Accord-UK throughout the Relevant Period*' (Document 202517, Auden/Actavis's RSSO, paragraph 3.73). There is no evidence of this.

[21] In relation to informal 'intervention' such as the Teva discussion in 2007, in fact, the CAT held in *Phenytoin* that the DHSC had not '"*effectively regulated" the tablet price*' and that *'[w]e do not doubt that the DH would have preferred an even lower price*' (*Pfizer and Flynn* [2018] CAT 1, paragraphs 381 to 382). The CAT's conclusion on this discussion and those with Pfizer and Flynn was that '*We find it very difficult to conclude from these events that by early 2013 Pfizer or Flynn's conduct was in practice constrained either by intervention from the DH, or anticipation of that intervention … We therefore do not think that the DH was, in fact, exercising, or able to exercise, buyer power in a way that effectively constrained Pfizer or Flynn's conduct*' (*Pfizer and Flynn v CMA* [2018] CAT 1, paragraphs 234 to 235). Having rejected Pfizer's application for permission to appeal this aspect of the judgment as having no reasonable prospect of success, the Court of Appeal noted that '*It is important to start by noting two fundamentals of the [CAT] judgment*' (market definition and dominance), and went on to note that '*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*' (*CMA v Pfizer and Flynn* [2020] EWCA Civ 339, paragraphs 192 and 217). It is not plausible that the DHSC's discussions with Teva (or Flynn//Pfizer) in relation to phenytoin – which have been found not to have imposed an effective constraint on Flynn/Pfizer themselves in relation to phenytoin – demonstrate an effective constraint on a different undertaking, Auden/Actavis, in relation to a different drug.

legislative amendment. However, throughout, the DHSC powers did not exert an effective constraint on Auden/Actavis.

8. As explained in section 3.E.I of the Decision, until September 2015 the only legal power available to the DHSC to intervene in the price of Auden's hydrocortisone tablets was the Reserve Power in s.262(1) NHS Act 2006. AM Pharma, the entity that sold hydrocortisone tablets until September 2015, was not a member of any voluntary scheme.[22]

9. During this period, the Reserve Power was subject to limitations:[23]

   a. With respect to generic drugs, there was no enforcement regime to underpin any exercise of the Reserve Power or the supporting power in section 264 NHS Act 2006 to require the provision of information[24] (which would enable the DHSC to determine that a current price was excessive, or what a reasonable price would be). Section 265(8) NHS Act stated that any price limit or requirement under sections 261 to 264A could only be enforced under regulations providing for a right of appeal, and no relevant regulations existed.

   b. The Reserve Power (and the supporting information-gathering power in section 264) was only exercisable after consultation with the BGMA. The DHSC had no established process or agreement with the BGMA on the exercise of these powers, including the factors to which the DHSC would have regard when determining any price reduction.[25]

   c. Instead of using the Reserve Power, the DHSC's policy with respect to the pricing of generic medicines was to rely on competition in the market to control prices. Where markets did not function well, the DHSC's policy was to have statutory or voluntary schemes in place, rather than consider one product in isolation.[26]

   d. Although the DHSC was resourced to develop, operate and maintain its schemes, it did not have the resources or appropriate infrastructure and

[22] Document 205217, Auden/Actavis's RSSO, Annex 1 paragraph 2.3.
[23] During the course of this investigation the CMA spoke with DHSC officials to clarify the DHSC's understanding of the scope of its powers during the Unfair Pricing Abuses (Document 01931, Note on DHSC powers agreed between DH and CMA, July 2017). The CMA therefore rejects Auden/Actavis's submission that it has failed to engage with the DHSC on the availability of its powers (Document 205217, Auden/Actavis's RSSO, Annex 1, paragraph 2.1. See also paragraphs 2.4 to 2.5). The DHSC's account is in any event consistent with the CMA's interpretation of the powers.
[24] Now, as of 7 August 2017, section 264A. Note that the same would apply to s. 261(7) NHS Act, which was in force until 6 August 2017, and allowed for the Secretary of State, after consultation with the industry body, to require a voluntary scheme member to provide information for the purpose of enabling the scheme to operate or facilitating its operation.
[25] Document 01931, paragraph 2, Note on DHSC powers agreed between DH and CMA, July 2017.
[26] Document 01931, paragraph 3, Note on DHSC powers agreed between DH and CMA, July 2017.

implementing framework in place to determine the fair and reasonable price of an individual generic drug.[27]

10. From September 2015 onwards, following the transfer of the business activities of Auden to Actavis, hydrocortisone tablets were sold by Accord-UK, a member of the voluntary PPRS and Scheme M.

11. As explained in section 3.E.I of the Decision, Actavis's status as a PPRS member meant that from September 2015 until 7 August 2017 the Reserve Power was no longer available to the DHSC to intervene in the price of hydrocortisone tablets. Section 262(2) NHS Act provided that the Reserve Power was '*not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies*'.[28] As a result, the only formal route available to the DHSC to intervene in Actavis's pricing from September 2015 until 7 August 2017 would have been the provision in paragraph 30 of Scheme M.

12. As explained in section 3.C.X.f of the Decision, paragraph 30 provided that the DHSC '*may intervene*', should it *'identify any significant events or trends in expenditure that indicate the normal market mechanisms have failed to protect the NHS from significant increases in expenditure'*.[29] However, this provision was also subject to limitations:[30]

    a. In practice, any '*intervention*' attempted by the DHSC would have triggered the dispute resolution procedures under Scheme M.[31] Although it was expressly non-contractual, Scheme M operated on a similar basis to a bilateral agreement in which the parties undertake to resolve issues between themselves and refer them to external resolution where that fails.[32] Disputes were to be resolved by a panel comprising a DHSC appointee, a BGMA appointee and a chair agreed between the DHSC and the BGMA. Both the DHSC and the Scheme M

[27] Document 01931, paragraph 3, Note on DHSC powers agreed between DH and CMA, July 2017.
[28] This position was amended from 7 August 2017 to address concerns that '*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*': Debate on the Health Service Medical Supplies (Costs) Bill, 24 October 2016.
[29] DHSC, *Revised long-term arrangements for reimbursement of generic medicines – Scheme M* [March 2010], available here, see paragraph 30.
[30] See Document 01931, paragraph 6, Note on DHSC powers agreed between DHSC and CMA, July 2017.
[31] Scheme M did not include any detail as to what such an '*intervention*' by the DHSC would involve: paragraph 30 listed the factors to which the DHSC would have regard in examining the reasonableness of a Scheme member's prices, but did not explain how the DHSC would go about intervening, or how a 'reasonable' price would be determined.
[32] The DHSC and Scheme members undertook '*that issues arising […] may be normally resolved by discussion between them*'. However, where significant issues (such as '*refusal by the Department to agree a price increase under the Scheme*') could not be resolved by discussion, the Scheme allowed for either party to refer the issue to dispute resolution. Scheme M, paragraph 35.

member concerned would be required to make their case to this panel, via written and oral submissions.[33]

b. There would have been no certainty of outcome for the DHSC. Its view would not have been binding and Actavis was free to leave the voluntary Scheme M at any time, including in response to an unfavourable panel ruling.[34] The Scheme document made clear that non-compliance with its terms led not to compulsion to comply, but to expulsion from the Scheme,[35] and that '*A Scheme member may, at any time, withdraw consent for the voluntary Scheme to be treated as applying to it*'.[36]

13. If Actavis had chosen to withdraw from Scheme M, the DHSC would have had no formal power to intervene in its pricing until 7 August 2017, since its status as a PPRS member would have precluded this. Although there was provision for voluntary scheme members to be ejected from a scheme under section 261(4) of the NHS Act, in order to remove a manufacturer or supplier from the PPRS it would be necessary for the Secretary of State to show that the PPRS was *'ineffective'* as regards that scheme member for the purpose of limiting that member's prices or profits, and give the company concerned the opportunity to make representations.[37] However, it would be difficult to find that the PPRS was '*ineffective*' on the assumption that the scheme member has complied with the provisions of the scheme.[38] The PPRS only applied to branded products: it was not the scheme's purpose to regulate unbranded generic drugs. Actavis's conduct in relation to hydrocortisone tablets would therefore not provide a reason for its expulsion on the grounds that the scheme was '*ineffective*' for the purposes of limiting Actavis's prices or profits. The CMA therefore rejects Auden/Actavis's suggestion that this was a realistic option for the DHSC.[39]

14. As explained in section 3.E.I of the Decision, as a result of the Costs Act, from 7 August 2017 until the end of the 10mg Unfair Pricing Abuse the Reserve Power was available once more to the DHSC in relation to Actavis's

[33] Scheme M, paragraphs 36-41.
[34] Scheme M, paragraph 44. It would do so by withdrawing consent for the voluntary Scheme M to be treated as applying to it.
[35] '*Any company that fails to comply with the Scheme or fails to provide information required under the terms of Scheme membership, or in any other way acts in a manner that would breach the Scheme, will be required to leave the Scheme*' (Scheme M, paragraph 14).
[36] Scheme M, paragraph 44.
[37] Section 261(4) and (5) NHS Act 2006.
[38] *Genzyme Limited v Office of Fair Trading* [2005] CAT 32, paragraph 273.
[39] Document 01454, Auden/Actavis's RSO1, paragraphs 2.39 to 2.41 and 3.29.2.

hydrocortisone tablets.[40] However, the Reserve Power is silent as to the method the DHSC should use to determine a price limit. As at the end of the 10mg Unfair Pricing Abuse on 31 July 2018, the DHSC had yet to consult on its methodology for exercising the Reserve Power.[41] It 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.

15. As explained in section 4.C.II.d of the Decision, the CMA therefore finds that as a matter of law the DHSC's 'regulatory' powers did not effectively constrain Auden/Actavis's market power during the Unfair Pricing Abuses.

[40] On 7 August 2017, the Health Act 1999 (Commencement No 17) Order 2017 also brought into force an additional power, under section 261(8) NHS Act. This allows for the Secretary of State to prohibit any manufacturer or supplier to whom a voluntary scheme applies from increasing any price charged by it for the supply of any health service medicine covered by the scheme. Though it has been available since August 2017, it was subject to the same limitations as the Reserve Power during the Unfair Pricing Abuses.

[41] 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 (DHSC: '*Legal requirements to provide information about health service products*', June 2018, page 35). 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*' (https://pharmaceutical-journal.com/article/news/government-delays-consultation-with-pharmaceutical-industry-over-generics-price-limiting-powers).

ANNEX C

Representations on 10mg hydrocortisone tablet product development

1. Auden/Actavis, AMCo and Cinven[42] submitted that AMCo could not be a potential competitor as it had not taken 'sufficient preparatory steps' to have 'real concrete possibilities' of entering the market as it did not have saleable product before November 2015 due to development issues with Aesica. These representations refer to development issues experienced subsequent to the entry of the 10mg Agreement. They stated that it is not the case that AMCo was never more than 6-8 months from market entry as the CMA said in the SSO and has found in this Decision. Specifically, they submitted that:

    a. Waymade's inability to obtain saleable tablets in October 2012 was an insurmountable barrier to entry.[43]

    b. There is no evidence that Waymade took steps to enter the market.[44]

    c. Waymade had concerns about entering the market in glass bottles rather than blister packs, which would have required further work.[45]

    d. AMCo had no ability to enter due to issues with the Aesica product (during the period of Cinven's ownership)[46]; there was no saleable product before November 2015[47], even though the CMA 'accepts' that this was prioritised at certain times.[48,49]

[42] Waymade made no representations directly on this issue.
[43] Document 205217, Auden/Actavis's RSSO, paragraphs 7.29-7.35
[44] Document 204967, Cinven's RSSO, paragraph 6.52; see also Document 205217, Auden/Actavis's RSSO, paragraph 7.32.
[45] Document 205217, Auden/Actavis's RSSO, paragraph 7.33.
[46] Document 204967, Cinven's RSSO, paragraphs 3.28 to 3.38 6.23 to 6.30 and Document 206665, Cinven's RLOF, paragraph 3.33.
[47] Document 204922, AMCo's RSSO, paragraphs 3.486 to 3.499; Document 205217, Auden/Actavis's RSSO, paragraphs 7.38 and 7.41.
[48] Document 204967, Cinven's RSSO, paragraphs 6.25 to 6.26.
[49] AMCo submitted a witness statement from [Aesica Employee] setting out her recollection of the 10mg development project at Aesica from January 2014, on which AMCo relied in support of its representations as outlined above. This witness statement does not include all the details of the interaction between AMCo and Aesica on development work as set out by the CMA in this Decision (see section 3.F.III and as further explained in this Annex). For example, as set out below, the application of the incorrect thickness of foil to the blister packs was discovered after the project had already been cancelled by AMCo (see paragraph 7.e below), rather than being 'quarantined' just because of that issue discovered in September 2014. In any case, this witness statement does not assist AMCo: for the reasons set out in this annex, AMCo had already met the threshold to be considered to be a potential competitor and any 'issues' or 'delays' do not undermine that assessment (Document 204922, AMCo's RDPS, for example at paragraph 3.318 citing Document 202000, witness statement of [Aesica Employee], dated 23 May 2017).

e. The parties do not agree with the statement that AMCo was never more than 6-8 months from entry.[50]

f. There was considerable work still required after the project was inherited from Waymade. This did not meet the standards to produce commercially due to tighter assay limits and a stability data condition imposed by the MHRA.[51]

g. AMCo did not only start development work in January 2014.[52] AMCo vigorously pursued development efforts throughout the infringement period[53] and in particular that there was no 'de-prioritisation' at certain times (for example: in 2013[54] or after signing the second written agreement). It took 3 years of consistent efforts to obtain saleable tablets.

h. [AMCo Senior Employee 1]'s email stating AMCo had 'market ready stock' (June 2014) does not show that AMCo was ready to enter the market. It did not have stock and the foil issue was discovered later. This email explains the rationale to enter the agreement was to obtain full label stock.[55] This is not evidence that the market was penetrable or that there were no insurmountable barriers to entry. This was AMCo calling the 'bluff' of Auden rather than proof of a route to market.[56]

i. AMCo knew that the tablets sourced from Aesica would not be available before April 2014 from its due diligence work.[57]

[50] Document 204967, Cinven's RSSO, paragraphs 6.23 to 6.30; Document 204922, AMCo's RSSO, paragraphs 3.486 to 6.489, and 3.774 to 3.776; Document 205217, Auden/Actavis's RSSO, paragraphs 2.85 and 7.38-7.41. AMCo submitted that the shelf life of the product (18 months when packaged in blister packaging) was a *'material issue'* to the development, as *'the industry standard is that wholesalers will not purchase medicines with a shelf life of less than twelve months'* (Document 204922, AMCo's RSSO, paragraph 3.472 and Document 206670 AMCo's RLOF, paragraphs 5.69-5.70, 5.79, 5.93, 5.106, 5.135, 5.141). These submissions do not undermine the CMA's finding that AMCo was a potential competitor to Auden/Actavis. Based on the 12 month timescale, there clearly would have been demand for the product during the first six months of its shelf life, and demand may have continued beyond that since (as discussed in footnote 2027 of the Decision) wholesalers may accept stock with a shorter shelf life on agreeable commercial terms.
[51] Document 205217, Auden/Actavis's RSSO, paragraph 7.32.3.
[52] Document 204967, Cinven's RSSO, paragraphs 6.24 to 6.25.
[53] Document 204922, AMCo's RSSO, paragraphs 3.249 to 3.474.
[54] Document 204967, Cinven's RSSO, paragraphs 6.28 to 6.29.
[55] Document 204967, Cinven's RSSO, paragraph 6.30.
[56] Document 204967, Cinven's RSSO, paragraph 6.67, in the context of insurmountable barriers to entry.
[57] Document 205217, Auden/Actavis's RSSO, paragraphs 7.31, 7.32.5, and 7.45-7.49.

j. There were ongoing difficulties with the Aesica development throughout such as the foil issue in September 2014 (meaning that the tablets could not be sold[58]) and the lack of saleable product by early 2015.[59]

k. Development issues called into question the commercial viability of entry and AMCo considered scrapping the Aesica project.[60]

2. The CMA does not accept these representations.

3. The key point made by Auden/Actavis, AMCo and Cinven is that AMCo could not have entered the market before it received stock from Aesica in November 2015. However, this denies the difference between actual and potential competition: the legal test for potential competition does not require the undertaking to be able to enter the market immediately at the point of entering the anticompetitive agreement. The legal test only requires that '*sufficient preparatory steps*' have been taken to have '*real concrete possibilities*' of entering the market within a sufficiently short period such as to impose competitive pressure on the incumbent: not that entry was imminent or that it would be successful. In addition, the fact that it takes longer to enter the market than anticipated does not mean that entry will not take place or that there is no relationship of potential competition. [61] As explained in the CMA's Decision, seminal judgments by the Courts of the EU have considered that undertakings in the pharmaceutical sector become potential competitors '*when those undertakings had made significant investments in order to enter the market and when they had already obtained MAs or had taken the necessary steps to obtain them within a reasonable period*'.[62]

4. Auden/Actavis' representations further misstate the legal test for an insurmountable barrier to entry. Development issues are surmountable, as demonstrated by the fact that AMCo successfully entered with its own 10mg product as manufactured by Aesica in 2016. That product was the same in terms of '*drug substance, composition, specification (including quality) and stability*' as the July 2010 10mg Validation Batches that Aesica manufactured for Waymade in 2010.[63] It is clear from the evidence that Waymade chose to focus on obtaining a 10mg MA rather than ensuring it

[58] Document 204967, Cinven's RSSO, paragraphs 3.76 to 3.85 and Document 206665 Cinven's RLOF, paragraph 3.33(b).
[59] Document 205217, Auden/Actavis's RSSO, paragraph 2.85; Document 206670, AMCo's RLOF, paragraphs 6.6 to 6.30.
[60] Document 205217, Auden/Actavis's RSSO, paragraph 2.85.5.
[61] See section 6.C.I.a of the Decision setting out the 'real concrete possibilities' legal test for potential competition.
[62] See section 6.C.I.a of the Decision, citing T-472/13 *Lundbeck v Commission,* EU:T:2016:449, paragraph 131.
[63] Document 200302, paragraph 5.1, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

had market-ready stock to sell under that MA once it was obtained. This is the sole reason it did not have market-ready stock in October 2012, and it falls far short of supporting a finding that development issues constituted an insurmountable barrier. In any case the CMA's case is not that Waymade could enter the market in October 2012, just that it was close enough to being able to do so (with a MA and an approved production process) that it exerted a competitive threat over Auden.

5. At all times from October 2012 it is clear that AMCo was above the threshold of having taken 'sufficient preparatory steps' to have 'real concrete possibilities' of entering the market from a development perspective.

6. Auden/Actavis has submitted that AMCo knew that its tablets sourced from Aesica would not be available before April 2014 from its due diligence work, citing a Deloitte report dated August 2012.[64] However, a later due diligence report dated October 2012 prepared by Deloitte explained that 'management's plan' was that '*hydrocortisone is planned to be launched in the UK in 2013, taking market share from the incumbent supplier'*.[65] Indeed, email exchanges from shortly after the transaction show Cinven and AMCo's management discussing '*Amdipharm's strategy and rationale for entering the hydrocortisone market in 2013*'.[66] This shows that Waymade and then AMCo expected that market entry could take place on that timescale. Irrespective of the remaining development work - which, as shown in the Decision, was minor at the time of the grant of the MA - and the unexpected delays with Aesica, AMCo's expectation from as early as 23 October 2012 was that it would enter the market for 10mg hydrocortisone tablets in 2013.[67]

7. The CMA does not agree that there were three years of consistent efforts by AMCo to bring the 10mg product to market. The strength of efforts to bring the Aesica product to market were directly correlated to AMCo's views of the stability of the 10mg Agreement and the security of its supply from Auden. Each instance in which AMCo meaningfully engaged with (or 'resurrected') its development efforts, ie when it no longer thought its tablets would be just a 'back up' to receiving supply from Auden, demonstrates that AMCo was never more than 6 – 8 months from being able to enter the market independently. However, AMCo did not engage with this product throughout the period of the 10mg Agreement. In particular, the CMA finds that:

[64] Citing Document 301595 'Project Glacier Final Report – Volume I Commercial Due Diligence' dated 10 August 2012.
[65] Document 202506, Deloitte report: 'Project Ampule Final Due Diligence report – Volume I Commercial Due Diligence' dated 23 October 2012, page 9.
[66] Document 301627, email from [✂] to [Amdipharm Senior Employee] dated 15 November 2012.
[67] Document 202506, Project Ampule, Final due diligence report – Volume I Commercial due diligence, page 9.

a. Contemporary documents show that AMCo's own 10mg product was a '*back up'* supply, *'a protective project to ensure continuity of supply'* and a *'contingency against failure to supply from Auden*' (see paragraph 6.284 and section 6.D.II.c.ii. ('*AMCo's treatment of its 10mg tablets as a "back-up" in case the 10mg Agreement ended'*) of the Decision. AMCo did not engage with this evidence in its representations on the SSO.

b. As set out in the Decision, the work AMCo needed to do was extremely limited after acquiring the project from Waymade. Besides following up on the optimisation of the assay method that Waymade had commissioned in July 2012, the only outstanding work was manufacturing further batches of the product, work which Waymade's product development team was ready to take on in October 2012 before they became aware that the 10mg MA had been included in the sale to Cinven.[6869] Contrary to the case parties' submissions, there was not '*lots of further work required by AMCo*'. In particular, the CMA finds that:

   i. AMCo did not seriously engage with the 10mg development until December 2013 when there was an internal meeting to discuss next steps.[70] Ordering one batch of product in August 2013 and leaving it stored in bulk at Aesica without instructions on how to pack it since October 2013 does not constitute a serious engagement with the 10mg development. This is especially apparent from contemporaneous emails which show that AMCo had '*no plan to market Aesica manufactured material*' or, at the very least, was not sure whether to pursue the development.[71]

   ii. AMCo's lack of engagement with the 10mg development up until December 2013 is further evidenced by the fact that it was only in December 2013 that AMCo revisited the stability issues affecting its product, an issue which Waymade had already determined was due to the assay method back in July 2012.[72] It is striking that senior staff members who were previously at Waymade, such as [Amdipharm Senior Employee], did not engage with this again

[68] Document 300319, email from [✂] to [Amdipharm Senior Employee] dated 19 October 2012.
[69] The CMA does not consider that the formal variations submitted to the MHRA derived from the change of ownership, including those affecting the artwork, constituted substantial hurdles in bringing product to market.
[70] Document 202582, calendar invite '*Hydrocortisone – next steps*' from [AMCo Employee] to [AMCo Senior Employee 7], [AMCo Senior Employee 4], [✂], [Amdipharm Senior Employee] and [AMCo Employee] for 13 December 2013.
[71] See, for example, Document 200066, email chain between [AMCo Employee] and [Amdipharm Senior Employee] from 7 and 8 November 2013.
[72] Document 202238, email from [✂] to [✂] dated 27 July 2012.

until this moment in time, particularly when optimising the assay method was found by Waymade to be '*the only issue (…) preventing us from launch*' in July 2012.[73]

iii. It was only in January 2014, when the negotiations with Auden hit a standstill, that AMCo '*[r]esurrected the development*' of 10mg hydrocortisone tablets.[74] It (i) set up a cross-functional team for the Aesica development, (ii) mapped out the timeline for launch, (iii) got Board approval to pursue the project, (iv) placed an order for three batches of 10mg hydrocortisone tablets for commercial supply (equating to a total of 45,000 packs of 30 tablets in blisters), (v) decided to pack the batch held in bulk in Aesica since October 2013 in blister packs, (vi) asked Aesica to do optimisation work the assay method and (vii) requested that Aesica procure, install and commission a blister feeder at Aesica's plant. This series of actions and the intensity of the correspondence concerning the 10mg development in January 2014 alone is in stark contrast with the lack of any kind of serious engagement with the project since Cinven acquired Amdipharm in October 2012. All of these actions could have been taken at any time since October 2012, yet they were only carried out in January 2014.

iv. The optimisation work of the assay method was carried out within weeks by Aesica in late January 2014 and February 2014. In April 2014, AMCo submitted a variation to the MA to have the new assay method registered to its licence, which was granted on 1 May 2014. As per the change in the assay method, the change '*had no impact on quality or stability of the product, other than to ensure accurate results for assay were reported'*.[75]

v. From AMCo's meaningful engagement with the 10mg development in January 2014, it took AMCo only seven full months to receive the August 2014 Batches, despite experiencing extraordinary delays, particularly with the commissioning of the blister feeder (as set out in paragraph 6.278 of the Decision).

c. AMCo '*advised Aesica that the project is now parked*' and cancelled '*the order for the 4th batch and any other subsequent orders'* from Aesica as a result of entering into the 10mg Agreement in June 2014.

[73] Document 202227, email from [Waymade Employee] to [Amdipharm Senior Employee] dated 16 July 2012.
[74] Document 202665, AMCo – Strategic Development Business Development & Licensing (EPRM) presentation dated May 2014, slide 8.
[75] Document 200302, paragraph 4.4, Aesica's response to the CMA's section 26 notice dated 5 September 2016.

d. AMCo received the three August 2014 Batches at its warehouse which it believed to be compliant with its MA. Contemporary evidence supports this: [AMCo Senior Employee 1]'s email is clear on its face that AMCo had cancelled the development project with Aesica when it entered the Second Written Agreement (see section 6.D.II.c.II (in particular '*AMCo suspends its own 10mg product development on the same day as entering into the Second Written Agreement*' of the Decision). AMCo even sold its hydrocortisone API to Aesica in December 2014.

e. In September 2014 Aesica discovered that the August 2014 Batches had been packaged in foil that was too thin for the specifications on the MA (see section 3.F.III.l of the Decision). AMCo could have manufactured additional batches in the correct foil as soon as the issue was detected in September 2014. Rather than ordering new batches, AMCo considered whether it could vary its MA or apply for a batch-specific variation to deal with this issue. The reason for this was that AMCo considered that the wrongly packaged batches could still function as a back-up product. AMCo separately also considered whether the batches could be sold abroad. The foil packaging issue does not undermine that AMCo was able to enter the market within '*a such a period of time as would impose competitive pressure*'[76] on Auden. This is for the following reasons:

    i. First, this was a problem with the foil packaging that was used, not an intrinsic problem with the tablet: AMCo's 10mg MA assumed a 25µm foil thickness but Aesica had packed the batches in blister packs that were 20µm thick. Aesica '*concluded that the use of 20 µm Foil instead of the registered 25 µm Foil will have no quality impact on the product, and is a compliance event only*.'[77]

    ii. Secondly, the issue around the foil thickness could have easily been resolved by simply manufacturing another batch of 10mg hydrocortisone tablets packed in the correct thickness foil. Although AMCo initially submitted the variation application to the MHRA to add 20 micron thickness foil packaging to its 10mg MA in order to be able to release the August 2014 Batches, it ultimately withdrew the application in favour of Aesica manufacturing a further batch: '*[w]e will NOT be varying the*

[76] See section 6.C.I.a of the Decision.
[77] Document 200269, email from [✂] to the DMRC dated 31 October 2014.

current UK licence to add 20µm foil onto the licence. All were in agreement that this is not required as Aesica can supply us FP [final product] *packed using 25µm foil with no issues*.'[78]

iii. Third, the issue around the foil thickness was not the real reason that AMCo did not enter the market – the decision not to launch was made as a consequence of the entry into the Second Written Agreement on 25 June 2014 (which ensured the continuation of the 10mg Agreement) and in any event which happened well before the discovery of the foil thickness issue (see section 6.D.II.c.II of the Decision (in particular '*AMCo suspends its own 10mg product development on the same day as entering into the Second Written Agreement*'). At that point in time, AMCo believed it had a saleable 10mg product.

iv. Finally and in any case, the fact that Aesica would deliver the tablets in the wrong foil in August 2014 (and which had been packed in July 2014) was not knowable to the parties when the 10mg Agreement was entered into by Waymade in October 2012, when it was transferred to AMCo at the end of that month, or when the agreement was renewed in June 2014. This later mistake, for which AMCo shared responsibility,[79] can therefore not influence AMCo's position vis-à-vis Auden at those earlier moments at which the CMA has established that AMCo exerted competitive pressure on Auden such that it could be found to be a potential competitor.

v. In the second half of February 2015, AMCo again decided to '*resurrect our original plan and market our product in the UK*'.[80] As a result, AMCo (i) ordered the purchase of hydrocortisone API and (ii) placed a purchase order for a batch of 10mg hydrocortisone tablets from Aesica. Again, despite having completely discontinued the production of 10mg hydrocortisone tablets for AMCo in June 2014 and despite the fact that there were extraordinary delays relating to the one of the excipients (calcium stearate), Aesica was able to supply AMCo with market-

[78] Document 201941, email from [AMCo Senior Employee 7] to [AMCo Employee], [✂], [✂] and others dated 5 May 2015 (emphasis added).
[79] Document 200310, Aesica's Exception Report number 1419270. The report concluded that the root cause for the error was AMCo's failure in reviewing and approving the packing items. See also Document 202886, AMCo's Deviation Report Form of 2 December 2014. AMCo's report states that '*[t]he failure on AMCo's part to identify the error on review is attributed to weakness in the review process and human error*'.
[80] Document 202783, email from [AMCo Employee] to [✂] dated 14 April 2015.

ready product on 2 November 2015 (31,026 packs) – i.e. within eight months of receiving the purchase order.

8. This evidence on AMCo's contemporaneous expectation of the timeframe for entry is coherent with the CMA's view that whenever AMCo meaningfully engaged with the Aesica development, it took less than a year for AMCo to have market-ready product.

9. This timeframe is aligned with what it took other suppliers to enter the market after being granted an MA for 10mg hydrocortisone tablets. For instance, it took Genesis Pharma five to six months, Renata eighteen months, Bristol two to three months and Alissa ten months. By contrast, Resolution Chemicals entered the market as soon as it was granted the MA.[81]

10. There is no evidence that AMCo seriously considered 'scrapping' the Aesica project (and in any case any decision to 'scrap' the project after the 10mg Agreement was entered into would not be inconsistent with the CMA's finding that AMCo agreed not to enter the market independently). To the contrary, after cancelling the 10mg development in June 2014, AMCo asked Aesica to develop 10mg hydrocortisone tablets for other territories outside the UK.[82]

[81] AMCo argued that other suppliers took approximately the same amount of time as AMCo to launch their 10mg hydrocortisone tablets (Document 204922, AMCo's RSSO, paragraphs 3.497 and 3.498). However, AMCo's comparison is flawed since it refers to the total amount of time from initial development to launch of other suppliers instead of focusing on the time it took these suppliers to enter the market since obtaining the MA. For instance, it took Alissa ten months to enter the market after being granted the MA while it took AMCo forty-four months to do so after the Cinven purchase of Amdipharm (and the 10mg hydrocortisone MA) in October 2012.
[82] Document 202717, email from [AMCo Senior Employee 5] to [Aesica Employee] dated 27 June 2014.

ANNEX D

Representations on demand for skinny label hydrocortisone tablets

I. 'There was no (or negligible) demand for skinny label hydrocortisone tablets before April 2016'

1. AMCo and Cinven each submitted that AMCo did not launch its skinny label 10mg tablets until May 2016 because it did not believe until April 2016 that there was demand for its 10mg tablets.

2. This representation changed over time and was not unambiguous:

    a. In their written representations on the 2017 SO:

        i. Cinven submitted that there was either a lack of customer demand for skinny label tablets throughout Cinven's ownership period,[83] or an absence of demand from key customers,[84] or '*a high degree of uncertainty as to the level of potential demand*'.[85]

        ii. AMCo submitted that there was either no customer demand or '*receptivity*',[86] or '*very low demand*',[87] or '*unknown market receptivity*'[88] for skinny label tablets until April (or May) 2016 and that, if there had been demand, it would have been confined to only 2-10% of the market not covered by the orphan designation.[89]

    b. In their written and oral representations on the SSO:

        i. Cinven submitted that having conducted market testing in mid-2014 AMCo had concluded that there was '*a clear absence of customer demand*' for skinny label tablets which lasted throughout Cinven's ownership period.[90]

        ii. AMCo also submitted that having conducted market testing in mid-2014, AMCo had concluded that there was '*no demand*'

[83] Document 203736, Cinven's RSO, paragraphs 5.38, 5.62, 5.66 and 5.100.4, 6.138 and 6.164.
[84] Document 203736, Cinven's RSO, paragraph 5.81.
[85] Document 203736, Cinven's RSO, paragraphs 6.52, 6.57, 6.81 and 6.83.
[86] Document 203797, AMCo's RSO, paragraphs 3.38, 3.271, 3.369. 7.62 (for lack of customer demand) and 1.12.3, 3.77. 3.290, 3.368. 3.371, 3.374, 3.471, 7.8.7, 7.51, 7.68, 7.138, 7.144, 7.199.6, 7.202, 10.13.4, 12.10.2, 13.78, 13.81 (for lack of market receptivity).
[87] Document 203797, AMCo's RSO, paragraph 3.40.
[88] Document 203797, AMCo's RSO, paragraph 3.339.
[89] Document 203797, AMCo's RSO, paragraphs 5.50 and 7.143.
[90] Document 204967, Cinven's RSSO, paragraphs 1.14.(f), 1.19, 3.2.(c)-(d), 3.3, 3.57, 3.58, 3.98.(b), 4.73, 5.32, 5.52, 6.34, 6.38, 6.44, 6.63, 6.71, 7.43, 9.25 and 10.16. See also Document 205517, transcript of Cinven's oral hearing of 9 September 2020, page 20, lines 11-13 and page 39, lines 20-21.

whatsoever, or a '*lack of market receptivity*', or '*substantial absence of customer receptivity*', for its skinny label 10mg tablets until April 2016.[91]

c. In response to a CMA request to identify all evidence relied on in making their submissions on the SSO:

i. Cinven submitted that AMCo had '*genuine and legitimate concerns*' that there was no demand for skinny label tablets throughout the Cinven ownership period.[92]

ii. AMCo submitted that feedback received from its '*main target customers*' in 2014, 2015 and 2016 showed that there was '*no market receptivity*' and that AMCo '*reasonably thought that there was simply no demand*' for skinny label tablets.[93]

iii. However, neither party submitted any contemporaneous evidence to support the submission that there was no demand (as opposed to uncertainty about the extent of demand).

d. In response to the 2021 letter of facts:

i. Cinven submitted that (a) there was a '*high degree of uncertainty regarding potential customer demand*' for skinny label tablets; and (b) '*it was not unreasonable for AMCo to consider that there was no market for its reduced indication product*'.[94]

ii. AMCo submitted that the '*total addressable market was negligible*' for its skinny label tablets and repeated its submission that it obtained negative feedback from its '*main target customers*' in 2014, 2015 and 2016.[95]

3. The parties' representations on the issue of demand for skinny label hydrocortisone tablets were therefore inconsistent: at various points they have claimed that there was clearly no demand whatsoever; AMCo was concerned that there might be no demand whatsoever; demand was limited to the portion of the market not covered by the orphan designation (which

[91] Document 204922, AMCo's RSSO, paragraphs 3.245, 3.247, 3.488, 3.681, 3.765 and 6.33.2 (for no demand) and 3.41, 3.71, 3.159, 3.207, 3.209, 3.235, 3.236, 3.248, 3.252, 3.607, 3.679, 3.680, 3.686, 3.692 and 5.104 (for no market receptivity) and 6.84.6 (for substantial absence of customer receptivity). See also Document 205628, transcript of AMCo's oral hearing of 10 September 2020, page 14, lines 5-6 and page 25, lines 8-12.
[92] Document 206428, Cinven's response to the CMA's section 26 notice of 9 April 2021, paragraph 1.16.
[93] Document 206433, AMCo's response to the CMA's section 26 notice of 9 April 2021, paragraphs 1.3, 1.7, and 1.13.
[94] Document 206665, Cinven's RLOF, paragraphs 3.21 and 3.23.
[95] Document 206670, AMCo's RLOF, paragraphs 5.8.3, 5.8.4 and 5.8.5.

they describe as negligible); there was no demand from specific customers; or simply that there was uncertainty about the extent of demand.

4. In contrast, the contemporaneous documentary evidence is consistent. It shows that throughout the period prior to Alissa's entry in October 2015, there was an expectation in the market that there would be demand for skinny label tablets once they were launched – as the number of suppliers that sought to enter with skinny label tablets attests – even if the extent of such potential demand was uncertain. There is in particular no piece of contemporaneous documentary evidence suggesting that any of the parties believed skinny label hydrocortisone tablets could not successfully enter the market or that there was no demand for the product. Nor is there any contemporaneous evidence of AMCo's 'market testing' in mid-2014.

5. As explained in section 3.E.IV of the Decision, the parties' contemporaneous estimates of the extent of demand pre-entry must be seen in context and fall into five key periods:

   a. March to October 2012.

   b. October 2013 to January 2014.

   c. April to June 2014.

   d. September 2014 to January 2015.

   e. March to October 2015.

a. March to October 2012: Waymade's and Cinven's assessments of demand

6. Waymade submitted its application for a 10mg MA (as a line extension of its existing 20mg MA) to the MHRA on 9 June 2011.[96] During subsequent correspondence with the MHRA, Waymade became aware of the orphan designation granted to Plenadren and on 15 March 2012 the MHRA informed Waymade that it could not be granted a full label MA.[97]

7. In June 2012, Waymade was approached by Cinven to sell its Amdipharm group.[98] Waymade issued an information memorandum on the Amdipharm group to Cinven on 6 July 2012. The memorandum identified the prospective

[96] Document 300185, email from [Waymade Employee] to [Waymade Senior Employee 1], [Amdipharm Senior Employee], [Waymade Senior Employee 3] and others dated 9 June 2011.
[97] Document 300223, email from [✂] to [Waymade Employee] dated 15 March 2012. Document 300227, MHRA RFI dated 5 April 2012.
[98] Document 200003, Waymade's response to the CMA's section 26 notice dated 18 May 2016, paragraph 6.1.

10mg MA as a potential generator of significant revenue for the Amdipharm group. It stated, as part of the '*Organic Growth Case*' for the UK:

> *'Line extensions offer significant upside. In particular, the development of a Hydrocortisone tablets 10mg x30 SKU provides the opportunity to tap into a market now worth over £30m'.*[99]

8. A later slide projected that 10mg hydrocortisone tablets would make an '*Incremental annual contribution on average (2013-2016)*' of £3,720,000. The '*Ease of Win*' was categorised as medium.[100] At Auden's prevailing ASP in July 2012 (£31.81), this would have translated to annual sales of 116,944 packs or 9,745 packs monthly: 13% of total volumes in 2013 (see table 3.7 of the Decision).

9. Following further correspondence, the MHRA confirmed to Waymade on 13 July 2012 that it could not obtain a full label 10mg MA.[101] By 13 July 2012 Waymade had resolved definitively not to challenge this decision.[102]

10. The news that it could only obtain a skinny label 10mg MA did not diminish Waymade's expectations of demand for its 10mg hydrocortisone tablets. Instead, the risk Waymade perceived was that other suppliers would also enter and be successful in winning market share.

11. An external review of the Amdipharm business prepared ahead of its sale[103] by the consultancy Pharmacloud following meetings with Amdipharm management and dated 25 July 2012 noted that Amdipharm planned to launch its 10mg hydrocortisone tablets in 2013, '*with sales reaching £4.2m in the year after launch*'. At Auden's prevailing ASP in July 2012 (£31.81), this would have translated to annual sales of 132,034 packs or 11,002 packs monthly: 14% of total volumes in 2014 (see table 3.7 of the Decision). The review identified as a '*key risk*' whether there would be further entrants:

> *'Other companies enter the hydrocortisone 10mg tablet market and the total market size shrinks [in value terms] due to declining prices'.*

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[99] Document 202512, slide pack entitled '*PROJECT AMPULE Information memorandum*' dated 6 July 2012, slide 39.
[100] Document 202512, slide pack entitled '*PROJECT AMPULE Information memorandum*' dated 6 July 2012, slide 82.
[101] Document 300274, email from [✂] to [Waymade Employee] dated 13 July 2012.
[102] Document 300271, emails between [Waymade Employee] and [Waymade Senior Employee 1] dated 13 July 2012. Document 300267, email from [Waymade Senior Employee 1] to [Waymade Employee] dated 13 July 2012. Document 300274, email from [Waymade Employee] to [Waymade Senior Employee 1] copied to [Amdipharm Senior Employee] dated 13 July 2012.
[103] See Document 202510, email from [AMCo Senior Employee 1] to [✂] dated 27 June 2013, describing the report as a document '*viewed by Cinven during the Due Diligence*' of the Amdipharm purchase.

12. Such was the value that was placed on Waymade's 10mg skinny label MA that the risk of further entry was regarded as a '*High risk*'.[104]

13. This contemporaneous documentary evidence from 2012 made no suggestion that Amdipharm would not have been able to successfully enter the market despite having a skinny label MA – rather the perceived risk was that other suppliers would also enter successfully and the value of the MA would be eroded as a result of price competition from further entry.

14. Further evidence of Waymade's contemporaneous sales expectations for its 10mg skinny label hydrocortisone tablets is provided by a spreadsheet that [Amdipharm Senior Employee] sent to [Waymade Senior Employee 1] on 25 September 2012 (two days before Waymade was granted the 10mg MA). In the spreadsheet, [Amdipharm Senior Employee] estimated that Waymade could achieve a market share of between 15% and 35% if it launched its 10mg hydrocortisone tablets. This translated into a yearly profit of between £4.3 million and £10.1 million.[105]

15. Waymade's belief that there would be strong demand for its skinny label hydrocortisone tablets is further demonstrated by additional information it shared with Cinven prior to the acquisition of Amdipharm. In September 2012, Waymade informed Cinven that it projected launching its 10mg tablets in July 2013 and achieving sales of 40,000 packs in the fourth quarter of 2013 (equating to 9% of total volumes), 120,000 in 2014 (13%) and 160,000 (17%) in 2015.[106]

16. In the final commercial due diligence report Deloitte prepared for Cinven (dated 23 October 2012), Deloitte reported on Amdipharm's management's plans with respect to skinny label 10mg hydrocortisone tablets, which were '*planned to be launched in the UK in 2013, taking market share from the incumbent supplier*' with '*Price £35.00 and volume 160,000 by 2015*'. Amdipharm management predicted a £5.6 million annual revenue uplift by 2015 as a result.[107]

17. However, Cinven's management and Deloitte were less optimistic – not because they did not believe that skinny label tablets would be successful in the market, but because they believed there would be multiple skinny label

[104] Document 202511, external review of Amdipharm key products dated 25 July 2012, slide 10.
[105] Document 300290, spreadsheet titled 'Hydrocortisone 10mg tablets sales data Jul12' attached to an email from [Amdipharm Senior Employee] to [Waymade Senior Employee 1] dated 25 September 2012 (document 300289).
[106] Document 202320, spreadsheet titled 'Ampule – UK products' attached to an email from [AMCo Senior Employee 4] to [AMCo Senior Employee 1] dated 9 October 2012 (document 202319). See table 3.7 of the Decision for total monthly volumes in the relevant years.
[107] Document 202506, final due diligence report prepared for Cinven dated 23 October 2012, slides 9 and 32.

entrants who would compete the price down. Deloitte commented on Amdipharm's strategy: '*High risk of new competitors in addition to [Amdipharm] which would impact market prices and [Amdipharm's] potential market share*'.[108] As a result:

> *'Cinven's sensitivity lowers management's volume and price assumption by 30% in each year of the plan to reflect the scenario of several players in the market rather than two as management assume. This is a reasonable reflection of the impact of additional competitors entering the market at a similar time to Ampule [Amdipharm]'.*[109]

18. Ultimately, Cinven's 'sensitivity' on hydrocortisone (ie that there would be other suppliers entering the market with their skinny label own tablets) reduced Amdipharm's revenue plan by a total of £2.9 million by 2015.[110] However, the evidence from this transaction clearly shows the belief that there would be successful entry for skinny label tablets in 2013.

19. In October 2012, shortly after obtaining its 10mg MA, Waymade succeeded in securing a supply agreement with Auden for 2,000 packs per month of 10mg full label tablets at £1 per pack. In interview, the key individuals who negotiated that arrangement explained that it was agreed in order to preserve the volumes Auden ordered from its CMO Tiofarma:

    a. [Auden Senior Employee 1] stated that '*as long as we, we gave them supply, which would again maintain our volumes … that was acceptable*'.[111]

    b. [Amdipharm Senior Employee] of Waymade stated: '*maybe the inference from me is that, you know, he [[Auden Senior Employee 1]] can supply me or I'll get someone else to supply me, and if he wants to retain the manufacturing volumes, then he might agree to supply me*'.[112]

20. This explanation of the rationale for the supply deal shows that both Waymade and Auden expected there to be demand for skinny label hydrocortisone tablets. It would not otherwise be necessary for Auden to take steps to maintain its volumes in response to Waymade's potential entry.

[108] Document 202506, final due diligence report prepared for Cinven dated 23 July 2012, slide 32.
[109] Document 202506, final due diligence report prepared for Cinven dated 23 July 2012, slide 12.
[110] Document 202506, final due diligence report prepared for Cinven dated 23 July 2012, slide 12.
[111] Document 301380, transcript of [Auden Senior Employee 1] interview dated 23 May 2018, page 68.
[112] Document 200349, [Amdipharm Senior Employee] interview transcript dated 4 August 2016, pages 14-15.

b. November 2013 to February 2014: AMCo's and Auden's assessments of demand

21. Waymade's 10mg MA and the 10mg supply agreement with Auden were transferred to AMCo as a result of Cinven's acquisition of Amdipharm on 31 October 2012.

22. Thereafter AMCo received monthly supplies of heavily discounted full label 10mg hydrocortisone tablets from Auden (2,000 packs per month at £1 per pack until the end of 2012, 6,000 packs per month at £1 per pack from January 2013 onwards), which it was able to sell for a significant profit.

23. In interview, [Auden Senior Employee 1] explained that after the transition from Waymade, Auden continued to supply AMCo on these terms in order to preserve its CMO volumes: '*after the move from Waymade to Amdipharm … In 2012, we supplied Amdipharm at a price of £1 per pack*'. This was because AMCo ceased to be a '*pure wholesaler*' when it acquired the 10mg MA from Waymade; and '*[w]e* [Auden] *wanted to protect and maintain our volumes ordered through Tiofarma for 10mg tablets as well [as for 20mg tablets]*'.[113] As before, this rationale in itself shows that Auden expected there to be demand for skinny label hydrocortisone tablets: it would not otherwise be necessary for Auden to take steps to maintain its volumes in response to AMCo's potential entry.

24. Between November 2013 and January 2014 AMCo conducted two sets of negotiations with Auden in parallel: one to obtain a formal written supply agreement for 10mg tablets, and another regarding the proposed acquisition of Auden's hydrocortisone business.

25. Having targeted obtaining a formal written supply agreement from Auden since March 2013, AMCo sent the first draft supply agreement to Auden on 15 November 2013.[114] It proposed a three-year supply of 10mg hydrocortisone tablets to AMCo for a price of £1 per pack and specified an '*Estimated Order Quantity*' of 18,000 packs per month.[115] AMCo therefore proposed once more to triple its volumes. The 18,000 packs was equivalent to what AMCo expected it could sell if it entered independently with its own product and equated to 24.5% of total 10mg volumes in 2013 (see table 3.7 of the Decision). Internally, AMCo had prepared a spreadsheet which

[113] Document 00725, Witness Statement of [Auden Senior Employee 1] dated 12 September 2016, paragraphs 1.19 to 1.20.
[114] Document 202552, email from [Amdipharm Senior Employee] to [Auden Senior Employee 1] dated 15 November 2013.
[115] Document 202553, draft "Own Label" Product Supply Agreement (for Hydrocortisone) by and between Auden Mckenzie (Pharma Division) Limited and Amdipharm Limited, page 20, Schedule A. See also Document 202557, email from [Amdipharm Senior Employee] to [✂] dated 15 November 2013.

showed that AMCo considered '*60% of the market available to us*' and that it could '*get 40%*' of that 60%, equivalent to 24% market share or 18,000 packs a month in 2014 if it launched its own skinny label product.[116] This spreadsheet, and the presumptions underpinning it, demonstrate very clearly that AMCo believed that a substantial part of total 10mg hydrocortisone tablets volumes (60%) would have been contestable had it launched its own skinny label tablets and that AMCo believed it could take 40% of those volumes if it launched its skinny label tablets – giving it 24% of volumes as a whole.

26. However, Auden resisted AMCo's attempt to increase its volumes. On 18 December 2013 [Auden Senior Employee 1] told [Amdipharm Senior Employee] that '*We need to discuss Hydro volumes*'.[117] On 19 December 2013 [Auden Senior Employee 1] asked [Amdipharm Senior Employee] to '*alter the volume on the hydro agreement as discussed*'.[118] On the same day, AMCo noted that Auden was '*being increasingly aggressive and threatening that the orphan drug status of their product means that our product (which does not have adrenal insufficiency as an indication) is not comparable to theirs*'.[119]

27. This newly aggressive stance from Auden prompted AMCo to assess the commercial prospects of its skinny label tablets. On the following day, 20 December 2013, [AMCo Employee] emailed [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Senior Employee 6] referring to '*the discussion yesterday … around the 10mg tabs*' and asking AMCo's management to confirm the assumptions behind their projection of an annual revenue of £6 million from the product.[120]

28. [AMCo Senior Employee 4] replied:

> *'I'm not sure where the discussion of £6M has come from as I wasn't there however the total market is circa 30k packs per month so if we*

[116] Document 202660, spreadsheet titled 'model (2)' attached to document 202659, email from [AMCo Senior Employee 6] to [AMCo Senior Employee 4] dated 23 May 2014. See 'Product X' figures in the 'assume generics launched' and 'Sheet 1' tabs. Although the spreadsheet was attached to an email in May 2014, it is likely that it was prepared in late 2013: it modelled all potential scenarios, including generic entry, from January 2014 onwards and assumed (subject '*to check*') an Auden ASP of £40 (Auden's ASP in May 2014 reached £53.65). The information in the 'current' tab matches the numbers AMCo used for its internal forecasts in December 2013 – see for instance, Document 202597, email from [AMCo Employee] to [AMCo Senior Employee 1] and [AMCo Senior Employee 4] dated 20 December 2013. The number of packs, ASP and total sales in the email are identical to those listed in the 'current' tab of the spreadsheet (Document 202660).
[117] Document 202596, email from [Auden Senior Employee 1] to [Amdipharm Senior Employee] dated 18 December 2013.
[118] Document 202596, email from [Auden Senior Employee 1] to [Amdipharm Senior Employee] dated 19 December 2013.
[119] Document 200160, minutes of Mercury Pharma Group Limited management meeting on 19 December 2013.
[120] Document 202597, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4] and [AMCo Senior Employee 6] dated 20 December 2013.

had our own product there is no reason why it couldn't be at this level of revenue.

The reason we only sell 6000 packs per month is that is all the stock we currently get.'[121]

29. The prevailing market price (Auden's ASP) in December 2013 was £36.03. If AMCo had sold its stock at the same price its prediction of £6 million in annual revenue would have equated to sales of 166,528 packs per year or 13,877 packs per month: 46.3% of total volumes according to [AMCo Senior Employee 4]'s data. (In fact total volumes of 10mg hydrocortisone tablets in 2013 were 73,560 packs per month (see table 3.7 of the Decision), which would have AMCo an 18.9% market share).

30. AMCo therefore not only believed that it could successfully enter the market with its skinny label tablets, but also that it would achieve significant sales if it were to do so. In interview, [AMCo Senior Employee 4] stated that she would have expected demand to come primarily from smaller, independent pharmacies, who would make purchasing decisions on price:

'an independent makes their own decision. So, there'll be some independents that wouldn't care, it would be about price … there will be some independents that just want to buy the cheapest and don't really care what indications'[122]

31. A further internal AMCo email sent by [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 8] on 2 January 2014 again stated that AMCo would successfully enter the market and questioned how much of a barrier to entry and expansion would be created by the orphan designation – believing that a substantial part of the market would be contestable to skinny label suppliers:

'only 22% of Rx's [prescriptions] are specified as Adrenal, and there are multiple other indications widely in use, not the 90+% for adrenal insufficiency that [Amdipharm Senior Employee] was once referring to. That means labelling shouldn't be that important, hopefully 😊 Pharmacists will dispense our product, regardless of label and [Auden Senior Employee 1[']s claims that we have an inferior product is

[121] Document 202597, email from [AMCo Senior Employee 4] to [AMCo Employee], [AMCo Senior Employee 1] and [AMCo Senior Employee 6] dated 20 December 2013.
[122] Document 201513, transcript of interview with [AMCo Senior Employee 4] dated 23 October 2017, page 42 lines 20-27 and page 43 lines 1-7.

irrelevant anyway, when it can be shown to be bioequivalent. It just doesn't have the labelling for one protected indication'.[123]

32. This email shows that [AMCo Senior Employee 2] was bullish about the prospect of skinny label entry being successful. He noted that the overwhelming majority of prescriptions for hydrocortisone tablets were open and believed that pharmacists would dispense AMCo's product in response to open prescriptions because it was bioequivalent.

33. In a separate email to [Amdipharm Senior Employee] on the same day, [AMCo Senior Employee 2] explained that he thought that 100% of the market would be contestable to skinny label entrants despite the orphan designation: '*That gives us a bit more strength to say to [Auden Senior Employee 1] that we don't mind having limited labelling. Pharmacists will use it anyway, regardless of labelling. Therefore, we should still be arguing using 100% of the market as our negotiating position for supply volumes!*☺[124]

34. During this period AMCo also assessed whether to purchase Auden's MAs for 10mg and 20mg hydrocortisone tablets. Initially, [AMCo Senior Employee 2] speculated that [Auden Senior Employee 1] wanted to sell the hydrocortisone business '*because he knows generics may be around the corner*'.[125] [AMCo Senior Employee 1] agreed: '*I bet loads of people are trying to get onto the market too*'.[126]

35. The anticipation of potential future skinny label entry led AMCo to consider submitting an offer with a low upfront amount '*on the basis that we think there will be generic competition and we don't think the orphan drug status is safe, plus yearly milestones if it does remain unique*'.[127]

36. Ultimately, AMCo '*decided not to pursue acquisition because seller's expectations of £150m (5x EBITDA) far outweigh AMCo's internal valuation which anticipates generic entry within 2-3 years*'.[128] AMCo therefore walked away from the acquisition because it expected successful skinny label entry within two to three years, substantially eroding the value of Auden's full label MAs.

[123] Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 8] dated 2 January 2014.
[124] Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.
[125] Document 200031, email from [AMCo Senior Employee 2] to AMCo staff dated 2 December 2013.
[126] Document 200163, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 2 January 2014.
[127] Document 200071, email from [AMCo Senior Employee 8] to AMCo staff dated 7 January 2014.
[128] Document 202629, AMCo strategic development monthly report for January 2014, page 3.

37. However, Auden continued to take the negotiating position that the orphan designation would be a barrier to expansion. Although AMCo made a further attempt to increase its supply volumes (to 7,000 packs per month, with a one-off order of 10,000 packs), [Auden Senior Employee 1] refused and threatened to '*take action to protect his product by advising all parties (mentioning DoH and MHRA amongst others, including major multiples*' that AMCo's skinny label tablets '*should not be dispensed against generic prescriptions*'.[129]

38. In mid-January 2014 it therefore appeared that the supply arrangement between Auden and AMCo would break down. Each party took precautionary measures.

i. AMCo's assessment of demand in anticipation of the Auden supply deal collapsing

39. AMCo's expectation that there would be demand for skinny label tablets was held consistently throughout the first half of 2014. There was no question in its mind that skinny label tablets would be successfully sold into the market – the only question was the extent of this demand.

40. In response to Auden's threat, [AMCo Senior Employee 2] recommended that AMCo prepare to launch its own product and continue researching the implications of the orphan designation:

> '*I think we need to now get a really clear plan in place how to launch our product, and to prepare for next batch, and also to counter-lobby the relevant stakeholders and point out that our product is in no way "inferior" from a quality perspective, and to clearly establish whether the adrenal insufficiency claim is a red herring or not. Is it really 95% of prescriptions that [Auden Senior Employee 1] claims, or nearer the 22% of prescriptions that was apparent from [✂] IMS MDI data.'*[130]

41. On 22 January 2014 AMCo held a PPRM (Portfolio Pipeline Review Meeting) where it set out a five-year forecast for sales of its skinny label 10mg tablets, including the following '*Assumptions*':

> *'Vol: 12,000 packs/month*
>
> *NSP [Net sale price]: £38*

[129] Document 200085, email from [AMCo Senior Employee 2] to AMCo management dated 14 January 2014.
[130] Document 200085, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 4], [AMCo Senior Employee 1], [AMCo Senior Employee 8] and others dated 14 January 2014.

Indication limitations do not restrict sales.'[131]

42. Prior to the meeting, [AMCo Senior Employee 4] expressed her view that although AMCo should not assume stable prices following its launch ('*We can never assume a stable NSP when there is competition in the market*'), the volume projection was sufficiently conservative to allow for the emergence of further competition: '*the volume is quite low so I am comfortable with it remaining at 12k per month*'.[132] [AMCo Senior Employee 4] expressed no reservations regarding whether AMCo could successfully launch its skinny label 10mg hydrocortisone tablets – believing that the projected volume of 12,000 packs per month (equivalent to 15.7% of total 10mg volumes in 2014: see table 3.7 of the Decision) was '*quite low*'. Her only concern was that further competition would erode market shares and drive prices down.

43. A presentation summarising the outcome of the 22 January PPRM further demonstrates that AMCo believed it could achieve significant sales if it launched its 10mg skinny label hydrocortisone tablets. The presentation predicted that AMCo's skinny label sales would peak at £5.1 million per year in 2015 despite the fact its '*Indication is limited compared to the Auden product which could impact sales*'.[133] Using Auden's prevailing ASP in June 2014 (£37.20), this would translate into sales of 137,097 packs per year or 11,425 packs per month: 14.9% of total volumes in 2014 (see table 3.7 of the Decision).

44. AMCo's confidence in the competitiveness of its skinny label product is further demonstrated by the minutes of an AMCo board meeting on 29 January, where it reported its belief at the time that its '*own version would be able to compete with the Auden product, even if it does not have this indication, but investigations continue*'.[134]

45. In February 2014 an internal AMCo appraisal for its skinny label tablets showed that '*Sales per month are estimated to be 12,000 packs*' with 144,000 being sold annually.[135]

ii. Auden's assessment of demand in anticipation of AMCo entering

46. On the basis of its own belief that AMCo would soon launch its skinny label tablets and that there would be substantial demand for them, taking sales

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

away from Auden's full label tablets, Auden launched an initiative known as 'Project Guardian'. The aim of the project was to protect Auden's market share at a time when Auden anticipated that AMCo may enter the market with its own 10mg hydrocortisone tablets: i.e. to '*develop and deliver a strategy designed to ensure that its current market share for the supply of hydrocortisone tablets (10mg and 20mg respectively) is maintained or strengthened at a time when a competitors* [sic] *product (namely Amdipharm Mercury Company Limited* [AMCo] *hydrocortisone tablets 10mg and 20mg) threatens to weaken Auden McKenzie's market share*'.[136] The very inception of the project therefore recognised the competitive threat that would have been posed by a skinny label supplier in 2014. See section 3.F.III.h above.

47. To this aim, Auden engaged with external consultants ([Auden's External Consultant] Consulting Limited, MAP BioPharma, H2 Pharma and Salix Consulting) to explore different ways to protect its market position. Project Guardian's kick-off presentation prepared in February 2014 highlighted that:

    a. *'[N]ew competitor entry remains a real threat and action is necessary to avoid unnecessary decline in share (driven by prescriber ignorance or dispensers chasing margin on reimbursement)*' and that it was important to not be seen '*to be exploiting the NHS from pricing strategy or acting only to preserve commercial advantage in face of competition'.*

    b. *'It is therefore essential to be proactive ahead of Amdipharm's product entry into the UK market in an attempt to hold Auden Mckenzie share above 50% and as close to the existing position as possible'.*

    c. *'Prescribers <u>are</u> able to use unlicensed medicines but often barriers are put in the way by institutions / employers through specific policies because of the increased liability assumed. <u>We need to raise the profile of the issues concerning liability and risk</u>'.* (emphasis in original)

    d. *'The competitor product is unproven and will need to find its own place in the market – this provides some time for Auden Mckenzie to seize the initiative'*[137]

[136] Document 00062F, Professional Advice (Hydrocortisone) Proposal Prepared for Auden Mckenzie (Pharma Division) Ltd by [Auden's External Consultant] dated 6 February 2014, 2 Client Requirements.
[137] Document 00135, Project Guardian presentation dated February 2014, pages 9, 11, 16 and 33. See also Document 00064, untitled report containing analysis on hydrocortisone attached to Document 00063, email from [✂] (H2 Pharma) to [Auden Senior Employee 4] dated 18 February 2014: '*Strategy: make physicians aware that Auden's product is licenced* [sic] *for the broader adrenal insufficiency indication and the Amdipharm product is ONLY licenced* [sic] *only* [sic] *for congenital adrenal hyperplasia in children Make it clear that treatment of adrenal insufficiency in patients with primary (Addison's) and secondary (hypo-pituitarism) diseases will NOT be covered under the Amdipharm product licence.*'

48. Project Guardian therefore not only envisaged successful entry by AMCo's skinny label product (had it been launched in 2014) but that entry could potentially be very successful – with one of the key aims of the project being to hold Auden's '*share above 50%*'. Additionally, the Project Guardian materials recognised that it was permissible to used '*unlicensed medicines*' thereby acknowledging that there was scope for off-label dispensing (as explained above, this is not the same as use of unlicensed medicines).

49. The competitive threat posed by AMCo's skinny label tablets was further explained in a second bundle of Project Guardian materials prepared for Auden by Salix Consulting on 16 April 2014: '*Auden Mckenzie is reacting to a potential threat to its market share of hydrocortisone 10mg tablets […] The threat comes from new arrival, Amdipharm, whose product may be adopted as a cheaper alternative to the current market leader*'.[138]

50. Auden would not have engaged in Project Guardian if it had been confident that AMCo's skinny label tablets would only obtain negligible market share. That it felt moved to respond in such a concerted way demonstrates that Auden perceived a real prospect that there would be substantial demand for skinny label tablets and a real risk to its position from extensive off-label dispensing.

51. Between February and April 2014 Auden and its consultants developed letters to be sent to the Chief Pharmaceutical Officer, the MHRA, patient groups, specialists, superintendent pharmacists and pharmacy bodies in pursuit of this strategy.[139] Auden sought to highlight the purported risk profile to pharmacists, and the template letters to the Chief Pharmaceutical Officer and superintendent pharmacists asked whether they would find it appropriate to issue guidance to senior pharmacists on off-label dispensing.[140]

[138] Document 00139, Project Guardian communications proposal dated 16 April 2014, slide 3 (emphasis added).
[139] Document 00082, email from [Auden's External Consultant] to [✂] dated 31 March 2014. Document 00093, Document titled Key Contact First Engagement Email / Letter (Draft Text) attached to Document 00082, email from [Auden's External Consultant] to [✂] dated 31 March 2013. 'Final' template letters were circulated on 7 April 2014 following feedback from Auden: Document 00117, email and attachments from [Auden's External Consultant] to [✂] copying [Auden Senior Employee 4] dated 7 April 2014. See, for example, attached Document 00119.
[140] Document 00121, template letter to Chief Pharmaceutical Officers dated 14 April 2014; Document 00126, template letter to Superintendent Pharmacists dated 14 April 2014.

c. April to June 2014: AMCo's and Auden's assessment of demand

i. AMCo's assessment of demand in anticipation of agreeing a new supply deal with Auden

52. In April 2014, alongside Project Guardian, Auden returned to the negotiating table with AMCo and offered a new supply agreement. AMCo's monthly management pack for March 2014 stated, '*we are considering their [Auden's] offer to continue supplying AMCo with Hydrocortisone on an ongoing basis*'.[141] On 19 April 2014 [AMCo Senior Employee 1] told [AMCo Senior Employee 2]:

> *'[Auden Senior Employee 1] offered to continue to supply us … I think that he is not keen to get into a battle over the orphan drug status and its validity and so probably would do a better deal on better terms.*
>
> *I have asked [AMCo Senior Employee 5] what our Aesica cost and volume expectations are and I would say if [Auden Senior Employee 1] could get close to them it would be worth having a long term supply agreement with him.'*[142]

53. Having asked a colleague '*What we are forecasting per month after we switch to Aesica*',[143] [AMCo Senior Employee 5] provided the information on the Aesica costs and volumes on 22 April 2014: '*Monthly volumes from Auden is 6000 packs per month typically Price is £1.00. Forecast slightly higher 10000 from Aesica*'.[144] [AMCo Senior Employee 1] forwarded this exchange to [AMCo Senior Employee 4], stating: '*As discussed would be* good *to know the size of the market*'. [AMCo Senior Employee 4] replied on the same day: '*Last year it was 923k packs for the year so 77,000 packs per month.*' [145]

54. By the end of April 2014, AMCo was therefore forecasting selling 10,000 packs per month of its skinny label tablets: 13% of total volumes according to [AMCo Senior Employee 4]'s estimate of the total market size.

55. In April 2014, AMCo's management estimated that if it were to launch its own skinny label tablets by the end of May/early June, it would be able to achieve £1.6 million in sales (£1.4 million in terms of EBITDA).[146] AMCo

[141] Document 200108, AMCo Monthly Management Pack, March 2014, page 6. The pack was likely drafted in April and the reference to Auden's offer to continue to supply AMCo may have been inserted on the basis of [Auden Senior Employee 1] approaching [AMCo Senior Employee 1] in April 2014.
[142] Document 200105, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 2] dated 19 April 2014.
[143] Document 202646, email from [AMCo Senior Employee 5] to [AMCo Employee] dated 17 April 2014.
[144] Document 200106, email from [AMCo Senior Employee 5] to [AMCo Senior Employee 1] dated 22 April 2014.
[145] Document 200106, email from [AMCo Senior Employee 4] to [AMCo Senior Employee 1] dated 22 April 2014.
[146] Document 200108, AMCo Monthly Management Pack for March 2014, page 54.

continued to forecast that it would be able to sell more monthly packs of its skinny label tablets than the monthly packs of full label tablets it was obtaining from Auden at the time (6,000): on 17 April 2014 [AMCo Senior Employee 4] reported internally that AMCo '*will have increased volume once we have our own product in June*'.[147]

56. These estimates were all prepared at a time when AMCo was facing the threat of losing its heavily discounted supply from Auden and therefore faced potential financial exposure in the form of lost sales. If AMCo had been concerned about the likelihood of successful entry with its skinny label tablets then this would have been expected to have drawn comment. However, [AMCo Senior Employee 4] expected that skinny label tablets would be successful to such an extent that AMCo would increase its volumes if it launched (when compared to the volumes sold under the arrangement with Auden).

57. If AMCo staff had genuinely been concerned about the commercial prospects for AMCo in launching its own product, it would be a matter of significance which would have been expected to attract comment. However, it did not.

58. On 23 April 2014 [AMCo Senior Employee 2] noted, '*It seems that [Auden Senior Employee 1] isn't being quite as bold about his indication claims now, which may reflect our belief that it's not as important as he was once suggesting.*'[148] This suggests that [AMCo Senior Employee 2] retained confidence that skinny label tablets would be successfully launched in the UK – there is no suggestion he or other AMCo staff had any reservations or were in possession of any information to the contrary.

59. AMCo was contemporaneously assessing the possibility of acquiring Waymade's MA for full label 20mg hydrocortisone tablets. However, as with its potential acquisition of Auden's hydrocortisone business, AMCo decided not to acquire Waymade's MA because it believed there would be successful skinny label entry.

60. When commenting internally on the possible acquisition, [AMCo Senior Employee 2] once again cast doubt on the superiority of the fully indicated MA against its skinny label competitors, observing that '*in practice, this is just another dossier, with a minor advantage of the indication (which we don't believe is worth that much, but worth something potentially)*'.[149]

[147] Document 202645, email from [AMCo Senior Employee 4] to [✂] dated 17 April 2014.
[148] Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] dated 23 April 2014.
[149] Document 200109, email from [AMCo Senior Employee 2] to AMCo staff dated 11 April 2014.

Consistently with his views on the Auden MAs, [AMCo Senior Employee 2] stated that he did not think Waymade's 20mg MA was worth its asking price due to, among other factors, '*the uncertainty about the value of the label, and the risk of additional generics*'.[150] In other words, [AMCo Senior Employee 2] again expressed the concern that skinny label hydrocortisone tablets would successfully enter the market and undermine the market share held by full label tablets.

61. The impact of the risk of skinny label entry on the expected returns from Waymade's 20mg full label product led to AMCo and Waymade disagreeing over the value of the MA. In May 2014 [AMCo Senior Employee 2] informed Waymade:

> *'We believe that other companies might be developing and registering generics and therefore there is significant risk on the pricing environment'.*[151]

62. [AMCo Senior Employee 2] later communicated to Waymade that '*It is our [AMCo's] belief (because we have submitted a generic MA ourselves) that generics can launch with the limited labelling. Therefore generics aren't blocked from the market*'.[152]

63. In other words, AMCo did not pursue the acquisition of Waymade's full label MA because it believed it would be vulnerable to skinny label competition and that the additional indication would only offer '*a minor* [competitive] *advantage*' in the market place.

ii. The response to Project Guardian and the parties' conclusion of a new supply deal

64. Project Guardian received a lukewarm reception from stakeholders. For example, [Chief Pharmaceutical Officer for NHS England] informed Auden (on the advice of the MHRA) in writing that '*there are no material differences between the available generic immediate release hydrocortisone tablets and they are all bioequivalent to the brand leader*' and therefore '*I do not see that there are any risks to patient safety that would warrant any communication to senior pharmacists.*'[153]

65. Following the response from [Chief Pharmaceutical Officer for NHS England], [Auden Senior Employee 1] approached [AMCo Senior Employee

[150] Document 200109, email from [AMCo Senior Employee 2] to AMCo staff dated 11 April 2014.
[151] Document 200116, email from [AMCo Senior Employee 2] to [✂] dated 2 May 2014.
[152] Document 200116 email from [AMCo Senior Employee 2] to [✂] dated 15 May 2014.
[153] Document 00247B, letter from [Chief Pharmaceutical Officer for NHS England] to [Auden Senior Employee 1], [Auden Senior Employee 4] and [Auden's External Consultant] dated 20 May 2014.

1] by text message, beginning the final phase of negotiations that resulted in a new supply deal between Auden and AMCo. As part of those negotiations [AMCo Senior Employee 1] told [Auden Senior Employee 1] that AMCo was '*currently forecasting 12k packs per month*' for sales of its own skinny label tablets.[154]

66. On 27 May 2014 AMCo's management prepared a slide deck for a meeting with Cinven in which it presented its expectations for its skinny label tablets. Again it is clear from the presentation that AMCo anticipated that it would achieve strong sales if it launched its skinny label tablets: '*Hydrocortisone Tablets: - Projected NPV [Net Present Value: a measure of the profitability of the project over the medium term] of over £16M – Approval obtained by Amdipharm. UK Launch in June 2014*'.[155] There is again no suggestion that AMCo considered or had been made aware that there would be any difficulty in launching the product and making sales.

67. [AMCo Senior Employee 1] and [Auden Senior Employee 1] continued negotiations for a new supply arrangement during May and June 2014. They ultimately agreed that Auden would double AMCo's monthly volumes at the £1 supply price, to 12,000 packs. [AMCo Senior Employee 1] explained to colleagues on 15 June 2014:

> *'I went in with 12k per month when I knew that [AMCo Senior Employee 4] had forecast 10k per month with the view that we would have to negotiate – I suppose at that stage I thought I would settle for 10k*
>
> *… I told him [[Auden Senior Employee 1]] that if not we will launch our own'.*[156]

68. As of 15 June 2014, AMCo therefore continued to predict that it would sell 10,000 packs per month of its skinny label tablets if it launched. [AMCo Senior Employee 1] had used that projection, supplied by [AMCo Senior Employee 5], to calibrate his negotiation with Auden: he had told [Auden Senior Employee 1] that AMCo was forecasting sales of 12,000 packs per month and that if Auden did not supply AMCo, AMCo would launch.

69. Auden's concern remained the need to preserve its volumes from the threat of skinny label entry. [AMCo Senior Employee 1]'s threat that if Auden did not come to terms, AMCo would launch its skinny label product, could only

[154] Document 00149, email from [AMCo Senior Employee 1] to [Auden Senior Employee 1] dated 28 May 2014.
[155] Document 202666, email from [AMCo Senior Employee 7] to [AMCo Senior Employee 2] dated 27 May 2014 and document 202667, presentation titled 'Strategic Projects – Cinven 27.05.14', page 2.
[156] Document 200120, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 8] and others dated 15 June 2014.

succeed in securing better terms for AMCo if Auden understood that there would be demand for that product.

70. [AMCo Senior Employee 1]'s threat did succeed: the parties entered into a new supply deal effective 25 June 2014 in which Auden agreed to double AMCo's volumes at the £1 supply price to 12,000 packs per month. On the same day, AMCo suspended the development of its skinny label tablets. [AMCo Senior Employee 1] informed AMCo staff:

> *As you know we have subsequently signed a deal with Auden Mackenzie [sic] to source product from them and therefore our own product will not be launched in UK. The rationale for this arrangement is that their product has an indication, Adrenal Insufficiency, that our product does not and hence selling their product removes a competitive disadvantage.'*[157]

71. [AMCo Senior Employee 1] therefore rationalised AMCo's decision not to launch on the basis that skinny label hydrocortisone tablets might face '*a competitive disadvantage*' when compared to full label. However, he noted that in the absence of a new supply deal with Auden, AMCo had been planning to launch its product nonetheless:

> *'What I would like to stress though is that the work that you did to provide certainty of launch of our product gave those of us who were negotiating with Auden Mackenzie confidence to achieve the best deal possible for AMCo and I am sure that, as a result, Auden Mackenzie felt that they should agree to our terms.'*[158]

72. AMCo's decision not to launch its skinny label product and instead continue selling Auden's full label product meant there would not be a real test of the extent of demand for skinny label. In interview, [AMCo Senior Employee 2] explained:

> *'potentially, all the labelling could have been a nonsense and we might have been able to compete and take 50% of the market. Worse case, we might be restricted to the 5%; in truth it's probably somewhere in between … we were never able to really gauge and understand exactly where in between those two factors, we would naturally be able to supply the market. And that's why security of supply from Auden*

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

Mckenzie and the 12,000 packs was; represented a good deal for AMCo'[159]

d. September 2014 to January 2015: Auden/Actavis's assessments of demand

73. Further evidence demonstrating the belief that skinny label hydrocortisone tablets would successfully enter the market is provided by the impact of an Allergan (then known as Actavis) due diligence exercise conducted in the last quarter of 2014 and early 2015, to assess the potential purchase of AM Pharma. The threat of skinny label entry was such that, in [Auden Senior Employee 1]'s own words, the deal structure was changed to achieve *'a total and complete de-risking of Hydrocortisone for Actavis and only an earnout depending on their success to market Hydrocortisone tablets.'*[160]

74. The due diligence took place after Orion had been granted a skinny label MA for 10mg hydrocortisone tablets (on 25 November 2014) and this event had an immediate, negative impact on Allergan's interest in buying AM Pharma. The MA was subsequently transferred to Alissa.

75. In response to this new threat, Auden resumed Project Guardian, approaching the MHRA again and Orion directly to warn against off-label dispensing.[161] This once again demonstrates Auden's view that there would be material demand for skinny label tablets. However, both Orion and the MHRA again rebuffed Auden, with the MHRA repeating that:

> '*From the public health perspective, there are no material differences between the available generic immediate release hydrocortisone tablets; these are all bioequivalent to the brand leader.*'[162]

76. In a January 2015 presentation, Allergan estimated that skinny label entry would occur that year and would reduce Auden's market share by 60% and its prices by 90% over a three-year period. The due diligence was fully cognisant of the distinction between skinny and full label but recognised that off-label dispensing would occur ('*without indication for adrenal insufficiency and being launched and dispensed off label*'.)[163]

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[159] Document 201591, transcript of [AMCo Senior Employee 2] interview dated 12 October 2017, page 43 lines 13-20.
[160] Document 00263, email from [Auden Senior Employee 1] to Auden Senior Employee 5] dated 22 January 2015
[161] Document 00235, email from [✂] (Auden Mckenzie) to [✂] (MHRA) dated 28 November 2014. Document 00239, letter from [✂] to [✂], dated 1 December 2014. See also Document 00243, letter from [✂] to [✂], dated 1 December 2014. Document 00282, email from [✂] (Auden Mckenzie) to [✂] (MHRA) dated 4 December 2014.
[162] Document 00288, letter from to [✂] to [✂] dated 19 December 2014.
[163] Document 00706, Project Apple Presentation January 2015, Hydrocortisone Background.

77. On 9 January 2015 [Auden's External Consultant], the external consultant Auden engaged to advise on the first iteration of Project Guardian (targeting AMCo), advised Auden on the implications of Alissa's potential launch. [Auden's External Consultant] advised that skinny label tablets would be likely to successfully enter the market. He observed that '*Inadvertent off-label use is […] as likely with this [Orion/Alissa's] product as with any product that does not carry the extensive indications as the originator product*', and that '*This is becoming increasingly an issue as more products come to market with limited indications.*' [Auden's External Consultant] therefore advised that '*Superintendents would be unlikely to be too exercised about the introduction of the Orion [Alissa] product on to the market. This may change if there is a bioavailability issue that surfaces or if an adverse event arises*'.[164] In other words, [Auden's External Consultant] believed that superintendent pharmacists would not be concerned about dispensing a skinny label product off-label, unless a bioavailability issue arose.

78. As a consequence of the acknowledged threat to Auden's market share from off-label dispensing of skinny label tablets, Allergan reduced its offer for AM Pharma by £220 million (from £520 million to £300 million) and agreed an earn-out to address the risk of skinny label entry. As [Auden Senior Employee 1] explained to [✂] [Auden Senior Employee 5]:

> *'[t]he grant of this [Orion/Alissa] license was of concern to Actavis…[t]he new Hydrocortisone license [sic] grant resulted in the Executive board of Actavis raising concerns over the proposed deal to acquire Auden and negotiations stopped around mid-December. [✂] went as far as to say that Actavis were no longer excited about the deal and we should find a new acquirer, as Actavis were seriously concerned about the new Orion license been [sic] used 'Off label' and the impact this would have on their investment if they acquired Auden'.*[165]

79. This resulted in a new structure for the deal:

> *'This resulted in a meeting on 6th January 2015 in Marlow where a concept was floated and subsequently accepted by [✂] on 9th January … The deal agreed was as £300,000,000 + Hydrocortisone earnout … This deal represents a total and complete de risking of Hydrocortisone*

[164] Document 00254, email from [Auden's External Consultant] to [Auden Senior Employee 4] dated 9 January 2015.
[165] Document 00263/302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.

for Actavis and only an earnout depending on their success to market Hydrocortisone tablets.' [166]

e. March to October 2015: AMCo's assessments of demand

80. By late 2014 AMCo became aware that Alissa had been granted a skinny label MA for 10mg hydrocortisone tablets.[167] Contemporaneous internal AMCo documents relating to this market development demonstrate that AMCo believed that skinny label hydrocortisone tablets would successfully enter the market. Indeed, there is no reference to Alissa being likely to suffer any impediment as a result of its limited indication.

81. On 18 February 2015, AMCo re-engaged with its Aesica product and ordered sufficient API for '*2 year's worth*' of consumption (or '*115kg*'), estimating that AMCo would sell 12,000 packs a month of its skinny label tablets if they were launched.[168] On the same day, AMCo issued a purchase order to Aesica for 30,000 packs of 10mg hydrocortisone tablets, to be delivered on 10 June 2015.[169]

82. On 17 March 2015, [AMCo Employee][170] emailed [AMCo Senior Employee 1]:

'[w]e have had the Waymade order through @ £60 (1,500 packs) but AAH and Mawdsleys are still adamant they will not be ordering […] we do need to bear in mind that Alissa will be launching the Orion product very soon (possibly next month). As far as I am aware they do not have any restrictions on stock availability and they do have very good links to shortline in the market. There would be an argument for us to support the small number of accounts we have at last month's prices. Implementing a price rise is difficult when everyone knows that competition is around the corner'. [171]

83. Accordingly, in March 2015 [AMCo Employee] believed that Alissa would shortly be launching its skinny label product. Far from questioning the

[166] Document 00263/302324, email from [Auden Senior Employee 1] to [Auden Senior Employee 5] dated 22 January 2015.
[167] AMCo became aware that Alissa's product would be skinny label on 2 December 2014. See document 202952, email from [✂] to [AMCo Senior Employee 2], [AMCo Senior Employee 5] and [AMCo Senior Employee 7] dated 2 December 2014.
[168] Document 201070, email from [AMCo Employee] to [AMCo Senior Employee 1], [AMCo Senior Employee 4], [AMCo Senior Employee 2], [AMCo Senior Employee 7] and [AMCo Senior Employee 5] dated 18 February 2015. [AMCo Employee] explained that AMCo used 6kg per batch of the product and that each batch size of finished goods was 15,000 packs. Two years' worth of product (115kg) was therefore equivalent to 287,500 packs or circa 12,000 packs per month.
[169] Document 201932, purchase order 4500009470 issued by AMCo to Aesica on 18 February 2015.
[170] AMCo acquired Focus Pharmaceuticals Ltd, a speciality pharmaceuticals business, on 1 October 2014.
[171] Document 202792, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 17 March 2015.

likelihood of successful entry by a skinny label, she foresaw it being successful. Instead her focus was on how AMCo should react to what she understood as Alissa's impending entry, for example she believed a '*price rise*' would be '*difficult*' in such circumstances.

84. [AMCo Employee] 's strategy and views were endorsed by [AMCo Senior Employee 1]. On 18 March 2015, after discussing the matter with [AMCo Employee], [AMCo Senior Employee 1] reported to AMCo's management team that '*I gather from [AMCo Employee] that the Orion* [Alissa skinny label] *Hydrocortisone might be launched next month*. *She has managed to sell the Waymade Hydrocortisone at the new price but I have asked her to give the other customers another month at the old price just in case we are faced with competition*'.[172] Again, there is no suggestion from [AMCo Senior Employee 1]'s contemporaneous email that he believed that Alissa would struggle to enter the market with skinny label tablets – in fact he confirmed that AMCo would adapt its strategy in response to the likelihood of competition ('*I have asked her to give the other customers another month at the old price just in case we are faced with competition*').

85. On 19 October 2015, [AMCo Employee] emailed [AMCo Senior Employee 3] and wrote that '*Actavis are informing customers that Alissa are launching their hydrocortisone i.e. they have not done a deal. We may not want to hang around too long before processing in case customers cancel. The only way Alissa can sell is by dropping the price. Already Mawdsleys have declined the stock I had reserved for them. I don't know exactly when Alissa are launching but will try and find out*'.[173]

86. In line with this expectation that skinny label tablets would generate sales if launched, AMCo also considered selling skinny label tablets under the skinny label MA that its new subsidiary, Focus, was expected to obtain from the MHRA. On 20 May 2015, [AMCo Senior Employee 2] suggested as one of the options for the Focus skinny label tablets, to '*source some or all of our supply from them* [Focus], *particularly now that AM's* [Auden's] *product has been sold to Actavis anyway*'.[174]

87. This option was given further consideration on 5 August 2015 when Focus shared with AMCo the proposal for the management of 10mg and 20mg hydrocortisone tablets from Lamda, its CMO. Focus proposed a first scenario which was conditional on receiving supplies from Auden/Actavis

[172] Document 202780, email from [AMCo Senior Employee 1] to [AMCo Senior Employee 6] dated 18 March 2015.
[173] Document 202826, email from [AMCo Employee] to [AMCo Senior Employee 3] dated 19 October 2015.
[174] Document 202954, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 3] and [AMCo Senior Employee 6] dated 20 May 2015.

and a second scenario which was conditional on supplying under Focus's skinny label MA. The expected annual volume for this second scenario was 120,000 packs a year (10,000 packs per month) and an annual return of £2,310,000. These estimates were equivalent to what AMCo had expected to sell with its own skinny label product back in April 2014.[175]

88. Similarly, AMCo considered selling skinny label tablets from MIBE, another CMO, through a development project historically begun by the Mercury Pharma group. In June 2015 and September 2015 AMCo estimated that it would achieve 20% market share if it launched its MIBE product in 2016.[176]

f. Conclusion on the representation that there was no (or negligible) demand for skinny label tablets before April 2016

89. The evidence set out above is clear, consistent and unambiguous: each of the parties understood that there was demand for skinny label tablets before they were first launched in October 2015. In particular, from 2014 onwards AMCo consistently projected sales of at least 10,000 to 12,000 packs per month of its skinny label products.

II. 'AMCo's main target customers would not have bought its product'

90. AMCo and Cinven submitted that AMCo's belief that there was no demand for skinny label tablets was based on negative feedback obtained from its '*main target customers*'.[177]

91. Cinven submitted that '*it was not unreasonable for AMCo to consider that there was no market for its reduced indication product, in particular given that the independent pharmacies and short-line wholesalers which proved to be receptive […] were not AMCo's main customers*'.[178]

92. As explained in section 3.E.IV of the Decision and Annex D.I above, abundant contemporaneous evidence shows that, contrary to these submissions, it was AMCo's consistent belief that there would be demand for skinny label tablets, albeit the extent of such demand was uncertain.

93. In relation to 'feedback': there is no contemporaneous evidence (and AMCo and Cinven have not provided any) that would directly or indirectly show that prior to Alissa's entry AMCo received any kind of customer feedback relating

[175] Document 200144, email from [Focus Senior Employee 1] to [AMCo Senior Employee 1] and [AMCo Senior Employee 2] dated 5 August 2015; and document 200145, Hydrocortisone 10mg and 20mg tablet proposal.
[176] Document 202932, spreadsheet titled 'Hydrocortisone TABLETS 10MG X 30 – [✂]', see 'NPV#10 June15' and 'Sept-2015' tabs.
[177] Document 206665, Cinven's RLOF, paragraph 3.23, Document 204922, AMCo's RSSO, paragraph 3.247 and Document 206670, AMCo's RLOF, paragraph 5.8.4.
[178] Document 206665, Cinven's RLOF, paragraph 3.23.

to its skinny label tablets. There is in particular no contemporaneous evidence that AMCo conducted 'market testing' in mid-2014.[179]

94. In relation to the nature of AMCo's 'target customers': contrary to Cinven's submission, the contemporaneous evidence shows that short-line wholesalers (and, as a result, independent pharmacies) were among AMCo's target customers:

a. Waymade, AMCo's second most important customer for hydrocortisone tablets from October 2012 to June 2014,[180] was a short-line wholesaler with a customer base consisting '*of several thousand entities, most of which were retail pharmacists*'.[181] In June 2014, instead of contacting Waymade for the purposes of launching AMCo's skinny label tablets, AMCo decided to conceal its skinny label stock from Waymade and store it at its pre-wholesaler UDG: [✂] stated, '*I dont* [sic] *want Waymade to be aware of our stock holding of our own licensed product*'.[182]

b. Between June 2014 and March 2015, Mawdsleys, another short-line wholesaler, became AMCo's main customer for hydrocortisone tablets, purchasing more than full-line wholesalers AAH and Alliance combined.[183] Mawdsleys explained to the CMA that if one of Mawdsleys' preferred suppliers had entered earlier with skinny label tablets then Mawdsleys would have likely purchased them on a sale or return basis.[184]

c. Other short-line wholesalers such as [✂] and [✂], which were among the first to purchase Alissa's skinny label tablets when it entered the market,[185] were also some of AMCo's main customers for hydrocortisone tablets over a year prior to AMCo's entry in May 2016.[186] [Wholesaler] explained to the CMA that it would have been

[179] Document 204967, Cinven's RSSO, paragraphs 1.14.(f), 1.19, 3.2.(c)-(d), 3.3, 3.57, 3.58, 3.98.(b), 4.73, 5.32, 5.52, 6.34, 6.38, 6.44, 6.63, 6.71, 7.43, 9.25 and 10.16. See also Document 205517, transcript of Cinven's oral hearing of 9 September 2020, page 20, lines 11-13 and page 39, lines 20-21. Document 204922, AMCo's RSSO, paragraphs 3.41, 3.71, 3.159, 3.207, 3.209, 3.235, 3.236, 3.248, 3.252, 3.607, 3.679, 3.680, 3.686, 3.692 and 5.104 and 6.84.6. See also Document 205628, transcript of AMCo's oral hearing of 10 September 2020, page 14, lines 5-6 and page 25, lines 8-12.
[180] Document 200454, AMCo's sales data for 10mg hydrocortisone tablets from January 2013 to March 2016.
[181] Document 200003, Waymade's response to the CMA's section 26 notice of 5 May 2016, paragraph 16.
[182] Document 202691, email from [AMCo Senior Employee 5] to [✂], [AMCo Employee] and [AMCo Senior Employee 7] dated 26 June 2014.
[183] Document 200454, AMCo's sales data for 10mg hydrocortisone tablets from January 2013 to March 2016. See also Document 201513, transcript of interview with [AMCo Senior Employee 4] dated 23 October 2017, page 12 lines 21-23.
[184] Document 206612, note of call between the CMA and Mawdsleys of 3 March 2021, paragraph 2.10.
[185] Document 206017, Alissa's sales data for skinny label 10mg hydrocortisone tablets from October 2015 to April 2016.
[186] AMCo's sales data for 10mg hydrocortisone tablets from January 2013 to March 2016.

interested in AMCo's skinny label tablets as soon as they became available because they would contribute to the rebates that [wholesaler] received from AMCo.[187]

d. More generally, multiple short-line wholesalers had been part of AMCo's customer base since at least October 2012[188] and had open accounts with AMCo for hydrocortisone tablets since as early as April 2013.[189]

III. 'AMCo did not anticipate off-label use and so believed the addressable market was negligible'

95. AMCo submitted that it reasonably anticipated that its skinny label tablets '*could only be promoted, prescribed and dispensed for use by paediatric patients which accounted for a very small percentage of the overall adrenal insufficiency patient population, and that its total addressable market would therefore be negligible*'.[190]

96. The CMA cannot accept this submission.

97. Setting aside that AMCo's contemporaneous skinny label sales estimates (set out in section 3.E.IV.a of the Decision and Annex D.I above) show that its expected sales of skinny label tablets were far from negligible, it is a matter of fact that healthcare practitioners could, in practice, exercise their own professional judgment and prescribe and dispense skinny label tablets for off-label use, particularly in a case where products are bioequivalent, as is explained in section 3.E.III. Contemporaneous evidence demonstrates that AMCo understood that its skinny label tablets could be dispensed for off-label use. For example:

a. On 2 January 2014 [AMCo Senior Employee 2] sent two separate emails to members of AMCo's management team. In the first email [AMCo Senior Employee 2] expressed his view that '*labelling shouldn't be that important, […] Pharmacists will dispense our product, regardless of label and [Auden Senior Employee 1]'s claims that we have an inferior product is irrelevant anyway, when it can be shown to be bioequivalent. It just doesn't have the labelling for one protected indication'*.[191] In his second email, he reiterated that *'we don't mind*

[187] Document 206579, note of call between the CMA and [wholesaler] of 23 February 2021, paragraph 4.4.
[188] Document 202337, email from [AMCo Senior Employee 1] to AMCo's customers dated 18 October 2012.
[189] Document 300356, email from [✂] to [Waymade Senior Employee 4] dated 10 April 2013.
[190] Document 204922, AMCo's RSSO, paragraph 3.53.
[191] Document 200165, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 1] and [AMCo Senior Employee 8] dated 2 January 2014.

having limited labelling. Pharmacists will use it anyway, regardless of labelling'.[192]

b. In April 2014, AMCo's views on off-label use remained unchanged. After being approached by Auden concerning the possibility of entering into another supply deal, [AMCo Senior Employee 2] reported that '*[i]t seems that [Auden Senior Employee 1] isn't being quite as bold about his indication claims now, which may reflect our belief that it's not as important as he was once suggesting*'.[193]

c. In June 2014, when negotiating the Second Written Agreement, AMCo's external lawyer asked [AMCo Senior Employee 8]: '*Is there a risk of AmCo inadvertently supplying for orphan designation? What are the consequences if you do this?*' [AMCo Senior Employee 8] replied: '*Pharmacy bears the responsibility to ensure that the correct product is dispensed (which is why Auden has been writing to pharmacy, not us, to point out the fact that we don't have this indication). So long as we make sure that our product does not misrepresent itself as covering additional indications that are not on its licence (which will not happen), our Medical team consider that we would be ok. The issue would be how Auden react… I suspect we would end up in the OD dispute that we are now facing, but I don't think there is much we can do about that, unless we decide to abandon this product market which we really don't want to do.*' [194] [AMCo Senior Employee 8] therefore understood (correctly) that pharmacists were responsible for dispensing and could choose to dispense AMCo's skinny label tablets against an open prescription, and that provided AMCo did not misrepresent its product as full label this would not create liability for AMCo as a supplier. Instead, the issue would be '*how Auden react*': [AMCo Senior Employee 8] anticipated that in response to AMCo's launch Auden would likely intensify its efforts to persuade pharmacists against off-label dispensing, which it had already begun with Project Guardian ('*we would end up in the OD dispute that we are now facing*').

d. AMCo's expectation that its skinny label tablets would sell if it were to place them on the market was consistent with its views on off-label use of drugs expressed to Cinven in November 2014: '*The off-patent drugs bill that has been put forward to parliament does not negatively impact AMCo. It actually could provide opportunities for some of our off-patent*

[192] Document 200164, email from [AMCo Senior Employee 2] to [Amdipharm Senior Employee] dated 2 January 2014.
[193] Document 200107, email from [AMCo Senior Employee 2] to [AMCo Senior Employee 6], [AMCo Senior Employee 1] and [AMCo Senior Employee 8]: dated 23 April 2014.
[194] Document 201971, email from [AMCo Senior Employee 8] to Pinsent Masons dated 6 June 2014.

products to get new indications to allow doctors to prescribe these more widely. <u>However doctors are already allowed to prescribe products outside their approved indications (off label use), which is frequently practised today, so the impact is unlikely to be material.</u> An example of an AMCo pipeline product which could benefit from this bill is hydrocortisone which theoretically could obtain the adrenal insufficiency indication currently grand fathered to a competitive product'.[195]

e. Similarly, in February 2015 [AMCo Senior Employee 3] shared his view that if AMCo were to launch its skinny label tablets '*some of the use is off label in some instances (obviously we will never promote this way but clinicians can decide to use this way)*'.[196]

f. After Alissa's launch in October 2015, AMCo was made aware that AAH believed that '*[f]or sure independent pharmacies won't care*' about the difference in indications between full and skinny label tablets.[197]

98. Consistently with the contemporaneous evidence, [AMCo Senior Employee 4] confirmed to the CMA in interview that dispensing skinny label tablets for off-label use was not unexpected to AMCo: *'So, there'll be some independents that wouldn't care, it would be about price. Because this isn't the first drug that this has happened to in that sense, there's been lots of generic products over the years that have got a different sort from the brand originator*'.[198]

IV. 'Market conditions changed in April 2016'

99. AMCo and Cinven also submitted that market conditions 'changed' in April 2016: demand suddenly materialised, leading AMCo to immediately launch its skinny label 10mg tablets.[199]

100. As explained in section 3.E.IV of the Decision, skinny label hydrocortisone tablets were first launched in October 2015 (by Alissa with 10mg tablets). The reaction of customers and suppliers to the availability of skinny label tablets confirmed what had been expected – that there was demand for skinny label tablets and that customers would switch to using skinny label tablets. There was no change in market conditions beyond the fact that

[195] Document 202742, email from [AMCo Senior Employee 6] to [✂] dated 6 November 2014 (emphasis added).
[196] Document 202934, email from [AMCo Senior Employee 3] to [✂] and [✂] dated 2 February 2015.
[197] Document 200456, email from [✂] to [Focus Senior Employee 1] dated 9 December 2015.
[198] Document 201513, transcript of interview with [AMCo Senior Employee 4] dated 23 October 2017 pages 41 and 42, lines 19-26 and 1-2, respectively.
[199] Document 204922, AMCo's RSSO, section 3.L. See also Document 204967, Cinven's RSSO, paragraphs 1.14.(i), 3.2 (a), 3.96 and 10.7.(b).

skinny label tablets had launched and as a result the uncertainty over how much demand there would be for skinny label tablets was now being tested.

101. Market participants contacted by the CMA following the parties' representations confirmed that the market would have reacted in the same way had skinny label tablets been launched earlier than October 2015 (eg in 2013 or 2014). Price was generally acknowledged as an important factor in determining successful entry:

a. Alissa explained that it '*would have entered the market in the same way had it launched 9 months earlier. The only difference between entering sooner or later might have been the price*'.[200] Alissa added that it '*would have liked to have launched its skinny label hydrocortisone tablet earlier. There were no doubts that there would have been a market for the product if an earlier launch had occurred (for example in 2013, 2014 or 2015)*'.[201]

b. Resolution Chemicals explained that *'there would have been no reason why successful entry with a skinny label tablet could not have occurred earlier (for example in 2013, 2014 or 2015). The key issue to ensuring successful entry would have been offering a competitive price'*. Resolution also confirmed that it '*would have liked to have been able to launch its product much sooner than it did*' since '*being the first entrant would have enabled Resolution to take market share without needing to compete as aggressively on price*'.[202]

c. DE Pharma explained that '*demand for skinny label tablets would have evolved in exactly the same way if there had been earlier entry. The key issue would have been price. As long as skinny label hydrocortisone tablets were cheaper than Actavis/Accord's price there would have been buyers for them*'.[203]

d. Mawdsleys explained that the '*strategy would have been very similar if skinny label tablets had been available earlier (i.e. in 2014 or 2013)'* and that *'[i]f the product was bought on a sale or return basis then there*

[200] Document 206124, note of call between the CMA and [Alissa Senior Employee] of 23 December 2020, paragraph 15.
[201] Document 206413, note of call between the CMA and [✂] (Alissa) of 22 February 2021, paragraph 2.5 (emphasis added).
[202] Document 206344, note of call between the CMA and Resolution Chemicals of 4 March 2021 (emphasis added).
[203] Document 206579, note of call between the CMA and DE Pharma of 23 February 2021, paragraph 2.11.

would have been no risk for Mawdsleys in selling skinny label tablets'.[204]

e. Sigma Pharmaceuticals explained '*that there would have been nothing stopping Sigma from buying skinny label tablets if they had been available in the market earlier than when Alissa first entered*'.[205]

f. Day Lewis explained that it '*would have had no issues with purchasing 10mg skinny label tablets at an earlier time had they been available*' and that '*[t]he only reason that Day Lewis had not purchased skinny label hydrocortisone tablets earlier is because they were not on the market*'.[206]

102. As explained in Annex D.I.e above, from March 2015 onwards AMCo monitored the prospect of Alissa entering with its skinny label 10mg tablets, noting that this would make it difficult to continue increasing prices for the full label Auden tablets AMCo was selling.[207] As explained in section 3.F.III.q of the Decision, AMCo's observation of further independent entry to the market following Alissa's launch in October 2015 led it to the conclusion that: '*We cannot delay any longer as we […] have more arrivals entering the market, have our own agreement up for renewal in the summer, are starting to find it a little tougher to sell […].*'[208] What finally motivated AMCo to launch its skinny label 10mg tablets was therefore the scale of independent entry, which undermined the rationale for the 10mg Agreement and the '*market stability*'[209] on which it depended.

V. Representations on the CMA's approach to gathering evidence on market demand

103. Following the parties' representations that there was no demand for skinny label hydrocortisone tablets until April 2016 and that demand had suddenly materialised at that point in time the CMA approached market participants to clarify their previous responses to formal information requests and contemporaneous documents.

104. The CMA conducted this further information gathering exercise for completeness only. As explained in Annex D.I above, the extensive contemporaneous evidence contradicts the parties' submissions on this

[204] Document 206612, note of call between the CMA and Mawdsleys of 3 March 2021, paragraph 2.9.
[205] Document 206582, note of call between the CMA and Sigma Pharmaceuticals of 4 March 2021, paragraph 2.6.
[206] Document 206418, note of call between the CMA and Day Lewis of 8 February 2021, paragraph 3.2.
[207] See, for example, Document 202792, email from [AMCo Employee] to [AMCo Senior Employee 1] dated 17 March 2015.
[208] Document 202856, email from [AMCo Senior Employee 3] to [AMCo Senior Employee 1] dated 9 March 2016.
[209] Document 202847, email from [AMCo Senior Employee 3] to [AMCo Employee] dated 1 March 2016.

point. Moreover, the parties have not provided evidence that undermines that contemporaneous evidence. Nonetheless, the CMA conducted voluntary interviews with numerous market participants to clarify whether in their view there would have been demand for skinny label tablets prior to Alissa's entry in October 2015. The evidence they provided – that there would have been such demand – is summarised in Annexes D.II, III and IV above and was disclosed to the parties through the 2021 letter of facts.

105. In their representations on the letter of facts, the parties submitted that this further evidence could not be relied upon by the CMA, because:

a. It was provided *ex post* and was therefore hearsay.

b. It was provided in voluntary interviews rather than under the CMA's formal powers and recorded in call notes rather than verbatim transcripts.

c. It was obtained following a selective approach to evidence gathering, in which the CMA had sought inculpatory evidence but not exculpatory evidence.[210]

106. The CMA rejects these representations.

107. First, the CMA does not rely on the *ex post* accounts of market participants summarised in Annexes D.II, III and IV above in isolation. The evidential value of those accounts lies in the fact that they are consistent with and corroborate the extensive contemporaneous evidence discussed in Annex D.I above. In contrast, the parties' submissions on the issue of market demand are inconsistent, both in themselves and with the evidence, whether contemporaneous or *ex post*.

108. Second, the CMA is not required to conduct all evidence gathering under its formal powers. The CMA could not have used its formal power to compel answers to questions under section 26A of the Act in this instance since that power applies only to individuals connected to undertakings under investigation. The CMA therefore conducted voluntary interviews with market participants. That those interviews were not recorded in verbatim transcripts does not mean the notes that record them have no probative value. The notes were agreed with the participants as an accurate reflection of the calls before they were placed on the file and disclosed to the parties. AMCo's submission that because the information gathering was not conducted under

[210] Document 206670, AMCo's RLOF, paragraphs 3.9-3.13. Document 206667, Auden/Actavis's RLOF, paragraphs 1.3, 1.5 and 2.1-2.10. Document 206665, Cinven's RLOF, paragraphs 2.1-2.3 and 2.10-2.15. Document 206661, Waymade's RLOF, paragraphs 1.2-1.3.

formal powers, there was no requirement for the participants to ensure the information they provided was not false or misleading,[211] is wrong. The offence of providing false or misleading information to the CMA in section 44 of the Act applies in connection with any function of the CMA under the UK's antitrust regime. It applies equally to information provided voluntarily as to information required under formal powers.

109. Third, the CMA's approach was not selective or designed to elicit only inculpatory evidence. The questions the CMA asked market participants were prompted by the evidence they had previously provided, contemporaneous documents and the parties' representations.

VI. Conclusions on demand for skinny label hydrocortisone tablets

110. The evidence, both contemporaneous and *ex post*, therefore refutes the parties' submissions that there was no demand for skinny label hydrocortisone tablets prior to April 2016.

111. In any event, even if those representations were accepted, this would not undermine the CMA's findings that AMCo and Waymade were potential competitors of Auden/Actavis when they were party to the 10mg Agreement and that the 10mg Agreement had the object of preventing, restricting or distorting competition:

a. Waymade and AMCo clearly exerted competitive leverage over Auden/Actavis, as demonstrated in particular by Auden/Actavis's willingness to supply them with 10mg hydrocortisone tablets at a 97% discount to its other customers.

b. Uncertainty as to how a new entrant will fare when it enters the market is inherent in free and genuine competition. Undertakings are not permitted to substitute the certainty of cooperation for the uncertainty of competition.

[211] Document 206670, AMCo's RLOF, paragraph 3.11.

ANNEX E

Summary penalty calculations

1. The following summary penalty tables are to be read in conjunction with section 10 of the Decision which sets out which parties are liable for each of the penalties.

Table 1: Penalty calculation for Auden/Actavis for the 10mg Unfair Pricing Abuse

Step	Description	10mg Unfair Pricing Abuse Penalty Calculation			
1	Starting point as a percentage of relevant turnover	Relevant turnover	£17,058,504		
		Starting point percentage	30%		
	Penalty at the end of Step 1 (starting point)	£5,117,551			
2	Adjustment for duration	x 10.0			
	Penalty at the end of Step 2	£51,175,512			
3	Aggravating factor: Director involvement	15%			
	Mitigating factor: Compliance discount	-5%			
	Penalty at the end of Step 3	£56,293,063			
4	Allocation of step 3 penalty to ownership periods based on step 2 duration:	Period A1 & Period A3 (Accord-UK)	Period A2 (Accord-UK, Allergan)	Period A4 (Accord-UK, Accord, Intas)	Total
	Step 4 Penalty per ownership period after allocation	£40,643,592	£6,755,168	£8,894,304	£56,293,063
	Step 4 adjustment for specific deterrence and proportionality				
	Adjustment for specific deterrence and proportionality	£47,006,408	£67,544,832[212]	£35,505,696	
	Penalty per ownership period at the end of Step 4	£87,650,000	£74,300,000	£44,400,000	£206,350,000
5	Adjustment to take account of the statutory cap	-£59,271,700	N/A	N/A	
	Penalty at the end of Step 5	£28,378,300	£74,300,000	£44,400,000	£147,078,300
6	Leniency discount	N/A	N/A	N/A	
	Settlement discount	N/A	N/A	N/A	
	Penalty payable	£28,378,300	£74,300,000	£44,400,000	£147,078,300

[212] N.B.: from this point the calculation relates only to Allergan, as Accord-UK's penalty for period A2 is reduced to zero at step 5 as a result of which the CMA did not consider it necessary to conduct a separate step 4 analysis for Accord-UK.

Table 2: Penalty calculation for Auden/Actavis for the 20mg Unfair Pricing Abuse

Step	Description	20mg Unfair Pricing Abuse Penalty Calculation		
1	Starting point as a percentage of relevant turnover	Relevant turnover		£2,606,883
		Starting point percentage		30%
	Penalty at the end of Step 1 (starting point)	£782,065		
2	Adjustment for duration	x8.25		
	Penalty at the end of Step 2	£6,452,035		
3	Aggravating factor: Director involvement	15%		
	Mitigating factor: Compliance discount	-5%		
	Penalty at the end of Step 3	£7,097,239		
4	Allocation of step 3 penalty to ownership periods based on step 2 duration:	Period B1 & Period B3 (Accord-UK)	Period B2 (Accord-UK, Allergan)	Total
	Penalty per ownership period after allocation	£6,082,119	£1,015,120	£7,097,239
	Step 4 adjustment for specific deterrence and proportionality			
	Adjustment for specific deterrence and proportionality	£0	£984,880	
	Penalty per ownership period at the end of Step 4	£6,082,119	£2,000,000	£8,082,119
5	Adjustment to take account of the statutory cap	N/A	N/A	
	Penalty at the end of Step 5	£6,082,119	£2,000,000	£8,082,119
6	Leniency discount	N/A	N/A	
	Settlement discount	N/A	N/A	
	Penalty payable	£6,082,119	£2,000,000	£8,082,119

Table 3: Penalty calculation for Auden/Actavis for the 10mg and 20mg Agreements

Step	Description	10mg Agreements Penalty Calculation			20mg Agreements Penalty Calculation
1	Starting point as a percentage of relevant turnover	Relevant turnover		£48,464,781	£2,120,095
		Starting point percentage		30%	30%
	Penalty at the end of Step 1 (starting point)	£14,539,434			£636,029
2	Adjustment for duration	x3.75			x4.0
	Penalty at the end of Step 2	£54,522,879			£2,544,114
3	Aggravating factor: Director involvement	15%			15%
	Mitigating factor: Compliance discount	-5%			-5%
	Penalty at the end of Step 3	£59,975,166			£2,798,525
4	Allocation of step 3 penalty to ownership periods based on step 2 duration:	Period C1 & Period C3 (Accord-UK)	Period C2 (Accord-UK/Allergan)	Total	N/A (Accord-UK)
	Penalty per ownership period after allocation	£42,542,385	£17,432,782	£59,975,166	£2,798,525
	Step 4 adjustment for specific deterrence and proportionality				
	Adjustment for specific deterrence and proportionality	£0	£17,367,218[213]		£0
	Penalty per ownership period at the end of Step 4	£42,542,385	£34,800,000	£77,342,385	£2,798,525
5	Adjustment to take account of the statutory cap	-£14,164,085	N/A		N/A
	Penalty at the end of Step 5	£28,378,300	£34,800,000	£63,178,00	£2,798,525

6	Leniency discount	N/A	N/A		N/A
	Settlement discount	N/A	N/A		N/A
	Penalty payable	£28,378,300	£34,800,000	£63,178,300	£2,798,525

[213] N.B.: from this point the calculation relates only to Allergan, as Accord-UK's penalty for period A2 is reduced to zero at step 5 as a result of which the CMA did not consider it necessary to conduct a separate step 4 analysis for Accord-UK.

Table 4: Penalty calculation for AMCo for the 10mg Agreement

<table>
<tr><th>Step</th><th colspan="2">Description</th><th colspan="3">10mg Agreement Calculation</th></tr>
<tr><td rowspan="2">1</td><td rowspan="2">Starting point as a percentage of relevant turnover</td><td>Relevant turnover</td><td>£738,030[214]</td><td colspan="2">£8,347,516</td></tr>
<tr><td>Starting point percentage</td><td>30%</td><td colspan="2">30%</td></tr>
<tr><td></td><td colspan="2">Penalty at the end of Step 1 (starting point)</td><td>£221,409</td><td colspan="2">£2,504,255</td></tr>
<tr><td>2</td><td colspan="2">Adjustment for duration</td><td>x1.0</td><td colspan="2">3.75x</td></tr>
<tr><td></td><td colspan="2">Penalty at the end of Step 2</td><td>£221,409</td><td colspan="2">£9,390,956</td></tr>
<tr><td>3</td><td colspan="2">Aggravating factor: Director involvement</td><td>15%</td><td colspan="2">15%</td></tr>
<tr><td></td><td colspan="2">Mitigating factor: Compliance discount</td><td>-5%</td><td colspan="2">-5% (Advanz and the Amdipharm Companies only - applied after allocation of the penalty to the different ownership periods at the start of Step 4)</td></tr>
<tr><td>4</td><td colspan="2">Allocation of Step 3 penalty to ownership periods based step 2 duration</td><td>Period D1 (Amdipharm UK Limited)</td><td>Period D2 (The Amdipharm Companies/The Cinven Entities)</td><td>Period D3 (The Amdipharm Companies/Advanz)</td></tr>
<tr><td></td><td colspan="2">Penalty per ownership period after allocation, including step 3 Director involvement uplift (15%)</td><td>£254,620</td><td>£8,783,674</td><td>£2,015,925</td></tr>
<tr><td></td><td colspan="2">Additional step 3 compliance discount for Advanz and the Amdipharm Companies (-5%)</td><td>-£11,070</td><td>Cinven: N/A
The Amdipharm Companies:
-£381,899</td><td>-£87,649</td></tr>
<tr><td></td><td colspan="2">Penalty after applying Compliance Discount</td><td>£243,550</td><td>Cinven: £8,783,674
The Amdipharm Companies: £8,401,775</td><td>£1,928,276</td></tr>
</table>

[214] Amdipharm UK Limited and Waymade plc are jointly and severally liable for Period D1 during which they together formed part of the Waymade undertaking, which is why a different relevant turnover applies to this period.

	Step 4 adjustment for specific deterrence and proportionality			
	Adjustment for specific deterrence and proportionality	N/A	Cinven: £26,316,326 --- The Amdipharm Companies: £5,758,225	£5,771,724
	Penalty per ownership period at the end of Step 4	£243,550	Cinven: £35,100,000 Of which the Amdipharm Companies are jointly and severally liable for £14,160,000	£7,700,000
5	Adjustment to take account of the statutory cap	-£243,550	N/A	N/A
	Penalty at the end of Step 5	£0	£35,100,000 Of which the Amdipharm Companies are jointly and severally liable for £14,160,000	£7,700,000
6	Leniency discount	N/A	N/A	N/A
	Settlement discount	N/A	N/A	N/A
	Penalty payable	£0	£35,100,000 Of which the Amdipharm Companies are jointly and severally liable for £14,160,000	£7,700,000

Table 5: Penalty calculations for Waymade for the 10mg and 20mg Agreements

Step	Description		20mg Agreement Calculation	10mg Agreement Calculation
1	Starting point as a percentage of relevant turnover	Relevant turnover	£822,958	£738,030
		Starting point percentage	30%	30%
	Penalty at the end of Step 1 (starting point)		£246,887	£221,409
2	Adjustment for duration		x4.0	x1.0
	Penalty at the end of Step 2		£987,550	£221,409
3	Aggravating factor: Director involvement		15%	15%
	Mitigating factor: Compliance discount		N/A	N/A
	Penalty at the end of Step 3		£1,135,682	£254,620
4	Step 4 adjustment for specific deterrence and proportionality			
	Adjustment for specific deterrence and proportionality		£1,064,318	£0
	Penalty at the end of Step 4		£2,200,000	£254,620
5	Adjustment to take account of the statutory cap		N/A	N/A
	Penalty at the end of Step 5		£2,200,000	£254,620
6	Leniency discount		N/A	N/A
	Settlement discount		N/A	N/A
	Penalty payable		£2,200,000	£254,620

ANNEX F

Representations on step 4 of the penalties calculations

I. The parties' representations on the CMA's approach to financial benefit and specific deterrence at step 4 penalties

a. The parties' representations: approach to financial benefit

1. Cinven and AMCo argued that the CMA was not entitled to have regard to the '*gains'* made from the Infringement when considering an uplift to the penalty at step 4.[215]

2. AMCo and Cinven argued that it is wrong for the CMA to seek to '*disgorge*' profits, due to the risk of double jeopardy if the NHS pursues a damages claim. They argued that by having regard to the '*gains*' the CMA was stepping into the shoes of potential damages claimants in private litigation; and that this was particularly inappropriate where such claimants (in this case the NHS/DHSC) were also '*organs of the State*'.[216] AMCo also argued that '*the CMA is not a claimant in a follow-on damages action and it is wrong in principle for the CMA to conduct itself as one*', which it said could lead to double recovery and would be '*improper, disproportionate and unfair*'. [217]

3. Cinven asserted that the CMA cannot pursue a '*damages*' or '*restitutionary*' approach without having done such analysis (citing *Napp*).[218] Cinven also submitted that, even if the CMA's approach is not wrong in principle, the CMA cannot assess a penalty on the basis of a '*restitutionary approach*' without having assessed how prices would have evolved absent the 10mg Agreement (see below).[219]

4. In seeking to draw a comparison between a private damages action and the appropriate level of a penalty, Cinven and AMCo misrepresent the different roles each of private and public enforcement of competition law play. The CMA's role in imposing a penalty where a serious infringement has occurred is to punish and deter the infringing undertakings.[220] In calculating a penalty, Parliament has required the CMA to have regard to the seriousness of the infringement and the desirability of deterring both the undertaking on whom the penalty is imposed and others from entering into anti-competitive agreements and engaging in abuses of a dominant position.[221] As explained

[215] Document 205805, Cinven's RDPS, paragraphs 3.56 to 3.59.
[216] Document 205805, Cinven's RDPS, paragraphs 1.20, 3.56 to 58.
[217] Document 205848, AMCo's RDPS, paragraph 7.66; Document 205805, Cinven's RDPS, paragraph 3.58.
[218] Document 205805, Cinven's RDPS, paragraphs 3.60 to 3.64.
[219] Document 205805, Cinven's RDPS, paragraphs 3.59 and 3.60 to 3.64.
[220] *Kier Group v OFT* [2011] CAT 3, paragraph 166.
[221] The Act, section 36(7A).

at section 10.C.III of the Decision, in order to set the penalty at a level that will deter the undertaking in question and others, it is necessary that the penalty is not lower than the financial benefits achieved from the infringement. It is not relevant in this respect that the NHS and DHSC may be able to claim damages at a later point in time. Damages actions and the imposition of penalties pursue different outcomes: damages are compensatory in nature, whilst penalties seek to reflect the seriousness of the infringement and deter the infringing undertakings and other undertakings from engaging in future anti-competitive conduct. Any damages specifically related to the Agreements would be calculated in a different way to how the CMA has established the certain financial benefits Waymade and AMCo generated from the Agreements for the purposes of imposing penalties. These arguments are therefore dismissed.

5. As explained at section 10.C of the Decision the CMA penalties guidance specifically states that the CMA may have regard to the economic or financial benefit from the infringement when considering whether an increase in the penalty at step 4 may be appropriate. Similarly, the European Commission's Fining Guidelines also provide that in setting penalties and in particular when considering a specific increase for deterrence, the Commission will take into account '*the need to increase the fine in order to exceed the amount of gains improperly made as a result of the infringement where it is possible to estimate that amount.*'[222]

6. Cinven and AMCo's arguments which stated that the CMA has taken an unjustified approach to recovering the financial benefits are based on the wrong assumption that the CMA is taking a '*disgorgement*', '*damages*' or '*restitutionary*' approach to the penalties for the 10mg Agreement. The CMA has taken into account a number of considerations in calculating the penalties, including that the penalty should not be lower than the financial benefits the parties generated under the Agreements in order to deter the parties and other undertakings from committing infringements of competition law again in the future. This consideration of financial benefit is not restitutionary in nature.

7. Distributing the fine in proportion to the minimum direct benefit from the Infringement, and assessing by reference to that benefit whether an uplift to the fine is required, ensures that '*the link between culpability and the*

[222] Guidelines on the method of setting fines imposed pursuant to Article 23(2)(a) of Regulation No 1/2003, paragraph 31.

deterrent element in the penalty' is maintained.[223] This is a necessary part of calculating an effective fine. As the Court of Justice has noted:

> *'it follows from the case-law of the Court of Justice that the profit which the undertakings were able to derive from their practices is one of the factors to be considered in assessing the gravity of the infringement and that taking that factor into account is designed to ensure that the fine is deterrent.… It follows that … the basic amount will be increased where on an objective estimate of such improper gains it can be established that the level of the basic amount is insufficient to neutralise the profit which an undertaking derives from the infringement.*'[224]

8. By contrast, it is for the NHS/DHSC, as the end customer and sufferer of loss as a result, to sue for damages. There is no risk of '*double-recovery*': only the NHS/DHSC would be seeking to '*recover*' a loss. Fines imposed by the CMA are paid into the Consolidated Fund and not directly to the DHSC or the NHS.

9. In any event, private litigation (including whether a claim is brought at all, against which of the Parties, the likelihood of success and the quantum of any resulting damages) is inherently remote and uncertain. For example, even when an infringement is accepted to have occurred, in order to recover compensatory damages a claimant must still prove its loss and a direct link between the infringement and that loss.[225] In the CMA's view it would be inappropriate to rely on private litigation to achieve deterrence.

10. That does not change because the potential claimant in a follow-on damages action in this case would be the NHS, and therefore '*the State*'.[226]

11. In its submission Cinven argued that having regard to the gains from the 10mg Agreement was '*not supported by the CMA's statutory powers*' (notwithstanding that the CMA's penalties guidance specifically refers to it), citing *Genzyme*.[227]

12. The CMA rejects this argument. In *Genzyme* the CAT stated:

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[223] *Kier Group v OFT* [2011] CAT 3, paragraphs 174-175.
[224] C-189/02 P *Dansk Rorindustrie v Commission*, EUC:2005:408, paragraphs 292 to 294. See also paragraph 242: the factors relevant to assessing the gravity of an infringement include '*the conduct of each of the undertakings, the role played by each of them*' in the infringement and '*the profit which they were able to derive from those practices*'.
[225] C-199/11 *Europese Gemeenschap v Otis NV*, EU:C:2012:684, paragraphs 65 to 66.
[226] Compare C-199/11 *Europese Gemeenschap v Otis NV*, EU:C:2012:684: the European Commission is not precluded from bringing a damages action before a national court in relation to loss caused to the European Union by a competition law infringement.
[227] Document 205805, Cinven's RDPS, paragraph 3.56.

> *'the penalty is not to be fixed in terms of the 'gain' to the infringing party, but in terms of the sanction appropriate for the conduct, having regard to the need for deterrence'.*[228]

13. As authority for that statement the CAT cited *Napp v OFT*, paragraphs 507 to 509. In those paragraphs of *Napp*, the CAT had stated that '*We sympathise with the Director's intentions in increasing the penalty … by an amount representing Napp's 'gain' during the period of the infringement'*; but noted that in the context of that specific case, it was difficult to calculate that gain on a verifiable basis: this involved assessing the rate at which Napp would have lost market share if it had not priced below cost (involving various other assumptions such as the effects of tax rates over time). The CAT considered that '*The fixing of the penalty under section 36 of the Act should in our view be done by methods which are as simple as possible, and easily verifiable by the Tribunal*'.[229]

14. Ultimately, the CAT declined to approach the penalty by reference to financial gain because it was liable to understate the amount of the gain, resulting in a penalty without an effective deterrent:

> *'it seems to us that an arithmetical calculation of the 'gain' during the period of the infringement, of the kind carried out here, is likely to understate the real commercial gain from the infringing conduct, and thus risk being an ineffective penalty'.*[230]

15. The CAT's primary concern was therefore not whether having regard to the gain from the infringement was in itself a legitimate approach; but whether in the particular case, this resulted in an ineffective penalty because of the difficulties of calculating that gain (the CAT stated at paragraph 510 that this factor was the most significant in its conclusions). The CAT's concern was that the resulting penalty might be ineffective at achieving deterrence because it was in fact lower than the real gain from the infringement, which could not easily be quantified given the additional benefit to a dominant undertaking from predatory pricing that lies in '*the long-term strategic advantage of protecting a monopoly market share and the profits that flow from it for as many years as possible.*'[231]

16. The CAT's statement in *Genzyme* paragraph 706 was prompted by the same concerns (hence the CAT's citation of *Napp*): it prefaced that statement by the fact that '*In this case, as a result of the OFT's intervention,*

[228] *Genzyme Limited v OFT* [2004] CAT 4, paragraph 706.
[229] *Napp Pharmaceutical Holdings Limited v OFT* [2002] CAT 1, paragraphs 507 and 508.
[230] *Napp Pharmaceutical Holdings Limited v OFT* [2002] CAT 1, paragraph 510.
[231] *Napp Pharmaceutical Holdings Limited v OFT* [2002] CAT 1, paragraph 510.

it is difficult to show that Genzyme has made a significant gain from the infringement' (another exclusionary abuse: margin squeeze facilitated by bundling).[232]

17. The CAT recognised that each case will depend on its own circumstances when it comes to the penalty.[233] The present case is different from *Napp* (and *Genzyme*). As explained above, the minimum gain from the Agreements for Waymade and AMCo can be calculated on the basis of objective and verifiable criteria, which were also the basis of the Commission's *Lundbeck* and *Servier* cases, both specifically upheld by the General Court on the point of calculation of penalties on the basis of the value transfers received by the potential competitors. The CMA is thus able to calculate a sanction appropriate for the conduct, having regard to the need for deterrence. In assessing deterrence the amount of the gain must be relevant, as the CAT assumed in *Napp* and *Genzyme* – there can be no meaningful deterrent if the infringing undertaking makes a net gain from the infringement.

b. The parties' representations on the CMA's approach to financial benefit for the 10mg Agreement.

18. Cinven also submitted representations on the CMA's approach to financial benefit, stating that the CMA's approach overstated any financial benefit they themselves may have derived. Cinven argued both that its financial benefit has been overstated, and that the CMA is wrong to assess financial benefit without having first assessed how prices for 10mg hydrocortisone would have evolved absent the 10mg Agreement. Cinven considered that AMCo would have achieved lower profits under the 10mg Agreement than through independent entry, and that the appropriate comparison is between AMCo's profit under the 10mg Agreement and AMCo's profit if it entered.[234]

19. As section 10.C.III of the Decision explains, the financial benefit from the Agreements has been calculated by reference to the value transfer arising from Auden's supply of heavily discounted packs to AMCo and Waymade (and in the case of the 20mg Agreement also the Buyback). The CMA rejects the arguments from Cinven that these financial benefits are overstated.

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[232] *Genzyme Limited v OFT* [2004] CAT 4, paragraph 704.
[233] *Napp Pharmaceutical Holdings Limited v OFT* [2002] CAT 1, paragraph 535. Compare *Kier Group v OFT* [2011] CAT 3, paragraph 178, in which the CAT noted '*the limited precedent value of other decisions on penalties. Such cases are almost always fact specific*'.
[234] Document 205805, Cinven's RDPS, paragraphs 1.21, and 3.60 to 3.64; Document 206665, Cinven's RLOF, paragraphs 3.9 and 3.34-3.40.

20. Using the payments to the potential competitor has a clear basis in the Commission's pay-for-delay cases and has been upheld by the General Court in Alpharma's appeal in the *Lundbeck* cases. The Commission took into account to ensure deterrence the value transferred to the generics as they had not entered the market so had no relevant turnover in those markets, tying the value transferred to the need to deter. The Commission rejected the argument that it should have excluded profits made by the generic suppliers had they entered the market. In this case, the CMA has used AMCo and Waymade's relevant turnover as they made sales of the Auden/Actavis hydrocortisone tablets and then assessed whether a further uplift is required on the basis of the need to deter and the considerable size of the undertakings, which is consistent with the principles applied by the Commission.

21. The General Court has also already had occasion to rule on the appropriateness of using the payments to the potential competitor as the basis for calculating penalties over a hypothetical amount based on what the potential competitor may have made had it entered the market independently (which Cinven submits would be more appropriate). For example, in *Unichem* the General Court stated:[235]

> *'the amount of the value transfers, regarded as inducive, which Niche received under the Agreement, provides a better estimate of the profits that Niche obtained from its participation in the infringement than the value of the projected sales that it would have made during the infringement period if it had not participated in that infringement.*
>
> *In addition, the amount of the value transfer ultimately used in the Agreement is, as is apparent from paragraph 463 above, the result of a negotiation in which Niche participated. Accordingly, it is a better reflection of Niche's conduct and the role that it played in the infringement than the method proposed by the applicant, which is based on the value of sales that were not made during the infringement*.
>
> *Lastly, the method proposed by the applicant does not reflect the economic significance of the infringement as adequately as the Commission's method. The applicant's method is based on the price of the perindopril that the generic company would have sold if it had entered the market, whereas the economic significance of the infringement depends, to a large extent, on the — in principle, higher —*

[235] T-705/14 *Unichem v Commission*, paragraphs 465 to 467.

price of perindopril sold by the originator company during the infringement period. The economic significance of the infringement is therefore reflected more adequately in the amount of the fine through the method used by the Commission, since the parties necessarily took into account the maintenance of the price of perindopril in order to evaluate the amount of the value transfer to be granted to Niche.'

22. The General Court added in the same case:[236]

'…it would be paradoxical to establish the amount of the fine to be imposed on the generic company excluded from the market on the basis of the value, even estimated, of its sales, since the infringement consists precisely, for that company, in not selling its products. The use of a method of calculating the fine based on that value therefore would not adequately take into account the nature of the infringement in question'.

23. The facts of the Commission's cases were different from those at issue in the present case: Waymade and AMCo did generate turnover in the relevant market by selling the packs that Auden supplied to them at a large discount. As a result, the CMA is able at step 1 of the penalty calculation to use that turnover as a starting point for its calculation, whereas the Commission was unable to do so. The CMA has then taken into account at step 4 that the parties made a significant financial benefit from the Agreements over and above the amount arrived at after the first three steps of its calculation. Nonetheless, the comments from the General Court on why it is inappropriate to take into account the profits that would have been achieved had the potential competitor entered the market independently apply equally to Waymade and AMCo.

24. Waymade and AMCo generated certain profits under the Agreements, whereas the profits they would have made had they independently entered the market instead of entering into the Agreements are inherently uncertain.[237] The need to set the penalty at a level that deters the undertakings involved in the infringement justifies the fact that its amount is not less than the amount of the value transfer inducement provided for in the agreement.[238]

25. Therefore, in setting the penalty for the Agreements, with respect to which it is clear what financial benefits Waymade and AMCo generated under them,

[236] T-705/14 *Unichem v Commission*, paragraph 479.
[237] As confirmed by the General Court in T-705/14 *Unichem v Commission*, paragraph 500 and 501.
[238] T-705/14 *Unichem v Commission*, paragraph 502.

it would not be appropriate to take into account the profits these undertakings would have made had they entered the market independently.

26. AMCo submitted that the CMA had erred in measuring financial benefit for Periods D1-D3 on the basis that the CMA did not hold AMCo liable for the 10mg Agreement prior to 1 January 2013.[239] This is a misstatement of the CMA's case: the CMA has found that Amdipharm UK Limited is liable for the 10mg Agreement from 23 October 2012 onwards (see section 9 of the Decision). The CMA has therefore measured financial benefit for all three Periods.

27. AMCo further submitted that there is *'no proper basis'* on which the CMA may attribute joint and several liability to AMCo for Period D2 and any financial benefit for this Period would have been felt by Cinven alone.[240] This representation cannot be sustained: the Amdipharm Companies are jointly and severally liable for Period D2 for the reasons set out in section 9 and financial benefit has been assessed consistently with the approach set out in section 10.C.

c. The parties' representations on the CMA's approach to financial benefit for the 20mg Agreement

28. Waymade disputed the CMA's approach to financial benefit for the 20mg Agreements penalty, on the basis it overstated any financial benefit that Waymade itself may have derived, arguing that its own financial benefit for the 20mg Agreement should be net of the investment costs required to get 20mg hydrocortisone tablets to the stage of being a 'threat to entry'.[241]

29. The CMA rejects this submission. A similar argument was raised by Alpharma in the *Lundbeck* case,[242] and dismissed by the General Court. The General Court stated:

> *'… as regards the applicants' argument that it is necessary to deduct from the amount paid by Lundbeck the costs which the Alpharma group had incurred, in particular USD 3.9 million, corresponding to EUR 3.7 million, in buying or ordering citalopram, it must first of all be noted that those costs were not incurred for the purposes of the conclusion of the*

[239] Document 205848, AMCo's RDPS, paragraph 7.65
[240] Document 205848, AMCo's RDPS, paragraph 7.67
[241] Document 205799, Waymade's RDPS, paragraph 3.60 to 66
[242] T-471/13 *Alpharma v Commission,* paragraphs 290 and 428.

agreement at issue; consequently they are not to be deducted from the profit which the agreement generated for the group'.[243]

30. Further down in the same judgment, the General Court added:

'…the purpose of a fine is not simply to remove the benefits that an undertaking has obtained through its anticompetitive conduct, but also to deter that undertaking and other undertakings from engaging in such conduct. Thus, even assuming that, in not deducting the costs in question from the amount of EUR 11.7 million, the Commission imposed a fine which exceeded the net gain for the Alpharma group from the agreement at issue, that fine would nonetheless not be disproportionate. Furthermore, as the Commission stated in recital 1371 of the contested decision, the costs which that group had incurred were related to market entry rather than to conclusion of the agreement at issue; there was consequently no direct link between those costs and the amount of Lundbeck's payments'.[244]

31. The costs incurred by Waymade to develop its own 20mg product were related to market entry and not to the conclusion of the Agreements. It would not be appropriate to deduct them from the financial benefit Waymade generated from the Agreements when calculating Waymade's penalties.

II. The parties' representations on uplifts for size and financial position

32. Allergan submitted that a specific deterrence uplift is not justified on the basis that most of its turnover is derived from its business in the US, where there is no offence of excessive pricing, and that the CMA's reliance on Allergan's global turnover as justification for applying a specific deterrence uplift is erroneous.[245] Accord-UK made similar assertions with respect to both Allergan's and Intas' ownership periods.[246] Cinven submitted that the Commission has previously issued much lower fines and deterrence uplifts for serious infringements by undertakings with substantial out-of-market turnover (citing *Fentanyl* and *Power Cables*), and argue that turnover outside the jurisdiction is not a sufficient basis for the CMA's proposed uplift.[247]

33. Waymade submitted that a specific deterrence uplift is not required because Waymade is a small company with relatively small turnover.[248] AMCo

[243] T-471/13 *Alpharma v Commission,* paragraph 297.
[244] T-471/13 *Alpharma v Commission,* paragraph 429.
[245] Document 205791, Allergan's RDPS, paragraphs 55 (c), 63 to 68(a).
[246] Document 205813, Accord-UK's RDPS, paragraphs 1.15.1, 10.9.7, 10.26 to 10.27.
[247] Document 205805, Cinven's RDPS, paragraph 3.69.
[248] Document 205799, Waymade's RDPS, paragraph 3.56.

submitted that the CMA has materially overstated its financial position, and therefore that the specific deterrence uplift proposed is not required.[249]

34. These assertions are misplaced. The reason that the CMA's penalties guidance provides that step 4 is assessed by reference to an undertaking's worldwide turnover is to ensure that the penalty is sufficient to deter the specific undertaking: if only a fraction of worldwide turnover was used then the penalty would not sufficiently deter.

35. With respect to Waymade's submission, the size of an undertaking does not of itself determine whether a specific deterrence uplift is appropriate. The purpose of specific deterrence is to deter the undertaking in question from committing future infringements of competition law. All undertakings, irrespective of their size, can commit infringements of competition law. Specific deterrence is therefore a relevant consideration for the CMA in all cases, irrespective of the size of the infringing undertaking. The CMA has calculated all penalties in this case by reference to the specific facts of the case and the specific circumstances of each undertaking held liable for the penalties imposed.[250]

III. The parties' representations on relative size of uplifts set out in the 2020 DPSs

36. In the 2020 DPSs the CMA expressed the step 4 uplifts necessary to achieve specific deterrence in percentage terms. Accord-UK, Allergan, Intas, Waymade, Cinven and AMCo submitted that the Step 4 uplift percentages set out in the Draft Penalty Statements were disproportionately high in absolute terms, when compared to the level of financial benefit or when compared to the parties' respective financial indicators.[251]

37. Percentage uplifts are not particularly meaningful reference points in this case, considering the level of uplift required to ensure that the undertakings do not derive a financial benefit from the Infringements and the fact that the relevant turnover used in some of the penalty calculations is not an accurate representation of the scale of the infringing activity.

38. For example, uplifts of over 100% and 400% are necessary simply to ensure no financial benefit is earned from the infringements relating to periods A1

[249] Document 205848, AMCo's RDPS paragraph 2.24.2
[250] The CMA maintains that a specific deterrence uplift is required for Waymade in this case for the reasons set out in section 10.D.IV.c of the Decision.
[251] Document 205813, Accord-UK's RDPS, paragraph 10.37; Document 205791, Allergan's RDPS paragraphs 74 and 89; Document 205802, Intas/Accord-UK's RDPS paragraphs 86-87 and paragraphs 92-94; Document 205799, Waymade's RDPS, paragraph 3.74; Document 205805 Cinven's RDPS, paragraphs 3.85 and 3.91; Document 205848, AMCo's RDPS paragraphs 7.74 to 7.76.

and A2. While those uplifts may appear high in percentage terms, that is a reflection of the fact that penalties at the end of step 3 would have left these undertakings profiting from the Infringements. The further uplifts applied are a result of the other factors set out in step 4 of the CMA's penalties calculation. These are intended to deter undertakings of the size of Allergan, Intas and Cinven, while being specific to these undertakings' individual characteristics. As a result of percentages not being particularly meaningful, this Decision expresses the penalties at Step 4 in monetary terms rather than percentage uplift terms. Those monetary uplifts have been rounded down to the nearest £0.1million. The uplifts are however in line with the approach taken in the 2020 DPSs, subject to changes explained in the Decision (eg the application of a compliance discount to some but not all parties or a change made in response to representations received on the 2020 DPSs).

39. Each penalty was determined by the CMA having regard to the level of financial benefit, each party's individual size and financial position, and other case specific factors. As explained above, while some of the uplifts may appear high in percentage terms, that is a reflection of the financial benefit from the Infringements, together with the other factors already discussed.

40. With respect to the parties' comparisons between their respective penalties, simple comparisons between the percentage applied to one party and that applied to another are again not meaningful, as they do not take into account the underlying factors on which the uplifts were based. Each penalty was determined by the CMA having regard to the level of financial benefit, each party's individual size and financial position, and other case and party-specific factors. The uplift applied in each case is the result of many different choices made by the CMA as to what factors should be taken into account when setting the penalty in accordance with the framework set out in the CMA penalties guidance. In particular, the uplifts applied at step 4 also reflect the CMA's other case specific considerations set out in section 10.C of the Decision, specifically the overlaps between the Infringements where the CMA has avoided 'double-counting'. The CMA has taken a consistent approach to the penalties and the differences the parties cite in their representations arise as a result of factors specific to each party.

IV. The parties' representations on the CMA's authority for penalties to exceed financial benefit

41. Accord-UK, Intas/Accord-UK, Allergan and Cinven have also submitted that the CMA has no authority for penalties to exceed the level of the financial benefit:

a. Accord-UK stated that '*There is no authority that requires the penalty to cancel out any financial benefit, and nor is there any authority for fines to materially exceed the purported financial benefit.*' As the CMA can identify an '*excess*' in an unfair pricing case, this '*should not permit the CMA to apply its guidance in such a way as to impose 'enormous financial penalties*.'[252]

b. Intas/Accord-UK stated that the CMA has adopted a punitive approach which is not authorised or justified by the CMA's penalties guidance. If punishment is appropriate this is applied at step 1 in the assessment of gravity.[253]

c. Allergan claimed that the CMA has '*narrowly fixed*' on the alleged financial benefits then applied a further uplift.[254]

d. Cinven stated that CMA approach ensuring that the penalty significantly exceeds the estimated financial gain is contrary to its guidance.[255]

e. The parties further argued against the need for penalties to be very substantially above financial benefit.[256]

42. The CMA does not accept these representations. The Act is clear that the CMA must have regard to the desirability of deterring both the undertaking on whom the penalty is imposed and others from infringing the Chapter I and II prohibitions. Deterrence requires that the penalty does not just require the undertaking to repay its unlawful gains. As the General Court explained in *Alpharma*, *'…the purpose of a fine is not simply to remove the benefits that an undertaking has obtained through its anticompetitive conduct, but also to deter that undertaking and other undertakings from engaging in such conduct*'.[257] In its *Almamet* judgment, the General Court further held that a penalty cannot be set at a level which merely negates the profits from the infringement.[258]

43. In addition, the penalties are proportionate: the need for an uplift at step 4 has been assessed on an individual basis, factoring in the financial benefits obtained, the size of the undertakings as they currently exist and the fact that these are serious infringements of competition law.

[252] Document 205813, Accord-UK's RDPS, paragraph 1.15.5
[253] Document 205802, Intas/Accord-UK's RDPS, paragraph 88.
[254] Document 205791, Allergan's RDPS, paragraph 59.
[255] Document 205805, Cinven's RDPS, paragraphs 3.65 to 3.66
[256] Document 205791, Allergan's RDPS, paragraph 61
[257] T-471/13 *Alpharma v Commission,* paragraph 429.
[258] T-410/09 *Almamet v Commission*, paragraph 271.

V. Cinven's representations on the CMA's assessment of its financial indicators

44. Cinven submitted that in assessing indicators of Cinven's size and financial position, the CMA should [✂].[259] [✂].[260]

45. The CMA rejects the submission that it has failed to have proper regard to the nature of Cinven's fund structures.

46. As explained in section 9.B.III.d of the Decision, notwithstanding the complex structures of the core Cinven private equity group and the Fifth Cinven Fund, the Cinven Entities acted as one in relation to their investment in the AMCo Group. The Cinven Entities' argument [✂] [261] [✂]. As explained in that section, this argument focuses on corporate technicalities and ignores the economic reality, which is that the Cinven Entities exercised decisive influence over the Amdipharm Companies during their ownership period.

47. This is illustrated by the Cinven Entities' acknowledgement that '*one or more of the Cinven [Entities] have decisive influence for the purposes of the EU Merger Regulation*'[262] over (and therefore form an undertaking with) the portfolio companies whose financial information is included in these figures. Although the Cinven Entities expressly stated that this did not amount to an admission of decisive influence for the purposes of attributing liability,[263] as explained in section 9.III.d.vi of the Decision the concept of decisive influence in merger control is closely related to that in liability. This was, for example, recognised by the parties, the General Court and the Court of Justice in *Toshiba*.[264]

48. In any event, the Cinven Entities' statement that [✂].[265]

VI. AMCo's representations on the CMA's assessment of Advanz's financial indicators

49. AMCo submitted that the CMA had based its assessment of its size and financial position on inappropriate indicators. In particular, it argued that the CMA should have had regard to its profit and net assets.[266] In support of this argument it quoted the CAT's statement in Kier Group v OFT that '*For most*

[259] Document 205805, Cinven's RDPS, paragraph 3.78.
[260] Document 205805, Cinven's RDPS, paragraphs 1.25, 3.71 to 3.79.
[261] Document 205805, Cinven's RDPS, paragraph 3.73.
[262] Document, 205490B, Cinven's response to the CMA's section 26 notice dated 1 October 2020, paragraph 1.1(a)(ii).
[263] Document 205490B, Cinven's response to the CMA's section 26 notice dated 1 October 2020, paragraph 1.2.
[264] C-623/15 P *Toshiba v Commission.*
[265] See, for example, Document 200512, limited partnership agreement of the Fifth Cinven Fund (No. 1) Limited Partnership, clauses 13.3.1, 13.3.2 and 13.4. Clause 10.2.1 refers to the Fund's investments '*forming part of the Partnership Assets*'.
[266] Document 205848, AMCo's RDPS, paragraph 7.89.

companies profit and cash flow rather than turnover are the key issues, and companies are primarily valued by financial markets, and their directors remunerated, by reference to profit, cash flow and dividend, with turnover being a secondary consideration'.

50. However, AMCo did not quote the remainder of the paragraph: *'However, it has not been suggested by the Present Appellants that profit or profitability should replace turnover for present purposes, nor even that it should necessarily play as central a role. It is simply that it would be wrong not to give consideration to such profit information as is available, along with other relevant factors, when deciding on the appropriate penalty*.'

51. In this case, the CMA has considered such profit information and other indicators for Advanz as are available, relevant and less likely to be distorted by exceptional recent events such as restructurings. In particular, the CMA used Adjusted EBITDA and cashflow from operations as relevant profit measures because of the persistence of exceptional items in Advanz's income statement. The Adjusted EBITDA measure was taken from the Advanz's latest annual report, where it was cited as a 'non-IFRS measure' by which to assess its performance – in layman's terms, a measure that is not distorted by exceptional adjustments but reflects the underlying health of the business. Advanz's operating cash flow is also healthy notwithstanding its low net asset position, and is relevant to understanding Advanz's own financial strength.[267]

52. AMCo also submitted that the CMA has erred by *'not examining the financial position of AMCo by reference to what are for most companies the primary considerations*'[268]. However, as explained above, the CMA examined both these and other financial metrics used by Advanz, and considers that, for Advanz specifically, adjusted EBITDA and cashflow metrics are more meaningful and relevant for the CMA's proportionality assessment than profit after tax and net assets.[269]

VII. Waymade's representations on the CMA's assessment of its financial indicators

53. Waymade made representations on the CMA's approach to its financial indicators, which the CMA does not accept. Waymade argued that the CMA had based its assessment of its size and financial position on inappropriate indicators, in particular that the CMA should have greater regard to prior

[267] Advanz Pharma Corporate Presentation - June 2019 (www.advanzpharma.com/media/uploads/ADVANZ-PHARMA_Corporate-Presentation_June-2019_VF.pdf).
[268] Document 205848, AMCo's RDPS, paragraph 7.84.
[269] See also section 10 of the Decision, footnotes 3881 and 3888

years' turnover, profitability, and the specific circumstances of Waymade's business.[270]

54. However, although Waymade is currently loss-making, it was profitable at the time of the infringement. Furthermore, it became loss-making following the disposal of a profitable part of its business,[271] the proceeds of which were recently paid out as a large one-off dividend in 2019.[272]

55. Waymade also submitted [✂],[273] [✂].[274]

56. However, Waymade's liquidity position would have been substantially higher, had it not paid out a cash dividend of £13.7 million in 2019. Waymade's proportionality and affordability arguments relate to its decision to make a large one-off dividend payment of £13.7 million in 2019. [275]

57. Waymade also submitted that the CMA should have taken into account its cashflow metrics, consistent with its approach to Advanz.[276] The CMA's reasons for using cashflow metrics for Advanz are specific to the circumstances of that particular entity and are explained in section 10.D.IV.b of the Decision.

58. However, CMA also notes that Waymade reported net cashflow from operations of £[✂] in financial year ending 31 December 2020, and average net cashflow from operations of £[✂] for the 3 year period ending 31 December 2020. The CMA does not consider Waymade's penalty to be disproportionate in this context, when considered together with other financial metrics and case specific factors.

VIII. The parties' representations on liability for multiple infringements

59. Each of Accord-UK, Allergan and Waymade have made representations on the CMA's approach to proportionality in the context of imposing multiple penalties, to the effect that the CMA has not accounted properly for the fact that it is imposing multiple penalties and the result is disproportionate:

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[270] Document 205799, Waymade's RDPS, paragraph 3.77.
[271] In December 2014, Waymade sold a significant proportion of its busines to a third party for proceeds of over £15 million. Waymade also divested a property subsidiary, Sovereign House Properties Limited (formerly Waymade UK plc) in December 2018 for proceeds of £1.4million to [✂], at which point control was transferred from Waymade plc to [✂]. It remains part of the Waymade Capital group of companies. See also section 3.A.I of the Decision.
[272] Document 205799, Waymade's RDPS, paragraph 3.76.
[273] [✂] the CMA does not consider this penalty to be disproportionate
[274] Document 205799, Waymade's RDPS, paragraph 3.78.
[275] Waymade also states that the large one-off dividend is not relevant to the CMA's proportionality assessment, because it was not an '*ordinary course dividend*' .(Document 205799, Waymade's RDPS, paragraph 3.76). However, the CMA does not accept this, for the reasons outlined.
[276] Document 205799, Waymade's RDPS, paragraph 3.74.

a. Accord-UK[277], Allergan[278] and Waymade[279] stated that the fines are disproportionate and the CMA had not taken a 'step back' to assess whether the penalty at that level is necessary and proportionate as required by *Kier* and considering the facts of the case and position of the undertaking.

b. Accord-UK[280], Allergan[281] and Waymade[282] stated that the CMA should consider the cumulative impact of the penalties in the proportionality assessment. Waymade stated that following the 'totality' principle from *Kier* the CMA should consider the penalties in aggregate,[283]

c. Accord-UK[284], Allergan[285] and Waymade[286] pointed to the CMA's decisions in *Light Fittings* and *Drawer Wraps* where the CMA carried out a cross check across penalties imposed at the same time to ensure that the total penalty imposed was not disproportionate or excessive.[287]

d. Accord-UK stated that though the CMA has not taken into account twice the financial benefit or deterrence uplifts it has not considered the multiple uplifts in the round.[288]

e. Accord-UK stated that the CMA must consider the sum of the agreements and unfair pricing fines against the financial benefit to assess proportionality, and that had it done so it would have found the scale of the uplift applied jointly and severally to Allergan and Accord-UK for the 10mg Unfair Pricing Abuse in particular (explained in percentage terms as a 1,000% uplift in the 2020 DPS) to have been disproportionate.[289]

f. Allergan submitted there should be no additional uplift for Allergan for its penalty for the 10mg Agreement.[290] Allergan stated that there is no

[277] Document 205813, Accord-UK's RDPS, paragraph 5.11, and section 10.
[278] Document 205791, Allergan's RDPS, paragraphs 55(a), 57 to 59, 75 to 79, and 94 to 97.
[279] Document 205799, Waymade's RDPS, paragraphs 3.55 and 3.83; Document 206661, Waymade's RLOF, paragraph 9.5.
[280] Document 205813, Accord-UK's RDPS, paragraphs 10.49 to 10.51
[281] Document 205791, Allergan's RDPS, paragraph 96(c)
[282] Document 205799, Waymade's RDPS, paragraphs 3.70 to 3.71
[283] Document 205799, Waymade's RDPS, paragraph 3.85. Although Waymade made these representations on the CMA's approach at step 5, these have been dismissed in this Annex. It is settled case law that where multiple penalties are imposed the statutory cap applies separately to each (see T-446/05 Amann & Söhne and Others v Commission, paragraph 94).
[284] Document 205813, Accord-UK's RDPS, paragraph 1.15.7, 10.49 to 10.51
[285] Document 205791, Allergan's RDPS, paragraph 96(c)
[286] Document 205799, Waymade's RDPS, paragraph 3.87
[287] Document 205813, Accord-UK's RDPS, paragraphs 1.15.7, 10.49 to 10.51
[288] Document 205813, Accord-UK's RDPS, paragraphs 10.49 to 10.51
[289] Document 205813, Accord-UK's RDPS, paragraph 1.15.6.
[290] Document 205791, Allergan's RDPS, paragraph 97.

basis for additional uplifts and the CMA should *'take a step back*' at that stage.[291]

g. Accord-UK submitted that the CMA has not accounted properly for the overlaps in product market or duration and '*inherently interconnected*' nature of the infringements. Waymade and Accord-UK pointed to the CMA's market definition findings on a single market for hydrocortisone tablets.[292] Accord-UK submitted that either the CMA should consider these as a single infringement or reduce the penalties to account for overlaps.[293]

h. Accord-UK and Allergan[294] cited *Paroxetine*[295] and *Servier*[296] to state that the CMA should account for the overlaps between the infringements more fully. Accord-UK also cited *Napp*[297] and further cases to argue that the CMA has failed to treat Accord-UK consistently with other companies in equivalent positions by not reducing the relevant turnover nor applying a correction to reflect the overlaps between the infringements:[298]

i. AMCo stated that the CMA is required to take a step back and ask itself whether, in all the circumstances and '*in the round*', AMCo's penalty is necessary and proportionate.[299] AMCo does not, however, go on to say that the CMA has failed to take this '*step back*'; it rather argues that the penalty is not necessary nor proportionate as a result of errors made by the CMA at each step of the calculation.

j. Waymade has made representations on the application of the statutory cap and proportionality of the penalty in its representations on step 5, stating that because the penalties exceed the cap this is evidence that they are disproportionate. Waymade has submitted that the two penalties imposed on Waymade should be considered together and that the aggregated penalties cannot exceed Waymade's statutory cap:[300]

[291] Document 205791, Allergan's RDPS, paragraph 77.
[292] Document 205799, Waymade's RDPS, paragraph 3.85.
[293] Document 205813, Accord-UK's RDPS, paragraph 5.1.
[294] Document 205791, Allergan's RDPS, paragraph 96(d).
[295] Document 205813, Accord-UK's RDPS, paragraph 5.4.
[296] Document 205813, Accord-UK's RDPS, paragraphs 5.9 to 5.11.
[297] Document 205813, Accord-UK's RDPS, paragraph 5.3.
[298] Document 205813, Accord-UK's RDPS, paragraph 1.7.
[299] Document 205848, AMCo's RDPS paragraphs 2.4, 4.77, and 7.3.
[300] Document 205799, Waymade's RDPS, paragraph 3.84.

i. Waymade has submitted that the CMA should aggregate the two penalties on the basis of the CMA's findings on market definition which found one market for hydrocortisone tablets.[301]

ii. Waymade has cited the CAT's decision in *Kier* and stated that for the CMA not to consider the penalties in aggregate would '*fall foul of the 'totality' principle in relation to the cumulation of fines'* as confirmed in the CMA's *Drawer wraps* decision and considering the impact of the penalties at the time they will be imposed.[302]

60. The CMA has imposed separate penalties for each infringement. The fact that multiple penalties would be imposed on an undertaking or legal entity at the same time would not of itself be a reason to apply downward adjustments to those penalties.[303] In this respect, and as explained in section 10.C.V of the Decision the CMA has taken into consideration that multiple penalties are appropriate for those undertakings that engaged in two or more of the infringements.

61. However, for those undertakings the CMA has sought to take into account that multiple penalties are being imposed for infringements that cover the same product and geographic markets and for which the duration of the infringements overlap. In particular, the CMA has avoided double counting the relevant financial benefits and specific deterrence uplifts across multiple infringements, as is also explained in section 10.C.VI of the Decision. Contrary to the relevant parties' submissions, the CMA has therefore sought to ensure there is no double counting in this case.

62. The CMA's approach to these points ensures that the uplifts applied at step 4 do not include more than once the same analysis of financial benefit and specific deterrence for the relevant undertakings. The CMA has also taken a step back and ensured that the action it is taking in a single decision covering multiple penalties is not disproportionate or excessive.

63. The CMA's penalties are proportionate when considered against the facts of the size of the financial benefits obtained by Auden/Actavis, Waymade and AMCo, the size of the undertakings as they currently exist, and the gravity of the infringements which are market sharing agreements and serious abuses of a dominant position. It is essential that the penalties are high to deter the

[301] Document 205799, Waymade's RDPS, paragraph 3.85.
[302] Document 205799, Waymade's RDPS, paragraph 3.85-3.90.
[303] See *Vitamins* (Commission decision in case 37.512), as upheld by the General Court in T-15/02 *BASF v Commission*; *Freight forwarding* (Commission decision in case 39.462), as upheld by the General Court in T-267/12 *Deutsche Bahn v Commission* (upheld by the Court of Justice in C-264/*16 Deutsche Bahn v Commission*); and *Thread* (Commission decision in case 38.337) as upheld by the General Court in T-446/05 *Amann & Söhne and Others v Commission*.

addressees of the penalties and other undertakings from committing infringements of competition law: this does not mean that they are disproportionate.

64. There are no meaningful analogies with the cases on which the parties rely. In particular, *Paroxetine* and *Servier* do not have two separate types of infringements such as excessive pricing and market sharing: the infringements there arise from the same underlying agreements, hence the consideration of the overlaps for the purpose of setting penalties.

65. In relation to the representations on the relevant product market, although the CMA finds that the relevant market only segmented into separate product markets for each strength of hydrocortisone tablets after competitive entry occurred, it has only used 10mg turnover in the calculation of the penalty for the 10mg Agreement, and 20mg turnover in the calculation of the penalty for the 20mg Agreement, thus again avoiding using the same relevant turnover. This highlights why a '*correction factor*' as applied by the Commission in *Lundbeck* and *Servier* was not necessary or appropriate in the present case. In those decisions, the Commission imposed penalties on *Lundbeck* and *Servier* for each of a number of pay-for-delay cases they entered into, recognising that there was an overlap between the infringements '*which relate to the same product, citalopram, and largely to the same geographic areas and periods of time*'.[304] In exercising its discretion, the Commission applied a '*correction factor*' to address this. In the present case, however, the two Agreement infringements do not relate to the same product or periods of time, and the CMA has ensured only turnover relating to the relevant strength was used in the calculation.

66. In addition, in relation to Waymade's representations on the relevance of the findings on product market, the 10mg Agreement and the 20mg Agreement are separate infringements which the penalties should reflect as set out in section 10.C.V of the Decision. For example, the 10mg and 20mg Agreements had different characteristics as the 20mg Agreement featured the Buyback clause which the 10mg Agreement did not. It would not therefore be appropriate to see these as one infringement relating to one market. In addition, the CMA's calculation reflects the two strengths and behaviours without double-counting:

    a. The penalty for each infringement at step one is calculated by reference to turnover generated with respect to that specific product strength and the date of the end of the infringement ending; and

[304] See European Commission decision in *Lundbeck,* paragraph 1329.

b. There is no second deterrence uplift for the 10mg Agreement for Waymade.

67. As set out in section 10.C.V of the Decision, it is settled case law that the CMA is not required to aggregate the penalties imposed on an undertaking for the purpose of applying the statutory cap.[305] The CMA has considered that there are multiple penalties being imposed on Waymade at the same time as part of the proportionality assessment and as a result the CMA has not imposed a deterrence uplift for the 10mg Agreement in addition to that imposed on Waymade for the 20mg Agreement. The penalties are proportionate on the basis of Waymade's current size and financial indicators.[306]

IX. Parent company liability

68. Allergan and Cinven submitted that the penalties for which they are liable are disproportionate on the basis that they are liable *'purely'* on a parent company liability basis and had no direct involvement in the Infringements.[307] Accord-UK made similar arguments with respect to Allergan's culpability and noted that it too simply 'inherited' the pricing structure and the 10mg Agreement.[308]

69. Intas argued that the CMA should not exercise its discretion to hold Intas jointly and severally liable with Accord-UK for Period 4, alleging that the CMA has only taken this position because it has 'deeper pockets' than Accord-UK and that the CMA has considered factors pertaining to Periods A1-A3 when setting the uplift for Period A4. Intas also argued that there should be no uplift at step 4 on the basis that Intas' ownership was at the 'tail end' of the Infringement, that there is no evidence or reason to suppose that Intas will repeat the Infringement, and that the penalty after step 3 is sufficient to deter it.[309]

70. These submissions disregard the applicable legal framework: as described in section 9 (*Undertakings and attribution of liability*), the CMA has found that Allergan, the Cinven Entities and Intas are jointly and severally liable with their former/current subsidiaries and the resulting penalties by virtue of their having exercised decisive influence during their ownership periods.

[305] See section 10.C.V of the Decision.
[306] See section 10.D.IV.c.ii and section 10.VI.a of the Decision.
[307] Document 205791, Allergan's RDPS, paragraphs 4, 5, 54 to 56, and 59; Document 205805; Cinven's RDPS, paragraphs 1.23, 3.50 to 3.54, and 3.67.
[308] Document 205813, Accord-UK's RDPS, paragraph 10.2, 10.9.2, 10.9.5 to 10.9.6, 10.9.8 and 10.59.
[309] Document 205802, Intas/Accord-UK's RDPS, paragraphs 76 to 81, 96 to 97.

71. They also disregard the need for specific deterrence: as parent companies exercising decisive influence Allergan, the Cinven Entities and Intas failed to ensure their subsidiaries discontinued the conduct (even, in the case of Allergan and Intas, following the opening of the CMA's investigation). This of itself, in addition to the principle that the penalties should exceed the financial benefits accrued to these parties, demonstrates the need for specific deterrence. The level of uplift applied by the CMA to each penalty is appropriate for the reasons discussed above.

72. The CMA rejects Intas' submission that the CMA has conflated Periods A1-A4 when setting the uplift for Period A4. The CMA has approached the penalty calculations by reference to the different Periods specifically to ensure that the penalties are specific to the Infringements and the infringers, as is clearly demonstrated above.

X. Comparisons with other cases

73. All the parties argued that the penalties are too large, drawing comparisons with previous CMA cases.[310] The CMA is not bound by its previous decisions, and nor do the penalties imposed in previous cases provide any kind of maximum level of penalty that the CMA can impose in this case. The CMA can impose penalties in excess of those imposed in previous cases in appropriate circumstances. The CMA acknowledges that the penalties in this case are high comparative to other cases; however the specific circumstances of the case warrant penalties at this level, and these have been properly calculated in accordance with the CMA's penalties guidance and applicable case law.

XI. CMA's investigation as sufficient deterrent

74. Waymade submitted that it has '*already suffered it's (sic) "deterrence factor"*' by virtue of the internal resources and expense of external advisors it has incurred in responding to the CMA's investigation.[311] AMCo also argued that the burden of responding to the investigation, and its '*reputationally damaging nature*', means that the objective of specific deterrence has been satisfied.[312]

[310] Document 205813, Accord-UK's RDPS, paragraph, 10.13 to 10.27; Document 205802, Intas/Accord-UK's RDPS, paragraphs 86 to 87 and 92 to 93; Document 205791, Allergan's RDPS, paragraphs 55.e; and 80 to 83; Document 205805, Cinven's RDPS, paragraphs 1.7, 3.48 and 3.50; Document 205848, AMCo's RDPS paragraphs 7.10 to 7.13 and Annex 1; Document 205799, Waymade's RDPS, paragraphs 3.82.
[311] Document 205799, Waymade's RDPS, paragraph 3.57 and 3.93 to 3.94 and Document 206661, Waymade's RLOF, paragraph 9.4.
[312] Document 205848, AMCo's RDPS paragraphs 2.22 and 7.62.

75. The manner in which Waymade and AMCo chose to respond to the CMA's investigation, and the consequent burdens and reputational consequences of those choices, are a matter for them. They bear no relevance to the calculation of the penalties resulting from the CMA's infringement findings.

XII. Ownership of the direct infringer and participation in the relevant market has ceased

76. Allergan submitted that it has sold its generics business and its branded business is largely regulated by PPRS, and therefore no specific deterrence is required.[313]

77. Cinven submitted that it is unclear on what basis the CMA considers that specific deterrence is relevant as regards the Cinven Entities given that they no longer own AMCo.[314] Intas also asserted that there is no evidence that Intas might repeat the infringement.[315]

78. The CMA penalties guidance is clear that the purpose of specific deterrence is to deter the undertaking '*from engaging in future anti-competitive activity'*.[316] Similarly, Parliament has been clear in adopting changes to the Act that were implemented under the Enterprise and Regulatory Reform Act that the CMA must take into account the desirability of deterring both the undertaking on whom a penalty is imposed and others from entering into anti-competitive agreements or committing abuses of dominance. Nowhere does the CMA's guidance or the Act restrict the need to deter to committing repeat infringements of the same kind or in the same (or a similar) relevant market. The fact that these parties no longer own the directly infringing entity nor are active in the relevant market is not relevant to this assessment. It is also not necessary for the CMA to demonstrate that there is evidence that an undertaking may repeat the infringement or commit a different infringement of the Act in the future, as Intas suggested. The imposition of a penalty at a level that would deter Intas and others from committing another infringement of the Act is precisely aimed at reducing the risk that any such future infringements would occur.

XIII. Representations on the DHSC powers

79. The parties have submitted that powers of the DHSC to constrain prices at the time of the Infringement and at the time of this Decision mean that the uplifts for deterrence at step 4 are unwarranted. Similar representations are

[313] Document 205791, Allergan's RDPS, paragraph 68(b).
[314] Document 205805, Cinven's RDPS, paragraph 3.54.
[315] Document 205802, Intas/Accord-UK's RDPS, paragraph 81.
[316] CMA penalties guidance, paragraph 1.4.

made in the context of step 1 and the assessment of intention and negligence.[317]

80. Accord-UK[318], Allergan[319], Intas/Accord-UK[320] and Cinven[321] all submitted that the CMA has ignored constraints already faced by the pharmaceutical sector, including a more proactive approach by the DHSC and NHS in managing costs and the increased powers of DHSC introduced by the Health Service Medical Supplies (Costs) Act 2017 to regulate prices. All of these parties argued that the existence of these powers eliminates the possibility of the parties infringing competition law in this way again, and therefore that the uplifts for deterrence are not proportionate in the circumstances. Intas cited comments made by the CAT in *Phenytoin* in support of this assertion.[322] Accord-UK also submits that it is 'manifestly unfair' to increase Accord-UK's and Allergan's penalties '*due to the failure of the DH to use powers expressly granted to it by Parliament*'.[323]

81. The CMA does not accept these representations. First, the Health Service Medical Supplies (Costs) Act 2017 has no impact on whether or not suppliers of medicines can enter into an agreement under which the incumbent supplier of the relevant medicine makes payments to a potential entrant into the relevant market in return for which the potential entrant agrees not to enter the market independently.

82. With respect to the representations from Accord-UK, Allergan and Intas/Accord-UK in relation to the Unfair Pricing Abuses, it is overly simplistic to argue that the Health Service Medical Supplies (Costs) Act 2017 means there is no longer any need for deterrence in the generic pharmaceuticals sector.

83. The DHSC has yet to use its new powers. It has yet to consult on its methodology for using them, as it has publicly committed to doing.[324] How

[317] For example, Accord-UK also argues that DHSC was able to regulate prices and did not raise any concerns with the prices, and that the DHSC could not intervene (Document 205813, Accord-UK's RDPS, paragraphs 1.4.2, 3.9 to 3.11, 4.11, 4.25, 6.21 and 6.22.5.).
[318] Document 205813, Accord-UK's RDPS, paragraphs 6.21.1, 6.22.5, 10.7.2, and 10.10.
[319] Document 205791, Allergan's RDPS, paragraphs 41, 68(b) and 81(c).
[320] Document 205802, Intas/Accord-UK's RDPS, paragraphs 80 to 81.
[321] Document 205805, Cinven's RDPS, paragraph 3.55.
[322] Document 205802, Intas/Accord-UK's RDPS, paragraph 82, citing the CAT's decision in *Phenytoin*, (*Flynn Pharma Limited and Flynn Pharma (Holdings Limited) and Pfizer Inc and Pfizer Limited v Competition and Markets Authority* [2018] CAT 11), paragraph 461.
[323] Document 205813, Accord-UK's RDPS, paragraph 10.10.
[324] 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, see page 35). 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

effective these powers will be in practice is therefore far from certain. To the extent they leave open the possibility that suppliers autonomously raise their prices to levels that are excessive and unfair, the Chapter II prohibition will continue to apply.[325] There is no suggestion that suppliers will be unable to do so, as the DHSC is not proposing to fix prices across the generic sector at certain levels.

84. In any event, although the DHSC now has the ability to impose financial penalties for non-compliance with its price control and information-gathering powers, it has no power to address historic prices. Its powers are only of prospective effect.

85. The DHSC's powers are therefore aimed at intervention to reduce and limit the cost of drugs to the NHS going forwards. They are not aimed at punishing and deterring illegal activity, as the CMA's powers are. Relying solely on the DHSC's powers would allow undertakings scope to increase prices to excessive and unfair levels and to retain the resulting excessive profits reaped before the DHSC acted to impose a price limit. There will inevitably be scope for such a 'profit window'. The DHSC is required under section 262(1) NHS Act 2006 to consult with the BGMA (which can be expected to raise reasoned objections on behalf of the supplier that will need to be considered) before imposing a price limit; and like any public body, the DHSC has limited resources. It is not realistic to expect that it could act to intervene in a generic drug price in a sufficiently timely manner to prevent opportunistic price exploitation from recurring.

86. Further, as explained in section 10.D.I of the Decision, deterrence in any event is not only relevant to the specific sector in which an infringement takes place.[326] It is important that exploitative and exclusionary conduct is effectively deterred, whatever the relevant product or service.

87. In any event, the existence of DHSC powers to regulate prices going forward does not absolve parties of their obligation to comply with competition law.

XIV. Comparisons with the previous DPS issued in this case

88. Accord-UK noted that the uplifts at step 4 are larger than in the DPS previously issued by the CMA in this case and that the differences had not

because the DHSC 'wants to ensure the proposals are sufficiently robust beforehand' (https://pharmaceutical-journal.com/article/news/government-delays-consultation-with-pharmaceutical-industry-over-generics-price-limiting-powers).

[325] C-280/08 *Deutsche Telekom*, paragraph 80.

[326] See, for example, *Ping Europe Limited v CMA* [2018] CAT 13, paragraph 241: '*The CMA was also correct to consider deterrence on Ping, other golf club manufacturers and other manufacturers and wholesalers in retail sectors more generally*'.

been explained.[327] The decision to which the penalties relate is the current decision, not a prior provisional decision on liability and penalties by which the CMA is not bound. The larger uplift at step 4 is a function of the falling prices and market shares since the earlier DPS was issued on the excessive pricing case. A lower relevant turnover was used in this penalty calculation (as explained at section 10.D.IV.a (*Further factors relating to Period A2)* of the Decision) and for the reasons explained in the step 4 analysis a larger uplift at step 4 was considered appropriate in this case.

[327] Document 205813, Accord-UK's RDPS, paragraphs 10.52 to 10.56.