Decision of the Competition and Markets Authority

Competition Act 1998

Anti-competitive agreement with respect to fludrocortisone acetate 0.1 mg tablets

Case 50455

9 July 2020

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

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 Names have been replaced by a general descriptor of the individual's role.

Contents

Table of figures

1. INTRODUCTION AND EXECUTIVE SUMMARY

A. The purpose of this document

1.1. This Decision is addressed to:

(a) Aspen Pharmacare Holdings Limited[1] ('**Aspen Holdings**'), Aspen Global Incorporated[2] ('**Aspen Global Inc.**'), Aspen Pharma Ireland Limited[3] and Aspen Pharma Trading Limited,[4] which from at least 1 March 2016 formed part, together with Aspen Europe GmbH,[5] of an undertaking which is referred to in this Decision as '**Aspen**';

(b) Amilco Limited,[6] which from at least 1 March 2016 constituted an undertaking which is referred to in this Decision as '**Amilco**'; and

(c) Tiofarma Beheer B.V.[7] and Tiofarma B.V.,[8] which from at least 1 March 2016 together formed part of an undertaking which is referred to in this Decision as '**Tiofarma**'.

1.2. By this Decision, the CMA finds that Aspen, Amilco and Tiofarma (each a '**Party**' and together the '**Parties**') infringed the prohibition imposed by section 2(1) of the Act (the '**Chapter I prohibition**') and Article 101(1) of the Treaty on the Functioning of the European Union ('**TFEU**').[9]

1.3. A glossary and a list of key individuals referred to in this Decision are attached at Annex 1 and Annex 2.

B. Summary of the infringement

1.4. Fludrocortisone acetate 0.1 mg (100 microgram) tablets containing the active pharmaceutical ingredient ('**API**') fludrocortisone acetate ('**Fludrocortisone Acetate Tablets**') are a prescription-only medicine used primarily to treat

[1] A company incorporated in the Republic of South Africa under registration number 1985/0002935/06.
[2] A company incorporated in Mauritius under registration number C08078138.
[3] A company incorporated in Ireland under company number 525086 and registered as an overseas company in England and Wales under registration number BR020174.
[4] A company incorporated in Ireland under company number IE482868.
[5] A former Aspen company incorporated in Germany under registration number HRB 212474, which was registered as an overseas company in England and Wales under registration number FCO32051, and which formally merged with Aspen Pharma Ireland Limited effective from 1 July 2018.
[6] A company incorporated in England and Wales under registration number 08809708.
[7] A company incorporated in the Netherlands under company number KvK 23071995.
[8] A company incorporated in the Netherlands under company number KvK 23078797.
[9] Under the European Union (Withdrawal Agreement) Act 2020, section 2(1) of the European Communities Act 1972 (under which EU law has effect in the UK's national law) is 'saved' until the end of the Transition Period (section 1A, Withdrawal Act (as introduced by section 1, Withdrawal Agreement Act)). This means that directly applicable EU law, including Article 101(1) and Article 102 and Council Regulation (EC) No 1/2003, applies at the time of this Decision.

primary or secondary adrenal insufficiency. These are vital, life-saving drugs, on which thousands of patients depend. They are funded by the NHS, and, ultimately by the taxpayer. Patients have no choice but to take them and the NHS has no choice but to fund them.

1.5. Fludrocortisone Acetate Tablets have been off patent since 1971. Prescriptions for Fludrocortisone Acetate Tablets are usually open and without reference to brand, such that any generic supplier that entered the market could expect to win market share if it priced competitively.

1.6. In November 2014, Aspen acquired the UK marketing authorisation ('**MA**') for the cold storage version of Fludrocortisone Acetate Tablets ('**Cold Storage Fludrocortisone**') along with the associated business from the incumbent sole supplier of the drug. At the time, Cold Storage Fludrocortisone sold under the Florinef brand ('**Florinef**') was the only Fludrocortisone Acetate Tablets product licensed for direct supply in the UK and Aspen held significant market power in the relevant market.

1.7. Until February 2016, Cold Storage Fludrocortisone was supplied by Aspen in the UK at a list price a price set under the Pharmaceutical Price Regulation Scheme (£0.05 per tablet). Between 2014 and 2015, Aspen initiated a strategy to withdraw the Florinef brand (a practice known as 'debranding'), thereby taking it out of the Pharmaceutical Price Regulation Scheme, and to increase its price.

1.8. In November 2015, Tiofarma, working together with Amilco, obtained the first MA for supplying in the UK a generic, heat-stable, version of Fludrocortisone Acetate Tablets ('**Ambient Storage Fludrocortisone**') and Tiofarma manufactured sufficient volumes of the drug to supply all UK patients who required Fludrocortisone Acetate Tablets.

1.9. As a result of the potential competition from Amilco and Tiofarma, working together, Aspen faced material uncertainty as to its ability to pursue its strategy of increasing prices for Fludrocortisone Acetate Tablets without losing market share to the new entrant. Similarly, any new entrant would have faced material uncertainty as to its future market share and profits following entry.

1.10. Instead of entering the market independently and competing with Aspen, Amilco offered Aspen an exclusive licence to commercialise Ambient Storage Fludrocortisone in the UK under Tiofarma's MA in 2015.

1.11. On 1 March 2016, the Parties entered into a Supply and Distribution Agreement ('**SDA**') relating to the supply of Fludrocortisone Acetate Tablets for human use in the UK (the '**Relevant Market**'). The SDA had a contractual term of three years, but its actual duration was later cut short such that it was in force between 1 March 2016 and 19 October 2016 (the '**Relevant Period**'). The Competition and Markets Authority (the '**CMA**') finds that the SDA had the object and the effect of preventing, restricting or distorting competition in breach of the Chapter I prohibition and Article 101 TFEU (the '**Infringement**').

1.12. Having regard to its legal and economic context and its content and objectives, the SDA constitutes a market sharing agreement which can be regarded, by its very nature, as being harmful to the proper functioning of normal competition. In particular, the CMA finds that:

(a) Tiofarma and Amilco, working together, were at least potential competitors of Aspen in the market for the supply of Fludrocortisone Acetate Tablets for human use in the UK at the time of the SDA;

(b) Amilco and Tiofarma agreed not to enter the Relevant Market independently from Aspen, thereby preventing competition between the Parties and preserving Aspen's position as sole UK supplier of Fludrocortisone Acetate Tablets for the duration of the SDA; and

(c) In exchange, Aspen made significant value transfers, of a pecuniary or non-pecuniary nature, which were premised on the postponement of competition between the Parties and constituted significant benefits to Amilco and Tiofarma. Specifically, Aspen withdrew its own Cold Storage Fludrocortisone product from sale, making Tiofarma the sole manufacturer of the product for the UK market, and Aspen agreed to make significant payments to Amilco premised on the list price of Fludrocortisone Acetate Tablets being increased by more than 1,800% upon implementation of the SDA (from £0.05 to £1 per tablet), leading to Amilco being paid approximately 30% of the resulting revenues.

1.13. The CMA concludes further that the SDA had the effect of:

(a) neutralising the constraint arising from Ambient Storage Fludrocortisone for the duration of the SDA;

(b) delaying the likely independent launch of Amilco and Tiofarma's Ambient Storage Fludrocortisone until at least the end of the SDA; and

(c) artificially increasing the list price for Fludrocortisone Acetate Tablets, which is significantly beyond the level at which Aspen would have likely charged absent the SDA.

1.14. The SDA was cut short in October 2016 following the purchase by Aspen of all rights relating to Ambient Storage Fludrocortisone. On 3 October 2019, the CMA accepted commitments offered by Aspen to resolve competition concerns identified by the CMA relating to this acquisition (see below at paragraphs 2.8 to 2.12).[10]

C. Settlements and action being taken

1.15. Each Party signed a settlement letter confirming their agreement to the terms of settlement, including admitting that they had infringed the Chapter I prohibition and/or Article 101 TFEU in the terms set out in the Statement of Objections dated 3 October 2019,[11] which are now reflected in this Decision. Aspen and Tiofarma further agreed to pay a maximum penalty, as set out in their settlement letters.

1.16. The CMA hereby imposes financial penalties on Aspen and Tiofarma under section 36 of the Act in respect of the Infringement, as set out in Section 10. Whilst liable for a penalty, pursuant to section 36(8) of the Act, no financial penalty was calculated in relation to Amilco because it had no turnover in the last business year preceding this Decision.

1.17. On 1 June 2019, the CMA accepted a disqualification undertaking offered by a director of Amilco in connection with the Infringement.[12]

[10] See the CMA's case page at www.gov.uk/cma-cases/pharmaceutical-drugs-suspected-anti-competitive-agreements-and-conduct.
[11] Or in the case of Aspen, in the terms set out in a Summary Statement of Facts (see footnote 15).
[12] See the CMA's case page at www.gov.uk/cma-cases/fludrocortisone-acetate-tablets-director-disqualification.

2. THE INVESTIGATION

A. Conduct of the Investigation up to the Statement of Objections

2.1. On 10 October 2017, the CMA informed the Parties that it had opened a formal investigation under the Act (the '**Investigation**'),[13] having determined that it had reasonable grounds to suspect that:

(a) Aspen had infringed section 18(1) of the Act (the '**Chapter II prohibition**') and Article 102 TFEU; and

(b) Aspen, Tiofarma and another company[14] had infringed the Chapter I prohibition and Article 101 TFEU.

2.2. On 27 November 2017, the CMA determined that it had reasonable grounds to suspect that Amilco, together with the undertakings identified in the paragraph above, had infringed the Chapter I prohibition and Article 101 TFEU.

2.3. The CMA held 'state of play' meetings with each of the Parties to the Investigation in June 2018.

I. Settlement with Aspen

2.4. Aspen approached the CMA in June 2019 to explore the possibility of settlement. In line with the CMA's procedural guidance, on 5 July 2019 the CMA issued to Aspen a Summary Statement of Facts[15] for the purpose of enabling Aspen to decide whether or not to settle the case, and to give Aspen the opportunity to make submissions on any manifest factual inaccuracies in the Summary Statement of Facts. Aspen submitted limited representations on factual matters, which were accepted by the CMA and reflected in the Statement of Objections and this Decision.

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[13] The Investigation related initially not only to the supply of Fludrocortisone Acetate Tablets in the UK, but also to another corticosteroid medication. On 3 May 2018, the CMA closed the separate limb of the Investigation relating to that second drug on administrative priority grounds, on the basis set out in a letter sent to the Parties on 14 May 2018.

[14] On 3 May 2018 the CMA decided on administrative priority grounds not to pursue further the Investigation in relation to this company.

[15] According to paragraph 14.9 of the CMA's *Competition Act 1998: Guidance on the CMA's investigation procedures in Competition Act 1998 cases* (CMA8, 18 January 2019), a business with which settlement discussions take place before a Statement of Objections is issued, will be presented with a Summary Statement of Facts setting out the key facts and evidence upon which the CMA relies to support its view that there has been an infringement of competition law, including the nature, scope and duration of such suspected infringement.

2.5. The CMA also issued a draft penalty calculation to Aspen and gave Aspen the opportunity to make limited representations on the draft penalty calculation as part of settlement discussions.[16]

2.6. On 24 July 2019, Aspen signed a settlement letter confirming its agreement to the terms of settlement and to paying a maximum penalty of £2,101,954 (the '**Aspen Settlement Letter**'), as announced by the CMA on 14 August 2019.[17]

2.7. By signing the Aspen Settlement Letter, Aspen admitted its involvement in, and liability for, the Infringement as set out in the Summary Statement of Facts, subject to the manifest factual inaccuracies it identified which are reflected in this Decision, and it agreed to co-operate in expediting the process for concluding the Investigation. The Aspen Settlement Letter, including the terms of settlement and the final draft maximum penalty calculation annexed to it, sets out all the conditions of that settlement.

II. Acceptance of Commitments from Aspen

2.8. When Aspen approached the CMA in June 2019 to explore the possibility of settlement in this Investigation, it also indicated to the CMA that it wished to explore the possibility of offering commitments with a view to addressing competition concerns identified by the CMA as arising from another element of the Investigation, specifically the acquisition by Aspen of the rights[18] over Ambient Storage Fludrocortisone developed by Tiofarma through a Sale of Assets Agreement dated October 2016 ('**SAA**'). Following engagement with the CMA, Aspen made a formal offer of commitments on 24 July 2019.

2.9. On 14 August 2019, the CMA published a notice of its intention to accept Aspen's offer of commitments. The CMA provided interested parties until 2 September 2019 to make representations on the offer of commitments.

2.10. Following further discussions with the CMA, and consideration of the representations received, Aspen made a final offer of commitments on 17 September 2019 (the '**Commitments'**). The CMA accepted the

[16] According to paragraph 14.15 of CMA8, a business with which settlement discussions take place will be given the opportunity to make limited representations on the draft penalty calculation within a specified time frame as part of settlement discussions, provided that these are not inconsistent with its admission of liability.
[17] See the CMA's case page at www.gov.uk/cma-cases/pharmaceutical-drugs-suspected-anti-competitive-agreements-and-conduct.
[18] Including the marketing authorisations to supply this product in the UK, granted by the MHRA under PL numbers 17299/0001 and 17299/0002.

Commitments on 3 October 2019 by means of a decision made under section 31A of the Act.[19]

2.11. Following acceptance of the Commitments, and pursuant to section 31B(2) of the Act, the CMA is no longer investigating whether Aspen infringed the Chapter II prohibition and Article 102 TFEU with respect to the SAA.

2.12. Further, in light of the acceptance of the Commitments and for reasons of administrative priority, the CMA decided not to investigate any further whether the Parties had infringed the Chapter I prohibition and Article 101 TFEU by entering into the SAA.

III. Issuance of the Statement of Objections

2.13. On 3 October 2019, the CMA issued a Statement of Objections to the Parties in which it made a provisional decision that Aspen, Tiofarma and Amilco had infringed the Chapter I prohibition of the Act and/or Article 101 by entering into the SDA.

B. Conduct of the Investigation following the issuance of the Statement of Objections

I. Settlement with Tiofarma

2.14. Following the issuance of the Statement of Objections, Tiofarma approached the CMA to explore the possibility of settlement. Tiofarma submitted limited representations on manifest factual inaccuracies it identified in the Statement of Objections that were accepted by the CMA and have been reflected in this Decision.

2.15. The CMA also issued a draft penalty calculation to Tiofarma and gave Tiofarma the opportunity to make limited representations on the draft penalty calculation as part of settlement discussions.[20]

2.16. On 18 December 2019, Tiofarma signed a settlement letter confirming its agreement to the terms of settlement and to paying a maximum penalty of £186,442 (the '**Tiofarma Settlement Letter**'), as announced by the CMA on 23 January 2020.[21]

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[19] See the CMA's decision to accept binding commitments offered by Aspen at https://assets.publishing.service.gov.uk/media/5d94c607ed915d5540d5b093/Case_50455_-_Commitments_Decision.pdf.
[20] According to paragraph 14.15 of CMA8: see footnote 16.
[21] See the CMA's case page at https://www.gov.uk/cma-cases/pharmaceutical-drugs-suspected-anti-competitive-agreements-and-conduct.

2.17. By signing the settlement letter, Tiofarma admitted its involvement in, and liability for, the Infringement as set out in the Statement of Objections, subject to the manifest factual inaccuracies it identified which are reflected in this Decision, and it agreed to co-operate in expediting the process for concluding the Investigation. The Tiofarma Settlement Letter, including the terms of settlement and the final draft maximum penalty calculation annexed to it, sets out all the conditions of that settlement.

II. Settlement with Amilco

2.18. Following the issuance of the Statement of Objections, Amilco approached the CMA to explore the possibility of settlement. Amilco submitted limited representations on manifest factual inaccuracies it identified in the Statement of Objections that were accepted by the CMA and have been reflected in this Decision.[22]

2.19. On 29 June 2020, Amilco signed a settlement letter confirming its agreement to the terms of settlement (the '**Amilco Settlement Letter**'). Whilst liable for a penalty, no financial penalty was calculated in relation to Amilco owing to the undertaking having had no turnover in the last business year preceding this Decision (see paragraph 10.29).

2.20. By signing the settlement letter, Amilco admitted its involvement in, and liability for, the Infringement as set out in the Statement of Objections, subject to the manifest factual inaccuracies it identified, which are now reflected in this Decision. It therefore withdrew its representations on the Statement of Objections and agreed to co-operate in expediting the process for concluding the Investigation. The Amilco Settlement Letter, including the terms of settlement annexed to it, sets out all the conditions of that settlement.

III. Further steps prior the issuance of the Decision

2.21. Following the issuance of the Statement of Objections, a Case Decision Group was appointed within the CMA to act as decision maker on whether or not, based on the facts and evidence before it and taking account of the representations on manifest factual inaccuracies made by Tiofarma and

[22] Prior to approaching the CMA to explore the possibility of settlement, Amilco submitted written and oral representations to the CMA on the matters referred to in the Statement of Objections. However, as a result of settlement and the admission of liability on the basis of the evidence and provisional findings set out in the Statement of Objections, Amilco has withdrawn these written and oral representations.

Amilco, the legal test for establishing an infringement had been met, and whether the Investigation remained an administrative priority.[23]

C. Evidence gathering and engagement

I. Aspen

2.22. On 10, 11 and 12 October 2017, the CMA entered and conducted a search of Aspen's UK business premises under a warrant[24] granted by the High Court under section 28 of the Act. The CMA took copies of a number of documents during this search and requested the preservation and production of certain categories of documents located outside Aspen's UK business premises. These were taken away by the CMA and, following the onsite search, the CMA conducted a review of the evidence preserved.

2.23. The CMA requested further information and/or documents from Aspen under section 26 of the Act on 10 October 2017, 8 November 2017 and 19 April 2018.

2.24. The Irish national competition authority, the Competition and Consumer Protection Commission (the '**CCPC**'), additionally issued a formal request for information to Aspen's Irish group companies (Aspen Pharma Trading Limited and Aspen Pharma Ireland Limited) on 10 October 2017, pursuant to Article 22 of Council Regulation 1/2003. Aspen elected to submit the responsive documents directly to the CMA on a voluntary basis, with the agreement of the CMA and the CCPC.

2.25. On 31 October 2017, Aspen agreed, in response to a request from the CMA, that it would produce documents held by certain custodians based in South Africa in response to the notice issued by the CMA on 10 October 2017 under section 26 of the Act. These documents were received by the CMA on 12 November 2018.

2.26. The CMA conducted compulsory witness interviews with the following current or former employees of Aspen, using its formal powers under section 26A of the Act, on the following dates:

(a) [Aspen Employee 1], 19 October 2017;

(b) [Aspen Employee 2], 20 October 2017; and

[23] The role of the Case Decision Group is described in paragraphs 9.11 and 11.30 to 11.34 of CMA8.
[24] Warrant issued by the High Court on 10 October 2017, under claim number CP-2017-000008.

(c) [Consultant to Aspen], 25 October 2017.

2.27. Additionally, the CMA conducted voluntary interviews with the following current or former employees of Aspen on the following dates:

(a) [Aspen Employee 28], 7 November 2017;

(b) [Aspen Employee 8], 8 November 2017;

(c) [Aspen Employee 3], 9 November 2017;

(d) [Aspen Employee 9], 9 November 2017;

(e) [Aspen Employee 7], 9 November 2017;

(f) [Aspen Senior Executive 2], 12 April 2018;

(g) [Aspen Senior Executive 1], 14 May 2018; and

(h) [Aspen Employee 1], 6 December 2018.

II. Amilco

2.28. On 12 October 2017, the CMA conducted a search of the domestic premises of [✂] [Person 1 acting for Amilco], under a warrant granted by the High Court under section 28A of the Act.[25] The CMA took copies of a number of documents during this search and requested the preservation and production of certain categories of documents (including mobile devices). These were taken away by the CMA and, following the onsite search, the CMA conducted a review of the evidence preserved and returned the mobile devices to [Person 1 acting for Amilco].

2.29. The CMA conducted compulsory witness interviews with two individuals who have a connection with Amilco, using its powers under section 26A of the Act, on the following dates:

(a) [Person 1 acting for Amilco], 14 December 2017 and 6 December 2018; and

(b) [Person 2 acting for Amilco], 14 December 2017.

[25] Warrant issued by the High Court on 6 October 2017, under claim number CP-2017-000008.

2.30. On 12 February 2018 and 15 November 2018, the CMA requested documents and information from Amilco under section 26 of the Act.

III. Tiofarma

2.31. On 10 October 2017, the Dutch national competition authority, the Autoriteit Consument en Markt (the '**ACM**'), made a formal information request to Tiofarma on behalf of the CMA, pursuant to Article 22 of Regulation 1/2003.[26] The documents obtained by the ACM were provided to the CMA on 14 November 2017.

2.32. Tiofarma provided further documents directly to the CMA on a voluntary basis on 20 August 2018.

2.33. The CMA conducted voluntary interviews with the following employees of Tiofarma on the following dates:

(a) [Tiofarma Employee 1], 22 November 2017 and 24 July 2018; and

(b) [Tiofarma Employee 3], 22 November 2017.

IV. Other sources of information

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

Figure 1: Third-party information requests

Category	Entity
Other generic drug suppliers active in the UK	[Company 2], [Company 4], [Pharmaceutical Company 2]
Buyers groups	[Buyer Group 1], [Buyer Group 2], [Buyer Group 3]
Consultants	[External Consultant 2], [External Consultant 1], [Consultant to Aspen]
Logistics provider	[Logistics Provider]
MA holders	Bristol Myers Squibb Pharmaceuticals Limited (original UK MA holder) [✂] (MA holder in France)
Manufacturers	Haupt Pharma Amareg GmbH,[27] [✂], Dechra Veterinary Products Limited (for Zycortal)

[26] Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (now article Articles 101 and 102).
[27] [✂].

NHS	NHS Business Services Authority (NHSBSA),[28] [NHS Health Board 1], [NHS Trust 1], [NHS Trust 2], [NHS Trust 3], [NHS Trust 4], [NHS Trust 5], [NHS Health Board 2], [NHS Trust 6], [NHS Trust 7], [NHS Trust 8], [NHS Trust 9], [NHS Trust 10]
Parallel Importers	[Parallel Importer 1], [Parallel Importer 2], [Parallel Importer 3], [Parallel Importer 4], [Parallel Importer 5], [Parallel Importer 6], [Parallel Importer 7], [Parallel Importer 8], [Parallel Importer 9], [Parallel Importer 10], [Parallel Importer 11], [Parallel Importer 12], [Parallel Importer 13], [Parallel Importer 14], [Parallel Importer 15]
Pharmacies	[Pharmacy 1], [Pharmacy 2], [Pharmacy 3], [Pharmacy 4], [Pharmacy 5], [Pharmacy 6], [Pharmacy 7], [Pharmacy 8], [Pharmacy 9], [Pharmacy 10], [Pharmacy 11]
Public bodies	Medicines and Healthcare products Regulatory Agency (MHRA), Department of Health and Social Care (DHSC), Health and Social Care Northern Ireland (HSCNI), Agence Nationale de Sécurité du Médicament et des Produits de Santé of France (ANSM), Direction Générale de la Santé of France (DGS)
Specialists	Society for Endocrinology, British and Irish Hypertension Society, IQVIA Solutions UK Limited
Veterinarians	Royal College of Veterinary Surgeons (RCVS), British Veterinary Association, British Small Animals Veterinary Association
Wholesalers	[Wholesaler 2], [Wholesaler 1], [Wholesaler 8], [Wholesaler 3], [Wholesaler 4], [Wholesaler 5], [Wholesaler 6], [Wholesaler 7]

2.35. The CMA conducted compulsory witness interviews with two individuals who have previously provided consultancy services to Aspen and/or Amilco, using its powers under section 26A of the Act, on the following dates:

(a) [External Consultant 1], 6 March 2018;

(b) [External Consultant 2], 6 March 2018.

[28] Two of the three information requests were made to NHSBSA on an informal basis on 6 April 2017 and 7 June 2017.

3. FACTUAL AND REGULATORY BACKGROUND

A. Key companies and individuals

I. Aspen

3.1. Aspen's parent company is Aspen Holdings, a pharmaceutical company listed in South Africa. Aspen Holdings owns a broad portfolio of branded and generic prescription products that are sold to wholesalers, hospitals and pharmacies in over 100 countries. It was founded in 1850 and its headquarters are in South Africa. Its website describes Aspen as '*a global specialty and branded multinational pharmaceutical company with a presence in both emerging and developed markets with approximately 10 000 employees at 70 established business operations in 55 countries. … We supply medicines to more than 150 countries.*'[29]

3.2. Aspen's consolidated turnover was ZAR 38.9 billion (approximately £2.1 billion) in the financial year ending June 2019.[30]

3.3. During the Relevant Period, Aspen carried out business in the UK through a number of wholly-owned legal persons incorporated in various jurisdictions:

(a) Aspen operated in the UK through a branch of Aspen Europe GmbH ('**Aspen Europe**'). Aspen Europe, which was incorporated in Germany, formally merged with Aspen Pharma Ireland Limited effective from 1 July 2018.

(b) Aspen also carried out business in the UK through Aspen Pharma Trading Limited, a company registered in Ireland and the holder of the MA for Cold Storage Fludrocortisone. Aspen Pharma Trading Limited supplied Cold Storage Fludrocortisone in the UK under the Florinef brand until it was withdrawn from the UK market by Aspen in February 2016. Aspen Pharma Trading Limited has also been the holder of the MAs for Ambient Storage Fludrocortisone since Aspen acquired it from Tiofarma.

(c) Aspen Pharma Ireland Limited, acting as Aspen's European headquarters and also registered in Ireland, operated in the UK through a branch registered in England and Wales since 1 July 2017.

[29] Aspen Group Overview, https://www.aspenpharma.com/group-overview/.
[30] Document PD0046, Integrated Annual Report 2019 - Aspen Pharmacare, http://www.aspen-reports.co.za/reports/2019/index.php.

3.4. All three companies are wholly owned by Aspen Global Inc., a Mauritian company that is in turn wholly owned by Aspen Holdings. Aspen Global Inc. is the holding company for Aspen's international businesses.

3.5. Aspen Holdings reported a turnover of ZAR 12.1 billion (approximately £660 million) for its '*Developed Europe*' geographic area, including France, Italy, Germany, the UK and the Netherlands in the year ending June 2019.[31]

II. Amilco

3.6. Amilco is a privately-owned company incorporated on 11 December 2013. [✂].

3.7. Amilco's report and accounts for the year ending on 31 December 2016 state that '[Amilco]*'s principal activity during the year continued to be manufacturing, marketing and distributing of pharmaceutical products*.'[32]

3.8. Amilco acted as Tiofarma's UK representative within the context of the SDA (which is described in detail in Section 4 below). During the Relevant Period, [Person 1 acting for Amilco] [✂][33] and oversaw Amilco's involvement in the work and negotiations that led to Amilco's entry into, and implementation of, the SDA. In that context, [Person 1 acting for Amilco] sought the assistance of a number of individuals [✂] (see further paragraphs 3.9 and 3.11).

3.9. [✂][34] [✂][35] [✂][36] [✂].[37]

3.10. While [Pharmaceutical Company 2] undertook the initial development work in relation to Ambient Storage Fludrocortisone (see further paragraphs 4.9. to 4.11) [Person 1 acting for Amilco] [✂][38].[39] He subsequently decided to utilise those assets for the purposes of the SDA through Amilco.

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[31] Document PD0002, Developed Europe – Aspen Pharmacare, https://www.aspenpharma.com/developed-europe/.
[32] Document FLC4846 and its attachment Document FLC4848 (Annex 2), Amilco's response to question 2, of the CMA's section 26 notice dated 15 November 2018. See also Document FLC1143, Amilco's response to Part 1, question 1, of the CMA's section 26 notice dated 12 February 2018.
[33] Document PD0061, [✂].
[34] [✂].
[35] [✂].
[36] [✂].
[37] [✂].
[38] At that point, the dossier for Ambient Storage Fludrocortisone was ready to be filed as an MA application with the MHRA (ie all data and documents required to do so had been obtained) (see paragraph 4.22).
[39] After [✂] the assets relating to Ambient Storage Fludrocortisone, [Person 1 acting for Amilco] subsequently caused those assets to be transferred to Tiofarma, which applied for, and obtained, an MA on [✂] behalf (see paragraphs 4.14 to 4.22). [✂] thereby retained ultimate beneficial ownership over (and cash flows arising from

3.11. A number of individuals with no formal connection to Amilco assisted [Person 1 acting for Amilco] with entering into and implementing the SDA. These individuals – namely [Person 2 acting for Amilco], who assisted Amilco and Tiofarma in various aspects of the development of Ambient Storage Fludrocortisone and the negotiation and implementation of the SDA;[40] [Person 3 acting for Amilco], who assisted Amilco and Tiofarma in relation to pharmacovigilance questions relevant to the application for an MA for Ambient Storage Fludrocortisone and also under the SDA;[41] and [Person 4 acting for Amilco], who '*provided regulatory services to Amilco*', including to assist '*Tiofarma in the application for the UK marketing authorisation*'[42] – [✂].[43]

3.12. Amilco acted as Tiofarma's UK representative within the context of the SDA (which is described in detail in Section 4 below).

3.13. Amilco's turnover in the year ending 31 December 2016 was £[✂].[44] Amilco achieved no turnover in the year ending 30 June 2019.[45]

III. Tiofarma

3.14. Tiofarma B.V. is a Dutch company that mainly provides services to pharmaceutical companies, including as a contract manufacturing organisation ('**CMO**'). Tiofarma B.V. is wholly owned by Tiofarma Beheer B.V., a holding company registered at the same address.

3.15. Tiofarma told the CMA that its capabilities are focused on development and production of final dosage forms of existing molecules.[46] The annual report

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ownership of) Ambient Storage Fludrocortisone, despite Tiofarma formally holding the MA for that product. Tiofarma has confirmed that it did not acquire any rights in relation to Ambient Storage Fludrocortisone. Tiofarma made no payment to [Pharmaceutical Company 2] or [Person 1 acting for Amilco] ([✂]) in relation to the transfer of data and documents relating Ambient Storage Fludrocortisone, as it did not acquire any rights.

[40] For instance, in September 2015, [Person 2 acting for Amilco] sent to Tiofarma the tasks to be undertaken by Amilco and Tiofarma in order to start supplying Ambient Storage Fludrocortisone (paragraph 4.23); he negotiated the cost of goods quoted by Tiofarma (paragraph 4.28); he prepared and approved a draft communication to wholesalers announcing the replacement of Cold Storage Fludrocortisone by Ambient Storage Fludrocortisone (paragraph 4.101); and he participated in the meeting of 1 July 2016 with Tiofarma and Aspen to discuss the forecasted volumes under the SDA (paragraph 4.129).

[41] See documents listed in footnote 114. [✂] (see Document FLC4846, Amilco's response to question 5(a) of the CMA's section 26 notice dated 15 November 2018).

[42] Document FLC4846, Amilco's response to question 6 of the CMA's section 26 notice dated 15 November 2018.

[43] Document FLC4846, Amilco's response to questions 5 and 6 of the CMA's section 26 notice dated 15 November 2018.

[44] Document FLC4846 and its attachment Document FLC4848 (Annex 2), Amilco's response to question 2, of the CMA's section 26 notice dated 15 November 2018.

[45] Document FLC7765, and its attachment Document FLC7766, letter from Amilco's accountants.

[46] Document FLC2074.2, Tiofarma's response to question 14, Annex 1A, to the ACM request for information dated 10 October 2017; Document FLC1981, page 10, lines 1 to 4, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.

and accounts of Tiofarma Beheer B.V. for the year ending 31 December 2019 state that its activities '*consist mainly of the production, distribution, analysis and sale of pharmaceutical, veterinary, biotechnological and cosmetic products, as well as trade in the raw materials required for these purposes'.*[47] Of particular relevance to this Decision, Tiofarma's activities include the manufacture of Ambient Storage Fludrocortisone for the UK market at a manufacturing plant in Oud-Beijerland, the Netherlands.

3.16. Tiofarma has a longstanding relationship with [Person 1 acting for Amilco] [✂] and carried out much development and CMO work for him.[48] Tiofarma has held MAs for Ambient Storage Fludrocortisone since November 2015. From 1 March to 30 September 2016, Ambient Storage Fludrocortisone was supplied in the UK under a Tiofarma livery pursuant to the SDA. Following the sale of its MAs to Aspen with effect on 1 October 2016, Tiofarma has continued manufacturing and supplying Ambient Storage Fludrocortisone to Aspen. Further details are set out below at Section 4.

3.17. Tiofarma Beheer B.V. reported a consolidated turnover of Euro 51.8 million in the year ending 31 December 2019.[49]

B. Fludrocortisone Acetate

I. Fludrocortisone acetate and treatment of adrenal insufficiency

3.18. A drug containing the API fludrocortisone was first authorised in the European Union ('**EU**') in 1954 and Fludrocortisone Acetate Tablets (as commercialised in its current form) were introduced in the UK in November 1988, as Florinef 0.1 mg tablets.[50] Amilco submitted that Florinef has been off-patent since 1971 and that the last regulatory data protection period in the UK expired in 1998.[51]

[47] Document FLC7772, Tiofarma's Annual report for year ending 31 December 2019.
[48] Document FLC1981, page 10 lines 24 to 26, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017 '[…] *we were able to do development work for him, and the CMO work afterwards. That has been a long standing relationship* […]*'.*
[49] Document FLC7772, Tiofarma's Annual report for year ending 31 December 2019.
[50] Document FLE0816, Tiofarma's MA application for Fludrocortisone Acetate 0.1mg Tablets (PL 17507/0058) CTD MODULE 2.5: Clinical Overview. After PL 17507/0058 was transferred to Aspen, the product licence numbers changed to PL39699/0089 (in respect of the DCP Licence) and PL39699/0090 (in respect of the National Licence).
[51] Document FLC4883, page 5, paragraph 3.3, submission made by Amilco to the CMA on 5 February 2019.

3.19. Fludrocortisone is the first-line treatment for the replacement of mineralocorticoids, and in particular aldosterone hormones,[52] in patients with primary or secondary adrenal insufficiency.

3.20. Adrenal insufficiency (also referred to as Addison's Disease) is a chronic, rare condition that occurs when the adrenal glands fail to produce any or enough of the natural hormones cortisol, aldosterone or the sex hormones.[53] Addison's Disease is often caused by an autoimmune disorder[54] or as a result of an infection (most commonly tuberculosis), adrenal cancer, haemorrhage or rare hereditary diseases, such as congenital adrenal hyperplasia.[55]

3.21. The Society for Endocrinology, a UK specialist body representing scientists and clinicians in the field of endocrinology, explained that:

> *'the initial diagnosis of primary adrenal insufficiency can be made by any doctor and is usually confirmed by an endocrinologist* […]. *Most patients present in life-threatening adrenal crisis when first diagnosed with primary adrenal insufficiency and then receive first large doses of hydrocortisone (=cortisol), which at high doses can compensate for the missing aldosterone. However, these doses would be too high and highly damaging to health if maintained routinely. Once the patient has recovered from the adrenal crisis (days to 1-2 weeks), they are switched to lower dose routine replacement doses of hydrocortisone and a routine replacement dose of fludrocortisone is immediately initiated.'*[56]

3.22. The Society for Endocrinology further explained that there is no alternative to the use of fludrocortisone for lifelong mineralocorticoid replacement in patients with primary adrenal insufficiency.[57]

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[52] Aldosterone is the major mineralocorticoid in the body. It is critical for maintaining blood pressure and regulating the salt balance in the body.
[53] Document PD0004, Auden Mckenzie guide to adrenal insufficiency for pharmacists, and Document PD0005, the Society for Endocrinology's Adrenal Insufficiency Patient Booklet Adrenal Insufficiency Patient Booklet.
[54] Document FLC1555, Diagnosis and Treatment of Primary Adrenal Insufficiency: An Endocrine Society's Clinical Practice Guideline, page 368: '*the most common cause of* [Primary Adrenal Insufficiency] *is autoimmunity (up to 90% in Western countries), followed by infectious diseases such as tuberculosis, adrenalectomy, neoplasia and various genetic causes* […]*'.*
[55] Document PD0004, Auden Mckenzie guide to adrenal insufficiency for pharmacists, https://www.pituitary.org.uk/media/204461/Adrenal-insufficiency-a-guide-for-pharmacists.pdf.
[56] Document FLC1571, Society for Endocrinology's response to questions 2 and 4, Annex 1, of the CMA's section 26 notice dated 28 February 2018.
[57] Document FLC1571, Society for Endocrinology's response to question 1, Annex 1, of the CMA's section 26 notice dated 28 February 2018. Other corticosteroids and the extent to which they can be used in place of fludrocortisone are discussed in paragraph 3.30 below.

3.23. The international guidelines on the treatment of patients with adrenal insufficiency, which are laid out in consensus clinical guidelines,[58] state that patients with aldosterone deficiency need to receive fludrocortisone.[59]

II. Fludrocortisone acetate and treatment of neuropathic postural hypotension

3.24. Fludrocortisone may also be used to treat Neurogenic (or neuropathic) postural hypotension ('**NPH**').[60] However this condition is likely to be relatively rare[61] and limited to patients with autonomic dysfunction diagnosed after extensive investigations in whom response to non-pharmacological therapy[62] does not resolve symptoms.[63] Moreover, the MAs for Fludrocortisone Acetate Tablets are not approved for the treatment of this condition and such use would therefore be considered to fall outside the license of the drug (commonly referred to as 'off-label').[64]

III. Overview of fludrocortisone acetate

a. Classification

3.25. Fludrocortisone acetate is the most common form of fludrocortisone, and the only form available in the UK. It is a type of synthetic corticosteroid that is administered orally. The Anatomical Therapeutic Chemical ('**ATC**') classification system developed by the World Health Organisation divides active substances into groups according to their composition and therapeutic properties. In the ATC system, corticosteroids are classified as steroids and

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[58] Consensus clinical guidelines are evidence-based guidelines, in this instance addressing the diagnosis and treatment of primary adrenal insufficiency. The guidelines cited in this instance were sponsored by the European Society for Endocrinology and the American Association for Clinical Chemistry and developed by a chair, selected by The Clinical Guidelines Subcommittee of the Endocrine Society, eight additional clinicians experienced with the disease, a methodologist, and a medical writer.

[59] See for instance Document FLC1555, Diagnosis and Treatment of Primary Adrenal Insufficiency: An Endocrine Society's Clinical Practice Guideline, paragraph 3.7. See also Document FLC1571, Society for Endocrinology's response to question 3, Annex 1, of the CMA's section 26 notice dated 28 February 2018.

[60] Document PD0006, National Institute for Health and Care Excellence - Postural hypotension in adults: fludrocortisone. https://www.nice.org.uk/advice/esuom20/ifp/chapter/What-is-postural-hypotension.

[61] For instance, in a series of over 500 diabetic patients in Italy, the prevalence of cardiovascular autonomic dysfunction was 1.8%. It also provides anecdotal data from a tertiary referral centre which states out of around 800 referrals a year, approximately 20 will be referred with a query of unexplained postural hypotension, of whom possibly 2 will require fludrocortisone. Document FLC4696, British and Irish Hypertension Society's response to question 4a, Annex 1, of the CMA's section 26 notice dated 11 October 2018.

[62] Non-pharmacological therapy may include postural and behavioural practices and good hydration.

[63] Document FLC4696, British and Irish Hypertension Society's response to question 2d, Annex 1, of the CMA's section 26 notice dated 11 October 2018.

[64] The British and Irish Hypertension Society stated that '*fludrocortisone can be considered first choice ('off-label') alongside midodrine which is licensed in the UK for severe orthostatic hypotension due to autonomic dysfunction*.' (Document FLC4696, British and Irish Hypertension Society's response to question 2b, Annex 1, of the CMA's section 26 notice dated 11 October 2018.) See below at paragraph 3.28 about the framework relating to the prescription of unlicensed drugs.

have glucocorticoid and/or mineralocorticoid properties. Fludrocortisone acetate belongs to the third level class H02A (Corticosteroids for Systemic Use) and fourth class H02AA (Mineralocorticoids). Similarly, the National Institute for Health and Care Excellence ('**NICE**') categorises fludrocortisone acetate within oral corticosteroids with high mineralocorticoid activity.

b. Formulation of fludrocortisone acetate

3.26. In the UK, fludrocortisone acetate is available in tablets, capsules or in liquid/oral suspension forms.

3.27. In tablet form, fludrocortisone acetate is only available in 0.1 mg strength. Fludrocortisone Acetate Tablets are the only licensed formulations of fludrocortisone acetate in the UK for human use. This Decision relates to the supply of Fludrocortisone Acetate Tablets. '*Florinef*' is the branded name of the Cold Storage Fludrocortisone supplied by Aspen in the UK until it was debranded and subsequently withdrawn from the UK market by Aspen, as explained at paragraph 4.8 below.

3.28. The other fludrocortisone acetate-containing formulations (ie capsules or liquid forms) are not licensed in the UK for human use, meaning that they are manufactured and sold without an MA from the UK Medicines and Healthcare products Regulatory Agency ('**MHRA**'). Off-label and unlicensed drugs can be prescribed only when the prescriber concludes, for medical reasons, that it is necessary to use the unlicensed or off-label form of the drug to meet the specific needs of the patient. Drugs may not be marketed for such off-label or unlicensed purposes. The relevant regulatory bodies have provided guidance to healthcare professionals when prescribing unlicensed or off-label medications.[65]

3.29. In capsules, fludrocortisone acetate is available in 50mcg and 100mcg strength. In liquid forms, fludrocortisone acetate is available in solutions of 125mcg/5ml, 150mcg/5ml, 20mcg/5ml, 250mcg/5ml, 25mcg/5ml, 500mcg/5ml, 100mcg/5ml and 50mcg/5ml.[66] Oral suspension fludrocortisone acetate is not recommended as a routine replacement option in adult patients

[65] Document PD0007, MHRA guidance – off-label or unlicensed use of medicines: prescribers' responsibilities, 1 April 2009.See also Document PD0008, General Medical Council's guidance on Good practice in prescribing and managing medicines and devices, March 2013.
[66] Document FLC1571, Society for Endocrinology's response to questions 8-10, Annex 1, of the CMA's section 26 notice dated 28 February 2018.

(who represent the majority of affected patients).[67] Figure 2 shows that tablets accounted for over 99% of fludrocortisone dispensed in England between 2014 and 2017.[68] A large variety of other formulations have also been used in small quantities.

Figure 2: Number of 0.1 mg equivalent doses of fludrocortisone acetate dispensed in England

	2014	**2015**	**2016**	**2017**
100 mcg tablets	13,738,672	14,453,597	15,117,029	15,732,774
100mcg/5ml solution	7,041	7,086	10,122	11,088
10mcg/5ml solution	3	-	-	-
125mcg/5ml solution	675	425	468	85
20mcg/5ml solution	395	358	242	29
250mcg/5ml solution	6,238	4,180	3,224	3,849
25mcg/5ml solution	4	38	30	15
500mcg/5ml solution	1,100	-	-	28
50mcg capsules	248	385	499	474
50mcg/5ml solution	8,941	9,124	8,453	8,440
62.5mcg/5ml solution	-	-	25	-
75mcg/5ml solution	-	-	5	-
150mcg/5ml solution	-	-	60	8
100 mcg tablets dispensed in the UK	15,960,071	16,811,644	18,060,207	18,477,234

Source: CMA analysis based on Document PD0012, PCA data for England and Document CMA001, CMA Fludro Formulations. Formulations converted into the equivalent of 0.1 mg doses (to ensure comparability against the number of tablets).

IV. Other corticosteroids

3.30. There are other corticosteroids that may also be used for the treatment of adrenal insufficiency, such as hydrocortisone, prednisolone and dexamethasone. Prednisolone and dexamethasone are not generally viewed as clinical substitutes for fludrocortisone acetate by prescribers.[69] In relation to hydrocortisone, the Society for Endocrinology noted that fludrocortisone acetate and hydrocortisone both have mineralocorticoid properties, with 40mg

[67] Document FLC1571, Society for Endocrinology's response to questions 8-10, Annex 1, of the CMA's section 26 notice dated 28 February 2018. Oral suspension fludrocortisone acetate is usually for limited use in young children and under special clinical circumstances.
[68] If raw PCA data is compared – effectively assuming 1ml, 1 capsule and 1 tablet are equivalent regardless of dosage – Fludrocortisone Acetate Tablets still account for 99% of fludrocortisone dispensed.
[69] Hydrocortisone, prednisolone and dexamethasone may be used as a replacement therapy when the production of cortisol is affected. Fludrocortisone acetate may be used a replacement therapy when the production of aldosterone is affected.

hydrocortisone equivalent to 0.1 mg fludrocortisone acetate;[70] however long-term high dose hydrocortisone treatment '*in lieu of fludrocortisone replacement is dangerous and not clinically feasible'*.[71]

V. Fludrocortisone Acetate Tablets for animal use

3.31. Fludrocortisone Acetate Tablets are not authorised for animal use.[72] Until March 2016, there was no authorised drug to treat Addison's disease in animals and so veterinarians prescribed Fludrocortisone Acetate Tablets to treat dogs[73] with Addison's disease. Since March 2016, Zycortal (desoxycortone pivalate) has been available to treat Addison's disease in dogs and is administered by subcutaneous injection. In contrast to fludrocortisone acetate, Zycortal is on the list of currently authorised veterinary drugs of the Veterinary Medicines Directorate.[74]

3.32. The Code of Professional Conduct for Veterinary Surgeons indicates that a product prescribed by a veterinarian should be authorised for use in the UK in the target species for the condition being treated.[75] This Code indicates that, if there is no medicine authorised in the UK for a condition affecting a non-food producing species, the veterinarian may treat the animal with a veterinary medicine authorised in the UK for use in another animal species or for a different condition in the same species. If there is no such product, a medicine authorised in the UK for human use may be used.[76]

3.33. As a result of the '*cascade'* set out in the Code of Professional Conduct for Veterinary Surgeons, since the introduction of Zycortal to the UK market in March 2016, veterinary surgeons have been obliged to prescribe Zycortal unless there is a good reason to prescribe an alternative. Financial reasons

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[70] Document FLC1571, Society for Endocrinology's response to question 11, Annex 1, of the CMA's section 26 notice dated 28 February 2018.
[71] Document FLC1571, Society for Endocrinology's response to question 11, Annex 1, of the CMA's section 26 notice dated 28 February 2018.
[72] Document FLC1834, Aspen's response to question 18 b, Annex 1, of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).
[73] [✂]. See Document FLC1946, Dechra's response to question 8, of the CMA's section 26 notice dated 21 May 2018.
[74] Document PD0009, Veterinary Medicines Directorate – Product Information Database http://www.vmd.defra.gov.uk/ProductInformationDatabase/.
[75] Document PD0010, RCVS Setting Veterinary Standards - Code of Professional Conduct for Veterinary Surgeons – Supporting guidance https://www.rcvs.org.uk/setting-standards/advice-and-guidance/code-of-professional-conduct-for-veterinary-surgeons/supporting-guidance/veterinary-medicines/ .
[76] The Code also notes that '*A decision to use a medicine which is not authorised for the condition in the species being treated where one is available should not be taken lightly or without justification. In such cases clients should be made aware of the intended use of unauthorised medicines and given a clear indication of potential side effects. Their consent should be obtained in writing'*.

are not considered appropriate reasons for departing from the '*cascade'*.[77] However, it may be acceptable to depart from the '*cascade'* where an animal is stabilised on a drug and the risk of transferring them is considered too great.[78] The British Small Animal Veterinary Association stated that '*Typically, a new product like this takes 3 to 7 years to become the when* [sic] *there is a human medical alternative which veterinary practices feel safe prescribing (evidence – introduction of Vetoryl in 2000, Amodip in 2015).*'[79]

3.34. Dechra Veterinary Products Limited ('**Dechra**')[80] provided estimates of the volume of fludrocortisone acetate used for veterinary treatments. This suggests that in 2015, around 6.6 million Fludrocortisone Acetate Tablets were used for veterinary supply, which fell to 2.6 million in 2016 and around 240,000 in 2017.[81] Dechra's estimated supply in 2015 is also close to that estimated by Amilco for the purposes of the negotiations of the SDA.[82]

C. Framework for prescribing and dispensing Fludrocortisone Acetate Tablets for human use

I. Fludrocortisone Acetate Tablets are a prescription-only medicine

3.35. Fludrocortisone Acetate Tablets are a prescription-only medicine used in primary and secondary care, where treatment is typically initiated by a specialist (an endocrinologist) on referral.

3.36. Prescription-only medicines such as Fludrocortisone Acetate Tablets are characterised by certain general features that impact upon the prescribing and dispensing decisions of healthcare professionals and pharmacies:

(a) Healthcare professionals select the relevant medicine to prescribe for the NHS patient based on what is therapeutically most appropriate and effective. Neither the NHS patient nor the healthcare professional are

[77] Document FLC1834 and its attachment Document FLC1847, Aspen's response to question 16, of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).
[78] Document FLC3490, British Small Animal Veterinary Association's response to question 6, Annex 1, of the CMA's section 26 notice dated 11 May 2018.
[79] Document FLC3490, British Small Animal Veterinary Association's response to question 10, Annex 1, of the CMA's section 26 notice dated 11 May 2018.
[80] Dechra is the manufacturer of Zycortal, the alternative treatment to Fludrocortisone Acetate Tablets in the treatment of dogs with Addison's disease described in paragraph 3.31 above.
[81] Document FLC1946 and its attachment Document FLC1945 (Annex 8, Fludro Zycortal Figures 23 May 2018), Dechra's response to question 9a, of the CMA's s26 notice dated 21 May 2018.
[82] Document FLC1143.14, email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] dated 11 January 2016 states '[…] *I have from a very reliable source in the vet field that usage for the vet market is 5500 packs of 100 per month in the UK. 5500 packs of 100's per month is 18150 packs of 30's per month.*' 5500 packs of 100 per month is c.6.6 million tablets a year.

particularly price-sensitive since they do not pay for the medicine. The NHS typically pays for the medicine.

(b) Once a patient is stabilised on a particular medicine therapy, there are often significant medical reasons why it is disadvantageous to alter their medication.

(c) The ability of the dispenser (typically the pharmacy) to decide which medicine to dispense is limited by the prescriber's decision (see paragraphs 3.37 to 3.40). Within the parameters of the prescription, the dispenser will typically choose the cheapest version of a medicine with a view to maximising its own margin, since it pays for the drug and will be reimbursed by the NHS at a fixed level (see paragraph 3.42).

II. Prescribing

3.37. The Society for Endocrinology explained that prescriptions are usually written by GPs and only in exceptional circumstances by the endocrinologist (eg initial start of treatment or when patients may run out of fludrocortisone acetate shortly after attending an endocrinology appointment).[83]

3.38. A prescriber can choose how prescriptive they are when writing a prescription for a medicine, which in turn has implications for the degree of choice that a dispenser may have when fulfilling a prescription. A prescriber may choose to write one of the following:

(a) an '*open'* or '*generic'* prescription for a medicine which only specifies the API,[84] or specifies the API together with one or more of the medicine's forms,[85] its strength,[86] and dose;[87] or

(b) a '*closed'* prescription for a medicine which specifies the particular brand, manufacturer or supplier.[88]

3.39. Prescribers are generally encouraged to write prescriptions using a medicine's generic name, eg '*fludrocortisone acetate*', regardless of whether a generic

[83] Document FLC1571, Society for Endocrinology's response to question 6, Annex 1, of the CMA's section 26 notice dated 28 February 2018.
[84] For example, '*fludrocortisone'*.
[85] For example, '*tablets*.
[86] For example, '*0.1mg*'.
[87] For example, '*to be taken daily*'.
[88] For example, '*Florinef*', the branded name of the drug supplied by Aspen in the UK until the end of February 2016.

product is actually available, unless there are specific clinical reasons not to do so.[89]

3.40. The Society for Endocrinology told the CMA that, in its experience, prescriptions for fludrocortisone acetate are usually open,[90] that is they specify the generic name and strength, without reference to supplier or brand. [✂], a consultant to Aspen, explained that in the UK most prescriptions are written generically. He also explained that in the case of fludrocortisone, prior to the debranding of Florinef, well over 90% of prescriptions used the generic name fludrocortisone rather than the brand name Florinef.[91]

3.41. Prescriptions also set out the dosage. To treat Addison's disease, the usual daily dose ranges from 0.05 milligrams (half a tablet of Fludrocortisone Acetate Tablet) to 0.3 milligrams (three tablets of Fludrocortisone Acetate Tablets) for adults. To treat congenital adrenal hyperplasia, the usual daily dose ranges from 0.1 milligram (one tablet of Fludrocortisone Acetate Tablets) to 0.2 milligrams (two tablets of Fludrocortisone Acetate Tablets).[92] Once it is established that patients with primary adrenal insufficiency suffer from mineralocorticoid deficiency, lifelong fludrocortisone acetate replacement is required, and the dosage will usually not change.[93] Fludrocortisone Acetate Tablets are usually taken once a day.

III. Dispensing

3.42. Pharmacies in England receive payment for the prescriptions they fulfil from the NHS patients' clinical commissioning groups ('**CCG**'s).[94] The reimbursement price paid by the NHS to pharmacies for any given drug is set

[89] Document PD0011, the Royal Pharmaceutical Society Prescribing Competency Framework under The Consultation Competency 4,4 states a prescriber '*Prescribes generic medicines where practical and safe for the patient and knows when medicines should be prescribed by branded product*.'
[90] Document FLC1571, Society for Endocrinology's response to question 5, Annex 1, of the CMA's section 26 notice dated 28 February 2018.
[91] Document FLC1991, page 45, lines 9 to 19, Transcript of interview with [Consultant to Aspen] on 25 October 2017. See also Document FLE0981, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 8 January 2016, headed '*for release term sheet – AGI/Tiopharma* [sic]': '*Brand shows virtual total is written as a generic'*.
[92] See Document PD0039, Tiofarma B.V.'s public assessment report for Fludrocortisone Acetate 0.1 mg Tablets. See also extracts of the internal guidelines on the treatment of patients with primary adrenal insufficiency: '*Mineralocorticoid replacement in* [primary adrenal insufficiency]: *We recommend that all patients with confirmed aldosterone deficiency receive mineralocorticoid replacement with fludrocortisone (starting dose, 50-100 micrograms in adults* […]*'.* (Document FLC1571, Society for Endocrinology's response to question 1, Annex 1, of the CMA's section 26 notice dated 28 February 2018 and its attachment Document FLC1555, paragraph 3.7).
[93] It may be required to increase fludrocortisone dose temporarily due to hot and humid climate conditions as this leads to a higher fluid and salt loss by sweating. See Document FLC1571, Society for Endocrinology's response to question 4, Annex 1, of the CMA's section 26 notice dated 28 February 2018.
[94] CCGs are the relevant purchaser in England. The purchasing entities differ in Scotland, Wales and Northern Ireland, but the CMA considers that this does not materially impact on the findings in this document.

out in a monthly publication, generally referred to as the Drug Tariff (see paragraphs 3.62 and 3.63) and remains the same whether an open prescription is filled by a branded product or a generic product (including parallel imports). Subject to clinical guidance (if there is any), pharmacies therefore have an incentive to dispense the cheapest medicine available, usually a generic product. Similarly, pharmacies have a financial incentive to purchase parallel imports if they are available more cheaply.

D. Regulatory framework for the supply of generic pharmaceuticals in the UK such as Fludrocortisone Acetate Tablets

I. Regulatory authorisation to supply generic products in the UK

3.43. An MA is the principal regulatory authorisation that a company must obtain in order to market and sell a pharmaceutical product in an EU Member State.[95] Each Member State has a national competent authority responsible for granting MAs. In the UK, this is the MHRA. An MA will only be granted if the pharmaceutical product meets satisfactory standards of safety, quality and efficacy in treating the condition for which it is intended.

3.44. Companies typically undertake (either by themselves or by contracting with third parties) substantial development work before they are in a position to apply for an MA for a particular drug. Common preparatory steps include the initial selection and development of pipeline projects,[96] the design and testing of potential manufacturing processes, stability testing, and bioequivalence studies.[97] The results of the above work are typically compiled in a single '*dossier'* which can be used to apply for an MA from the relevant national authority.

3.45. In the present case, Tiofarma, together with [Pharmaceutical Company 2], undertook the required development work to prepare the dossier for the MA for Ambient Storage Fludrocortisone (for further details see paragraphs 4.9 to 4.11 below).

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

[96] A developer of generic drugs decides whether to develop a new product based on the expected return on investment, which will be affected by the time and costs involved in developing a new product relative to the potential profits.

[97] The bioequivalence study compares the bioavailability of the generic drug to the bioavailability of the reference originator drug, in terms of rate and extent of absorption throughout the gastrointestinal tract. A similar rate and extent of absorption indicates that both medicines have a matching therapeutic effect and equal safety and efficacy profiles.

3.46. The MHRA aims to complete its review of most MA applications within seven months,[98] excluding the time taken to provide any further information or data required, which in practice can cause the application process to take substantially longer. As part of the MA application process, companies must typically inform the MHRA of their proposed supply chain for the drug in question (Section 3.D.II, below, contains further detail on the functions undertaken at each stage in a typical pharmaceutical supply chain). Companies are free to select the members of their supply chain so long as they can demonstrate that they each comply with applicable regulations. Once approved, salient information about the supply chain such as how and where the product is manufactured is listed on the face of each MA.[99] Supply chains can be changed after an MA is obtained through the MA variation process (see paragraph 3.48 below). Applicants must also demonstrate that they are capable of fulfilling the regulatory compliance duties relating to the relevant product (ie pharmacovigilance) and supply chain applicable to all MA holders.

3.47. Once granted, an MA is valid for five years before a renewal is needed.[100] Companies that decide to sell the same product in another EU Member State can obtain a '*duplicate*' of an MA which they already hold to facilitate that objective.[101] Tiofarma stated that this was the rationale for obtaining a duplicate MA (PL 17299/002) for Fludrocortisone Acetate Tablets.[102]

3.48. Companies seeking to vary an MA must first receive approval from the MHRA for all variations except those which have little or no impact on the quality,

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[98] Under DCP procedure, see Document PD0012, GOV.UK – Guidance – Apply for a licence to market a medicine in the UK, https://www.gov.uk/guidance/apply-for-a-licence-to-market-a-medicine-in-the-uk#DCP.
[99] Information about the uses of the drug (ie the therapeutic indications) are set out in the 'Summary Product Characteristics' document, which is published for each medicine by the MHRA and is published alongside the MA.
[100] See Document PD0014, Guidance on Renew: marketing authorisation for a human medicine https://www.gov.uk/guidance/renew-marketing-authorisation-for-a-human-medicine. During the Relevant Period, authorisations could only be renewed for another five-year period; however, under current legislation renewal can be for an unlimited period. See Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, OJ L 311 of 28.11.2001, Article 24 and the amendments in Directive 2004/27/EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, OJ L 136 of 30.04.2004.
[101] This allows companies to rely on the duplicate MA in the authorisation procedure before the relevant authority in that Member State. By doing so, they avoid the risk that changes need to be made that may affect the MA which they are relying on to make sales in the UK.
[102] '*Authorities in other jurisdictions may require that changes be made to a dossier before they will grant an* [MA] *in their jurisdictions. In order to ensure that the dossier being relied on for the UK authorisation does not need to be modified, it is common practice to obtain a duplicate authorisation (so that the second dossier can be modified, as necessary)*.' Document FLC2074.2, Tiofarma's response to question 17 g, Annex 1A, of ACM's request for information dated 10 October 2017. This statement is corroborated by Document FLE1024, email from [Tiofarma Employee 1] to [Aspen Senior Executive 2] dated 2 October 2016 in which he explains the reason for having a duplicate licence.

safety or efficacy of the product, such as administrative modifications (for example, a change of company name).[103]

II. The supply chain

3.49. This section provides a high-level description of the tasks that form part of the typical supply chain for pharmaceuticals in the UK (and how the Parties were involved in performing these functions in relation to Fludrocortisone Acetate Tablets).[104]

a. Manufacturing

3.50. To make, assemble or import human medicines in the UK, a company needs certain regulatory authorisations.[105] Manufacturing a drug involves the following key activities: (i) procuring the API; (ii) manufacturing the drug, which involves incorporating the APIs at the right strength, and with the required properties; (iii) packaging the drug; and, in some cases, (iv) delivering the product to UK pre-wholesalers.

3.51. Until the end of February 2016 (when the SDA came into effect), Aspen obtained its supplies of Cold Storage Fludrocortisone for sale in the UK from Haupt Pharma, a German manufacturer. Since 1 March 2016, Aspen has obtained its supply of Ambient Storage Fludrocortisone from Tiofarma. Tiofarma has sourced the API for Fludrocortisone from [✂] (a supplier of the API established in [✂]).

b. Wholesaling and distribution

3.52. Pharmaceutical products can be distributed to pharmacies directly or, more commonly, via wholesalers.[106] In order to supply drugs to any intermediary in the EU (other than the patient using the medicine), a supplier needs to be

[103] See Document PD0015, GOV.UK – Guidance – Medicines: apply for a variation to your marketing authorisation https://www.gov.uk/guidance/medicines-apply-for-a-variation-to-your-marketing-authorisation applying Regulation EC 1234/2008.
[104] Document FLC1834 and its attachment Document FLC1844 (Document 3), Aspen's response to question 10, of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).
[105] For instance, a company needs to demonstrate to the MHRA that its facilities and production processes comply with EU good manufacturing practice. See Document PD0016, the UK Government's Guidance on good manufacturing practice and good distribution practice at https://www.gov.uk/guidance/good-manufacturing-practice-and-good-distribution-practice. These functions are based on Document PD0017, the EU Good manufacturing and distribution practices relating to medicinal products for human use https://ec.europa.eu/health/human-use/good_distribution_practice_en.
[106] In the case of Fludrocortisone Acetate Tablets, Aspen has sold [✂]% of its volume to wholesalers and [✂] direct to pharmacies and hospitals. See Document FLC0397B and its attachment Document FLC0397I, Aspen's response to question 18, of the CMA's section 26 notice dated 10 October 2017 (s.26 notice is provided in Document FLC0149B).

granted a wholesale distribution authorisation ('**WDA**') by the MHRA.[107] Amilco acquired a WDA from [Pharmaceutical Company 1] in August 2015.[108]

3.53. The MHRA stated that an MA holder could outsource some or virtually all parts of the wholesaling and distribution functions, such as storage, distribution, transport, delivery and invoicing services.[109] In the case of Fludrocortisone Acetate Tablets, certain wholesaling functions were outsourced to [Logistics Provider] as described below:

(a) During the period of the SDA, when Tiofarma held the MA for Ambient Storage Fludrocortisone, formally the products manufactured by Tiofarma for Aspen were sold to Tiofarma's local representative, Amilco, who invoiced the products to Aspen. Aspen outsourced the distribution of products to [Logistics Provider].[110] As a result, all products were delivered by Tiofarma to [Logistics Provider]'s warehouse, who then organised the distribution in the UK to Aspen's customers, ie wholesalers and hospitals. Under this model, Aspen did not at any point take receipt of, store, or dispatch, the Fludrocortisone Acetate Tablets.

(b) Before and after the period of the SDA, when Aspen held the MA for the supplied product, the distribution of the relevant fludrocortisone product was subject to a similar supply chain, with the exception of the intermediation of Amilco.

c. Sales and marketing

3.54. Selling pharmaceutical products typically involves a number of tasks including marketing/promotional activities (though not typically for generic products such as Fludrocortisone Acetate Tablets),[111] determining the list

[107] To qualify for a WDA, the licensee must demonstrate its compliance with regulations on Good Distribution Practice and pass regular inspections of its facilities. See Document PD0018, EUROPEAN COMMISSION – Guidelines of 5 November 2013 on Good Distribution Practice of medicinal products for human use.
[108] Document FLC1143, Amilco's response to question 6, Annex 1, of the CMA's section 26 notice dated 12 February 2018. The CMA also notes in Amilco's submission that it lacked the infrastructure necessary to distribute pharmaceutical products in the UK, as it had leased the site specified under its WDA to a third party between the end of January 2015 and December 2016.
[109] Document FLC1863.1, paragraph 6, Note of call between CMA and MHRA dated 16 May 2018. For instance, [Logistics Provider] explained that it can provide most of these wholesaling functions. (Document FLC4653C, [Logistics Provider]'s response to question 1, of the CMA's section 26 notice dated 6 September 2018).
[110] Document FLC1834 and its attachment Document FLC1844 (Document 3), Aspen's response to question 10, of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).
[111] Aspen has told the CMA that it has not undertaken any promotion or marketing activities in relation to Florinef or the Ambient Storage Fludrocortisone during the Relevant Period. Document FLC1834 and its attachment Document FLC1844 (Document 3), Aspen's response to question 10, of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).

price/wholesale discount and contracting with/ issuing invoices to wholesalers and pharmacists.

3.55. Aspen has been responsible for sales of Fludrocortisone Acetate Tablets and determined the list price and wholesale discounts for it, before and throughout the period of the SDA. However, it did not carry out any marketing activity before or throughout the period of the SDA.

3.56. Wholesalers place orders with Aspen, which in turn orders the required quantity of tablets from the manufacturer.[112] [Logistics Provider] is responsible for invoicing customers on behalf of Aspen.

d. Regulatory compliance and pharmacovigilance

3.57. Companies selling pharmaceuticals in the UK must observe good pharmacovigilance practice, which is the minimum standard for monitoring the safety of medicines on sale to the public in the EU. This is regulated by the MHRA.[113]

3.58. Under the SDA, Aspen performed most, if not all,[114] aspects of the compliance function in relation to Ambient Storage Fludrocortisone.

e. The different routes to market available to new entrants

3.59. The ability of MA holders to outsource most of the required functions within the supply chain to third-party partners or contractors means that there are a number of possible routes to market available to an MA holder.[115] For example, a manufacturer or MA holder can sell its products directly to pharmacies, possibly using a third-party logistics provider, or can sell to a wholesaler which contracts with pharmacies on its own behalf.

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[112] Document FLC0452, Aspen's response to question 33, of the CMA's section 26 notice dated 10 October 2017 (s.26 notice is provided in Document FLC0149B).
[113] See MHRA's website on Document PD0019, GOV.UK - Guidance on Good pharmacovigilance practice.
[114] Tiofarma stated to Aspen that its '[…] *PV* [pharmacovigilance] *system and procedures* […] *are not set up and suitable for UK marketing authorisations and providing sufficient PV support*'. Document FLC3312, email from [Tiofarma Employee 5] to [Person 3 acting for Amilco] dated 18 February 2016. Document FLC3305, email from [Person 3 acting for Amilco] to [Tiofarma Employee 5] dated 19 February 2016. However, Tiofarma's Regulatory Affairs department and Quality Assurance department remained the contact for any queries regarding the product and product quality complaints respectively. Document FLC3327 (see English translation in Document FLC3327.1), email from [Tiofarma Employee 5] to [Aspen Employee 27] ([✂]) dated 30 March 2016.
[115] The MHRA stated that an MA holder could outsource some or virtually all parts of the wholesaling and distribution functions, such as storage, distribution, transport, delivery and invoicing services; Document FLC1863.1, paragraph 6, Note of call between CMA and MHRA dated 16 May 2018. For instance, [Logistics Provider] explained that it can provide most of these wholesaling functions. (Document FLC4653C, [Logistics Provider]'s response to question 1, of the CMA's section 26 notice dated 6 September 2018). [✂].

3.60. This is particularly the case in relation to drugs which are purchased primarily by wholesalers directly, as this limits the amount of sales and marketing infrastructure required to supply the market.

III. Pricing framework

3.61. The end customer of Aspen's UK products is the NHS – specifically CCGs – which must reimburse pharmacies for the drugs prescribed to patients. Patients registered with the NHS do not pay for their prescriptions for Fludrocortisone Acetate Tablets. However, CCGs do not negotiate the prices of Fludrocortisone Acetate Tablets with pharmaceutical suppliers or purchase the medicines directly from them. Moreover, CCGs have no formal powers enabling them to limit the price they pay for pharmaceutical products.

a. The mechanism for setting the reimbursement price of drugs in the UK

3.62. In England and Wales, the reimbursement price that pharmacies can claim from the NHS when fulfilling prescriptions is determined by a publication produced on a monthly basis by NHS Prescription Services, and generally referred to as the drug tariff ('**Drug Tariff**').[116] It outlines, amongst other things, the amounts that pharmacy contractors (or dispensing doctors) are to be reimbursed for the cost of medicines which they have supplied against NHS prescriptions.

3.63. The Drug Tariff provides that a pharmacist is reimbursed for medicines dispensed at a '*basic price*' ('**Drug Tariff Price**') readjusted for any clawback discount [117] or concessions[118] ('**NHS England Reimbursement Price**').[119] The Drug Tariff Price for a given drug reflects any voluntary or statutory price controls that may apply (see below).

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[116] See Document PD0020, NHSBSA – Drug tariff, https://www.nhsbsa.nhs.uk/pharmacies-gp-practices-and-appliance-contractors/drug-tariff. Separate equivalent publications are produced for Scotland and Northern Ireland. The CMA does not consider that the presence of separate Drug Tariffs materially affects the findings in this document.

[117] The clawback was designed to share with the NHS the profits pharmacies can make by purchasing drugs at below the price at which they are reimbursed. See *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 33.

[118] Concessions are variations of the Drug Tariff agreed between the DHSC and the Pharmaceutical Services Negotiating Committee ('**PSNC**'), usually when pharmacies would make a loss on the product if reimbursed at the Drug Tariff Price.

[119] The CMA has used the NHS England Reimbursement Price as the basis for its calculations of the price of Fludrocortisone Acetate Tablets to the NHS. The CMA has no reason to believe that the reimbursement price is materially different in the other nations; in any event, the volume dispensed in other nations is very small, such that any difference would be unlikely to materially change the CMA's calculations.

3.64. Products covered by the Drug Tariff are assigned to one of three categories (A, C or M) which determines how the NHS England Reimbursement Price is established for each product. Two of those categories are relevant for the present purpose:[120]

(a) Category C typically comprises drugs which are only available as a branded product or as a generic product from one or two sources. The Drug Tariff Price of a Category C drug is based on the list price of a particular proprietary product, manufacturer or, as the case may be, supplier ('**List Price**'); and

(b) Category A comprises drugs that are readily available as a generic from several sources. The Drug Tariff Price of a Category A drug is based on a weighted average[121] of the List Prices (ie before customer-specific discounts) of the following four suppliers: AAH Pharmaceuticals Limited ('**AAH**'), Alliance Healthcare (Distribution) Limited ('**Alliance**'), Teva UK Limited ('**Teva**') and Actavis UK Limited ('**Actavis**') on or before the 8th of the month being reimbursed.

3.65. From at least October 2014 to August 2016, Fludrocortisone Acetate Tablets were listed in Category C of the Drug Tariff. As a result, the Drug Tariff Price was based on Aspen's List Price, Aspen being the only supplier of Fludrocortisone Acetate Tablets in the UK.

3.66. In September 2016, Fludrocortisone Acetate Tablets were moved to Category A, where they remain. Since then, the Drug Tariff Price of Fludrocortisone Acetate Tablets has been based on the weighted average of the List Prices of AAH and Alliance.[122] These have in turn been based solely on Fludrocortisone Acetate Tablets supplied by Aspen.[123]

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[120] There is a third category, ie category M, which typically applies to product for which generics are readily available from several sources.
[121] In the weighted formula, AAH and Alliance prices have a weighting of 2, the prices from the other suppliers have a weighting of 1. Prices of parallel imported drugs are not taken into account in the calculation of the Drug Tariff Price.
[122] Document FLC0017, NHSBSA's response to question 1 and 4, of the CMA's information request dated 6 April 2017.
[123] Document FLC0046 and its attachment Document FLC0046.1, NHSBSA's response to the CMA's information request dated 7 June 2017; the Excel file supplied by the NHSBSA shows that the Drug Tariff calculation from September 2016 to May 2017 was based on a 30-pack supplied by AAH and Alliance, ie Ambient Storage Fludrocortisone supplied by Aspen, with one exception during this period: in March and April 2017, the calculation for the Drug Tariff Price was erroneously based in part on a parallel imported 100-pack of Fludrocortisone Acetate Tablets supplied by a wholesaler whose List Price was used for the Drug Tariff calculation. See also Document FLC0017, NHSBSA's response to question 4, of the CMA's information request of 6 April 2017.

b. The mechanisms for controlling the price of drugs in the UK generally

3.67. The Department of Health and Social Care ('**DHSC**') has been given certain powers to control the prices of drugs sold in the UK. The nature of these powers varies depending on whether a drug is branded or not, and on the relevant Drug Tariff category (see paragraph 3.64 above).

3.68. For the purpose of controlling prices of branded drugs, DHSC may rely either on:

(a) Voluntary schemes entered into by DHSC pursuant to section 261 of the National Health Service Act 2006[124] ('**NHS Act**'); or

(b) Statutory powers set out in sections 262 and 263 of the NHS Act to impose direct price controls on specific medicines; or

(c) Introducing an industry wide statutory scheme to control the price of medicines not covered by a voluntary scheme.[125]

3.69. For the purpose of controlling prices of generic drugs, DHSC has historically had a general policy of relying on competition between suppliers to control prices, as described above.[126] DHSC can also use its powers under section 262 of the NHS Act with regard to unbranded products. However, as set out in more detail in paragraphs 3.73 to 3.75, its ability to use these powers has been limited until recently.

c. Mechanism for controlling the price of branded drugs

3.70. Regulation of branded drug prices, under either voluntary schemes or statutory powers, aims to balance the need to provide adequate incentives to innovator companies to develop new drugs against the need to ensure that the NHS can supply necessary medicines within the constraints of its budget.[127]

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[124] Whilst the relevant sections of the NHS Act 2006 refer to the role of the Secretary of State for Health, in practice, that role falls to be discharged by the DHSC. For convenience we refer to the DHSC in this context. See *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11.
[125] Section 263 of the NHS Act grants the Secretary of State the power to introduce an industry-wide statutory scheme to control the price of drugs not covered by a voluntary scheme. The statutory scheme that was in force in that period only applied to branded medicine. From March 2016, Aspen supplied an unbranded version of Fludrocortisone Acetate Tablets and therefore the statutory scheme is not relevant for that period.
[126] Health Service Medical Supplies (Costs) Bill: Committee Stage Report, 2 December 2016, page 3.
[127] The PPRS is explicitly designed with the aim of ensuring '*that safe and effective medicines are available on reasonable terms to the National Health Service*' and promoting '*a strong, efficient and profitable pharmaceutical industry*', 2014 PPRS, page 9, paragraph 1.2.

3.71. A number of voluntary schemes have been agreed with industry bodies pursuant to section 261 of the NHS Act. One of these voluntary schemes is the Pharmaceutical Price Regulation Scheme ('**PPRS**').

3.72. Under the PPRS, a member has freedom, within certain parameters, to set the price of a new drug.[128] Once the price is set, the PPRS prevents the scheme member from increasing the price except in very limited circumstances.[129] Mechanisms to control generic prices are limited in practice.

3.73. Under Section 262(1) of the NHS Act, DHSC could, after consulting with the industry body, limit any price which may be charged by any manufacturer or supplier for the supply of any health service medicine. This extends to unbranded as well as branded drugs.

3.74. This power could not be used against a member of a voluntary scheme,[130] such as Aspen, until 7 August 2017, when The Health Service Medical Supplies (Costs) Act 2017 entered into force.[131] However, the exercise of this power by DHSC was not possible until supporting information-gathering regulations[132] were brought into force on 1 July 2018, under the new section 264A.[133]

3.75. In practice, the power available to the Secretary of State has not been used[134] by the DHSC to procure lower prices in the market with respect to Fludrocortisone Acetate Tablets. DHSC stated that it was aware the CMA was considering a potential investigation into this product.[135] It therefore did not challenge the price directly.

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[128] It is assumed however that prices at launch will be set at a level that is close to their expected value as assessed by the NICE. NICE assesses the clinical and cost effectiveness of most new medicines launched in the UK market. *The Pharmaceutical Price Regulation Scheme 2014*, Department of Health and Association of the British Pharmaceutical Industry, December 2013, paragraph 7.14.

[129] To increase its price, the scheme member can either (i) apply to the DHSC for approval to increase a price or (ii) seek to modulate its prices. It is very rare for a scheme member to seek individual price increases.

[130] Section 262(2) NHS Act, until 7 August 2017, provided that the power was '*not exercisable at any time in relation to a manufacturer or supplier to whom at that time a voluntary scheme applies*'.

[131] The Health Service Medical Supplies (Costs) Act 2017 (Commencement No. 1 and Saving Provision) Regulations 2017. Section 4 of the NHS Act amended section 262(2) NHS Act to state that '*If at any time a health service medicine is covered by a voluntary scheme applying to its manufacturer or supplier, the powers conferred by this section may not be exercised at that time in relation to that manufacturer or supplier* ***as regards that medicine***' (emphasis added).

[132] The Health Service Products (Provision and Disclosure of Information) Regulations 2018.

[133] Section 8 of the Act inserts a new section 264A into the NHS Act 2006, allowing for such regulations for purposes including '*the exercise by the Secretary of State of any powers under section 260 to 264 and 265*'.

[134] At least until the date of the Statement of Objections.

[135] Document FLC3630, DHSC response to question 4b, Annex 1A, of CMA's section 26 notice dated 20 August 2018. It also states: *'The Department has a policy, where if it feels a price is anti-competitive, it will refer the case to the Competition and Markets Authority (CMA)'.*

4. CONDUCT UNDER INVESTIGATION

A. Introduction

4.1. In this section, the CMA sets out:

(a) Aspen's plans, as the sole UK supplier of Fludrocortisone Acetate Tablets, to debrand Cold Storage Fludrocortisone and increase prices, and Amilco and Tiofarma's steps to enter the Relevant Market with a generic version of Fludrocortisone Acetate Tablets;

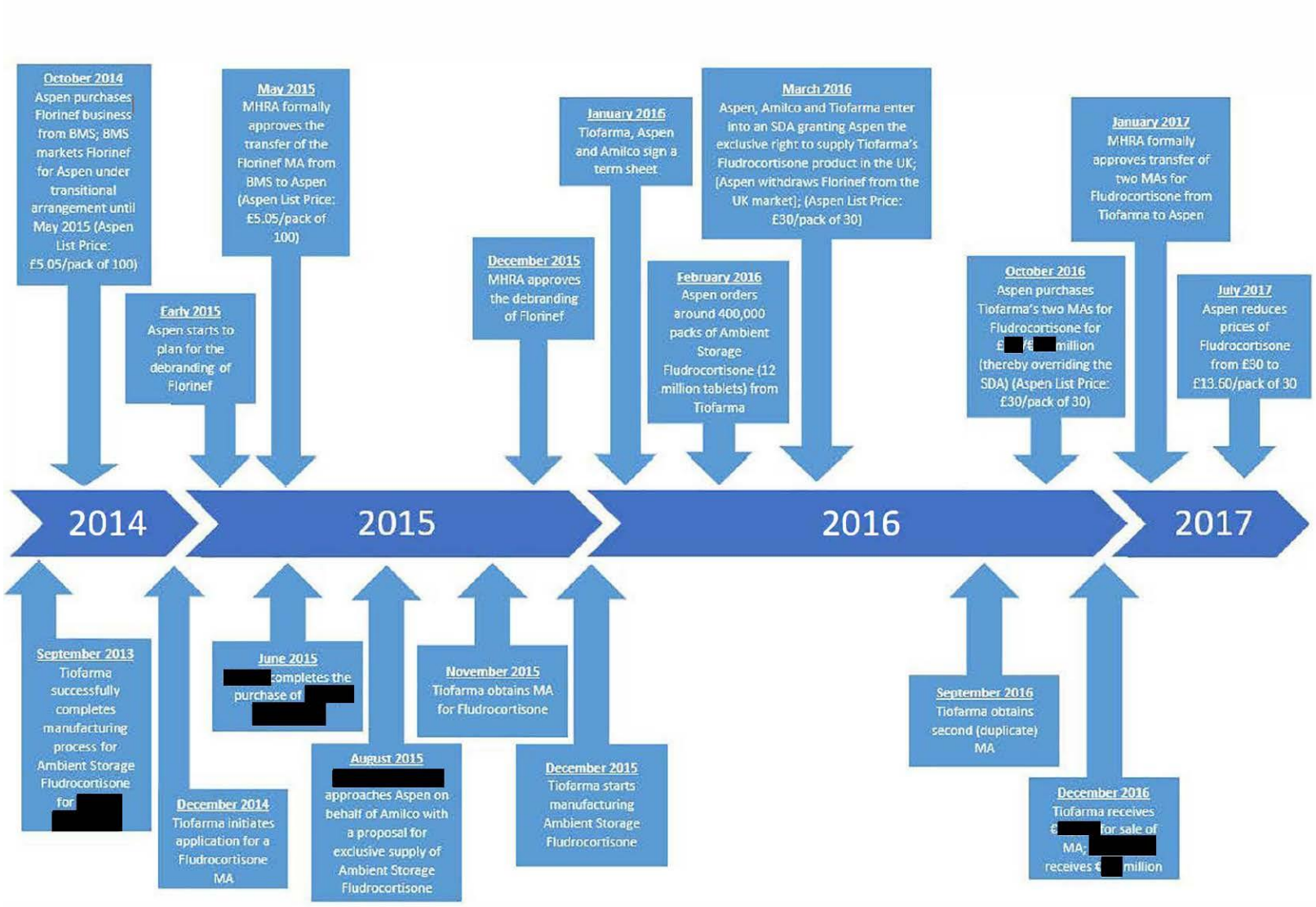
(b) The Parties' negotiations and agreement to enter into the SDA in relation to the supply of Ambient Storage Fludrocortisone, which led to Aspen replacing its Cold Storage Fludrocortisone by Ambient Storage Fludrocortisone, Aspen remaining the sole UK supplier of Fludrocortisone Acetate Tablets, and Aspen increasing its prices by more than 1,800%;

(c) How the SDA was terminated as a result of Aspen and Tiofarma entering into the SAA (and new supply agreement ('**Supply Agreement**')) for the purpose of transferring to Aspen of the worldwide rights (including MAs) attached to Ambient Storage Fludrocortisone;

(d) Evidence relating to third parties expressing interest in the MAs held by Tiofarma for Ambient Storage Fludrocortisone; and

(e) An overview of the pricing, costs, revenues and volume of the supply of Fludrocortisone Acetate Tablets since 2014. Since November 2014, Aspen has been the sole UK supplier of Fludrocortisone Acetate Tablets (other than parallel imports).

4.2. In the timeline below, the CMA sets out the key events that took place in the Relevant Market, before setting out a more detailed account of the relevant facts.


October 2014
Aspen purchases Florinef business from BMS; BMS markets Florinef for Aspen under transitional arrangement until May 2015 (Aspen List Price: £5.05/pack of 100)
Early 2015
Aspen starts to plan for the debranding of Florinef
May 2015
MHRA formally approves the transfer of the Florinef MA from BMS to Aspen (Aspen List Price: £5.05/pack of 100)
December 2015
MHRA approves the debranding of Florinef
January 2016
Tiofarma, Aspen and Amilco sign a term sheet
February 2016
Aspen orders around 400,000 packs of Ambient Storage Fludrocortisone (12 million tablets) from Tiofarma
March 2016
Aspen, Amilco and Tiofarma enter into an SDA granting Aspen the exclusive right to supply Tiofarma's Fludrocortisone product in the UK; [Aspen withdraws Florinef from the UK market]; (Aspen List Price: £30/pack of 30)
October 2016
Aspen purchases Tiofarma's two MAs for Fludrocortisone for £[redacted]/€[redacted] million (thereby overriding the SDA) (Aspen List Price: £30/pack of 30)
January 2017
MHRA formally approves transfer of two MAs for Fludrocortisone from Tiofarma to Aspen
July 2017
Aspen reduces prices of Fludrocortisone from £30 to £13.60/pack of 30
2014
2015
2016
2017
September 2013
Tiofarma successfully completes manufacturing process for Ambient Storage Fludrocortisone for [redacted]
December 2014
Tiofarma initiates application for a Fludrocortisone MA
June 2015
[redacted] completes the purchase of [redacted]
August 2015
[redacted] approaches Aspen on behalf of Amilco with a proposal for exclusive supply of Ambient Storage Fludrocortisone
November 2015
Tiofarma obtains MA for Fludrocortisone
December 2015
Tiofarma starts manufacturing Ambient Storage Fludrocortisone
September 2016
Tiofarma obtains second (duplicate) MA
December 2016
Tiofarma receives €[redacted] for sale of MA; [redacted] receives €[redacted] million

B. Parties' positions and conduct in the Relevant Market prior to the SDA

I. Aspen plans to debrand Florinef

a. Aspen enters the Relevant Market in 2014

4.3. On 31 October 2014 Aspen entered the Relevant Market through the purchase from Bristol-Myers Squibb ('**BMS**') of an MA for Cold Storage Fludrocortisone, along with its established Florinef brand and associated business, as part of the acquisition of a range of other, unrelated, drugs.[136] At that time, it was the only MA for Fludrocortisone Acetate Tablets in the UK. BMS had held a licence for Florinef since 1988, through its acquisition of E.R. Squibb & Sons Limited.[137] The transfer of the MA from BMS to Aspen was approved by the MHRA on 10 May 2015.[138]

4.4. From 31 October 2014 until the end of February 2016, Aspen sold Cold Storage Fludrocortisone under the Florinef brand in the UK.[139] Throughout this period, Haupt Pharma was the registered manufacturer and CMO for that product.[140]

b. Aspen unilaterally plans to debrand Florinef and increase its price

4.5. As a branded product, Florinef was subject to the system of price regulation under the PPRS (see paragraphs 3.70 to 3.72 above) and Aspen set a List Price of £5.05 for a pack of 100 tablets (approximately £0.05 per tablet) until the end of February 2016 (when Florinef was substituted by generic Ambient Storage Fludrocortisone). The NHS England Reimbursement Price was also £5.05 per pack of 100 tablets, based on Aspen's List Price (see Figure 5).

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[136] Aspen Global Inc. and BMS entered into an Asset Purchase and Sale Agreement for the acquisition of BMS' rights to its Florinef business in the UK and in other territories effective from 31 October 2014. Document FLC0281, BMS's response to question 8b, Enclosure 1, of the CMA's section 26 notice dated 10 October 2017.
[137] The MA had originally been granted to E. R. Squibb & Sons Limited, a predecessor of BMS, on 16 November 1988 under PL number 0034/5027R. The product manufactured pursuant to that MA had, since its approval, been marketed under the Florinef brand. Document FLC0028.1 and its attachment Document FLC0036.2 (Excel spreadsheet), MHRA's response to question 1, of the CMA's section 26 notice dated 3 May 2017 and Document FLC0281 BMS's response to question 1, Enclosure 1, of the CMA's section 26 notice dated 10 October 2017.
[138] Document FLC0073 MHRA's response to question 3 d(i) of the CMA's section 26 notice dated 18 July 2017).
[139] From 31 October 2014 to 10 May 2015 (ie until the MA was transferred to Aspen), BMS performed transitional services for the benefit of Aspen under the terms of a Transitional Services Agreement (Document FLC0281, BMS's response to question 6, of the CMA's section 26 notice dated 10 October 2017).
[140] Document FLC0452 and its attachment Document FLC0457, Aspen's response to question 15 (d), to the CMA's section 26 notice dated 10 October 2017.

4.6. Shortly after acquiring Florinef in late 2014, Aspen's [✂] team began to consider the possibility of debranding that product;[141] internal approval to debrand was eventually sought from Aspen's [✂] management in mid-2015,[142] who gave their approval in September 2015.[143] This project was part of a wider Aspen strategy to debrand a number of drugs within Aspen's UK portfolio so as to increase their prices while also reducing PPRS levies.[144] In an interview with the CMA, [Aspen Employee 1] explained that he recommended the debranding of Florinef internally because, '*in this instance* […] *relative to the other sort of steroid products that are on the market, this appeared to be much lower in price than those products* […]*'*.[145]

4.7. After approving the project, Aspen's [✂] management encouraged its UK commercial team to set a high price for Fludrocortisone Acetate Tablets following debranding.[146] In November 2015, the [✂] team planned to launch debranded Cold Storage Fludrocortisone at a price of £[✂] per pack of 100

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[141] 'Debranding' refers to the practice of discontinuing the branded version of a drug and launching a generic version instead. Replacing Florinef with generic Fludrocortisone Acetate Tablets is an example of debranding. An important consequence is that the product's pricing is no longer regulated by the PPRS (see paragraphs 8.2 to 8.13 for more detail on this practice).

[142] Document FLE0387, email from [Aspen Employee 1] to [Aspen Employee 3] dated 30 July 2016: '*The idea to de-brand was conceived by the* [✂] *team shortly after acquisition from BMS* […] *The* [✂] *team proposed* [to debrand Florinef] *in the period May to July* [2015] *with* [✂] *management and eventually this was approved to include into the ongoing UK de-branding project* '. Document FLE0074 email from [Consultant to Aspen] to [Aspen Employee 1] dated 17 November 2014. In fact, Aspen was made aware of the possibility to debrand Florinef even before its acquisition.

[143] Document FLE0093, email from [Aspen Employee 1] to [Aspen Employee 13] dated 1 September 2015: '*We have spoken with* [Aspen Senior Executive 1] *and* [Aspen Senior Executive 2] *about our strategy to de-brand Florinef. In principle, they approve*.'

[144] Document FLC1992, page 21, line 13 to page 23, line 13, Transcript of interview with [Aspen Employee 1] on 19 October 2017: [Aspen Employee 1] noted there were two benefits from debranding: avoiding the PPRS levy payable on products included in the scheme, and having flexibility to change the price. See also along the same lines, Document FLC1987, page 17, lines 13 to 19, Transcript of interview with [Aspen Employee 7] on 9 November 2017.
See also Document FLE0084, email from [Aspen Employee 1] to [Aspen Employee 23] dated 8 August 2015: '*For UK, for example, i know i have to reduce UK PPRS tax impact on profitability through de-branding where possible* […]*'* and Document FLE0101, Slide 2: *'PPRS Clawback Solution. De-brand portfolio where appropriate'* and slide 7.

[145] Document FLC1992, page 20, lines 2 to 6, Transcript of interview with [Aspen Employee 1] on 19 October 2017. In the same vein, see Document FLE0088, internal Aspen documents setting out the plan for 2015/16: this document notes that Florinef was considered to be under-priced compared to some of Aspen's other unbranded products, such as [✂] Tablets: '*Q2 2015 payment was £*[✂]*. ~ €*[✂] *at budget rate - slows performance of each branded medicine – particular impact on* […] *and Florinef. Support needed to prioritise selective de-branding projects:* […] *Florinef? underpriced relative to value £5.05 versus* [✂]*.'*

[146] Document FLE0958, [Aspen Senior Executive 1] noted in relation to the debranding of Florinef: '*Tell them to go big. Market Won't go away and still less than* [✂]'. This was in reply to [Aspen Employee 10] on the same date where it was noted '*They are assuming 4.5 times; but we could get them to push to 7 times (ie 30 GBP)*'. Also mentioning that Florinef debranding is a priority, see Document FLE0114, email from [Aspen Employee 16] to various Aspen personnel including [Aspen Employee 1] on 22 October 2015 *'Florinef - second priority for commercial team, as debranding can significantly increase the profitability – upside of around 1 million EUR expected'.*

tablets.[147] Evidence from January 2016 demonstrates that the [✂] team planned to '*go in steps*' to around £[✂] per pack of 100 tablets.[148]

4.8. In November 2015, Aspen submitted its application to debrand Florinef to the MHRA and the debranding was approved in December 2015.[149] At that time, Aspen expected that the unbranded version of that product could be brought to market at the beginning of April 2016,[150] at the increased price of £[✂] per pack of 100 already floated in November 2015.[151] However, the unbranded version of Florinef was not introduced in the UK, as instead Aspen entered into the SDA with Amilco and Tiofarma. Florinef continued to be sold by Aspen until the end of February 2016, at the List Price of £5.05 per pack of 100 tablets.

II. Amilco and Tiofarma take steps to enter the Relevant Market

a. The initial development work

4.9. Sometime between 2003 and 2008, [Pharmaceutical Company 2] ([✂]) initiated the development work for a generic version of Fludrocortisone Acetate Tablets with Tiofarma.[152] [Pharmaceutical Company 2] revived those efforts in 2011.[153]

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[147] Document FLE0124, email from [Aspen Employee 18] (Aspen Global Incorporated) to [Aspen Employee 7] and another Aspen employee dated 30 November 2015, referring to a '*potential 1st generic price point* £[✂].
[148] Document FLE0138, instant messaging discussion between [Aspen Employee 1] and [Aspen Employee 2] of Aspen Europe dated 8 January 2016: *'we were going to go in steps to circa* £[✂]*/pack'*. See also Document FLE0133, email from [Aspen Employee 11] to [Consultant to Aspen] on 6 January 2016 and Document FLE0599, electronic messaging between [Aspen Employee 3] and [Aspen Employee 1] dated 21 April 2017 where [Aspen Employee 1] stated that he had planned £[✂] per pack of 100 tablets for the debranded Cold Storage Fludrocortisone. See also Document FLE0603, email from [Aspen Employee 3] to [Aspen Senior Executive 1] and [Aspen Senior Executive 2], cc [Aspen Employee 1], dated 21 April 2017.
[149] Document FLC0397B, Aspen's response to question 13, of the CMA's section 26 notice dated 10 October 2017 (s.26 notice provided in Document FLC0149B).
[150] Document FLE0128, email from [Aspen Employee 16] to [Aspen Employee 24] and others dated 15 December 2015. In an earlier version of the project plan dated of October 2015, Aspen's expectation was that the product would be brought to market between February and July 2016 (See Document FLE0114, email from [Aspen Employee 16] to [Aspen Employee 24] and others dated 22 October 2015). In November, [Aspen Employee 2] described the status of that project as '*implemented effective Quarter 2 2016/2017*.' (Document FLE0119, email from [Aspen Employee 2] to [Aspen Employee 3] dated 16 November 2015 and Document FLE0123, conversation between [Aspen Employee 26] and [Aspen Employee 7] dated 1 December 2015).
[151] Document FLE0969 email from [Aspen Employee 3] to [Aspen Senior Executive 1] dated 14 December 2015.
[152] Document FLC1666.2, page 31, lines 9 to 10, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017; see also Document FLC1981, page 15, lines 22 to 24, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[153] Document FLC1666.2, page 31, lines 9 to 10 and page 14, line 9-11, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017; Document FLC1981, page 15, lines 22 to 24, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017; Document FLC2074.2, Annex 1A, Introduction, Tiofarma's response to the ACM's request for information dated 10 October 2017.

4.10. [Pharmaceutical Company 2] partnered with Tiofarma to carry out non-clinical work necessary to apply for an MA for Fludrocortisone Acetate Tablets from the MHRA.[154] [Pharmaceutical Company 2] also engaged Tiofarma to develop a valid manufacturing process for Fludrocortisone Acetate Tablets in the course of 2013, which Tiofarma successfully completed by September 2013.[155]

4.11. Late in the development process it emerged that, by chance, the manufacturing process developed by Tiofarma produced a more heat-stable version of that product.[156] Tiofarma submitted to the CMA that '[It] *did not specifically seek to develop a product that was stable at ambient temperatures*', and that this feature was discovered when it ran stability studies.[157] Whilst Cold Storage Fludrocortisone requires refrigeration between 2 and 8°C,[158] Ambient Storage Fludrocortisone can be stored at room temperature (up to 30°C).

b. Ambient Storage Fludrocortisone is excluded from the sale of [Pharmaceutical Company 2] to [Pharmaceutical Company 3]

4.12. Sometime in 2014, [Person 1 acting for Amilco] and [✂] entered into discussions with [Pharmaceutical Company 3] for the sale of [Pharmaceutical Company 2]. [Person 1 acting for Amilco] explained that they had agreed to exclude Ambient Storage Fludrocortisone from the sale to [Pharmaceutical Company 3] and that instead, the dossier for Ambient Storage Fludrocortisone would be transferred to Tiofarma, as a form of compensation in kind for the work that Tiofarma had undertaken in relation to Ambient Storage Fludrocortisone.[159]

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[154] Document FLC1666.2, page 34, lines 14-17, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017. See also Document FLC1981, page 15, lines 9 to 13, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[155] Document FLE0706, Tiofarma's process validation dated 2 September 2013.
[156] Document FLC1143, Amilco's response to question 12, Annex 1, of the CMA's section 26 notice dated 12 February 2018 and Document FLC1981, page 24 line 26 to page 25 line 4, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[157] Document FLC2074.2, Tiofarma's response to question 17f, Annex 1A, of the ACM's request for information dated 10 October 2017.
[158] Cold Storage Fludrocortisone tablets can be kept outside of refrigeration for up to 30 days, but should be consumed, or else disposed of, after this period. This means that the product requires refrigeration throughout the supply chain.
[159] Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 19, lines 26 to page 20, line 3: '*So* [✂] *had* agreed *that for that, basically for remuneration in kind for all the work that had been done, which was unpaid, for development, that we would give that dossier to Tiofarma* […]'. [Tiofarma Employee 1] confirmed that Tiofarma was not paid for the development work undertaken on Fludrocortisone (Document FLC2074.2, Tiofarma's response to question 8, Annex 1A, of the ACM's request for information dated

4.13. [Pharmaceutical Company 3] entered into a share purchase agreement to acquire [Pharmaceutical Company 2] on 26 January 2015 (with the transaction being completed in May 2015). As part of this transaction, it acquired around 40 pipeline products under development by [Pharmaceutical Company 2],[160] but not Ambient Storage Fludrocortisone. [✂].[161]

c. Tiofarma agrees to hold the new MA for Fludrocortisone Acetate Tablets as an undisclosed trustee for the benefit of Amilco

4.14. In late 2014, [Person 1 acting for Amilco] approached [Tiofarma Employee 1] to inquire whether Tiofarma would submit an application for a UK MA for Fludrocortisone Acetate Tablets on behalf of Amilco.[162]

4.15. [Person 1 acting for Amilco] explained to the CMA that Amilco was not in a position to submit an MA for Fludrocortisone Acetate itself because it was a '*virtual organisation*'[163] and lacked the quality assurance, regulatory, pharmacovigilance and medical information capabilities required to submit and maintain an MA in the UK.[164] Tiofarma, as registered manufacturer in relation to a range of products supplied in the UK, had such infrastructure.[165]

4.16. According to Amilco, the outcome of the discussions between [Tiofarma Employee 1] and [Person 1 acting for Amilco] was an undocumented agreement whereby Tiofarma would submit the application for an MA for Fludrocortisone Acetate Tablets under its own name and thus assume legal ownership of the resulting MA, but Amilco would retain the beneficial rights to the MA and direct what was done with it.[166]

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10 October 2017): '*Tiofarma did not receive upfront payment from* [Pharmaceutical Company 2] *for the product development work it had done*'.

[160] Document PD0003, Press release issued by [Pharmaceutical Company 3] in relation to the acquisition of [Pharmaceutical Company 2] by [Pharmaceutical Company 3]: [✂].

[161] [✂]. Document FLE0908, email from [Person 2 acting for Amilco] to [✂], dated 11 December 2014 and attachment Document FLE0809, [Pharmaceutical Company 2] Pipeline).

[162] Document FLC2074.2, Tiofarma's response to question 17a, Annex 1A, of the ACM's request for information dated 10 October 2017.

[163] Document FLC1666.2, page 17, lines 13 to 15, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.

[164] Document FLC1143, Amilco's response to question 7 of the CMA's section 26 notice dated 12 February 2018.

[165] Document FLC1981, page 20, lines 10 to 17, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017 and Document FLC1143, Amilco's response to question 10 of the CMA's section 26 notice dated 12 February 2018.

[166] Document FLC1143, Amilco's response to question 10, of the CMA's section 26 notice dated 12 February 2018: '[Person 1 acting for Amilco] *and* [Tiofarma Employee 1] *agreed that Tiofarma would submit the PL for this product and that Amilco would retain an interest in the resulting PL (PL No. 17299/001)'*, and Document FLC1666.2, page 8, lines 8 to 9, page 32 line 25 and page 106 lines 22 to page 107 line 6, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.

4.17. Tiofarma submitted that, under this arrangement, it '*did not acquire the beneficial rights to the marketing authorisation for fludrocortisone acetate tablets. The application was filed on behalf of Amilco*'.[167] [Tiofarma Employee 1] explained as follows: '[B]*asically we lent our infrastructure and as an implication, as a result of that, our name needed to be in the pack because that's the whole thing with being allowed to apply for a PL* [product licence].'[168] '[T]*he PL wasn't ours, it just had our name on it*.'[169] Tiofarma explained that there were clear efficiencies in submitting the MA on behalf of Amilco *'given* [Tiofarma's] *involvement in both the product development stage (and producing data for Module 3 of the dossier) and the likelihood that it would manufacture the product (after approval). In addition, Tiofarma had an interest in facilitating the launch of the* [Ambient Storage Fludrocortisone]*, because sales of the product would enable it to recover at least some of its development costs*.'[170]

4.18. That arrangement was never formalised through a contract between Amilco and Tiofarma. Instead, the CMA was told by both [Tiofarma Employee 1] and [Person 1 acting for Amilco] that the arrangement was based on mutual trust, developed over the course of a long-standing business partnership.[171]

4.19. [Tiofarma Employee 1] confirmed that this was the first occasion on which Tiofarma and Amilco (or indeed Tiofarma and any other company) had entered into arrangements under which Tiofarma would hold an MA on behalf of another company.[172]

d. Amilco and Tiofarma take steps towards market entry

4.20. In line with this arrangement, Amilco and Tiofarma took further steps with a view to entering the Relevant Market between December 2014 and January 2016, including (i) submitting the MA for Fludrocortisone Acetate Tablets,

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[167] Document FLC2074.2, Tiofarma's response to question 17 c, Annex 1A, of the ACM's request for information dated 10 October 2017; Document FLC0818, paragraph 8, [Tiofarma Employee 1]' *'Statement to the Competition & Markets Authority – CMA Case 50455'* dated 26 January 2018.
[168] Document FLC1981, page 30, lines 3 to 6, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[169] Document FLC1982, page 8, lines 24 to 25, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[170] Document FLC2074.2, Tiofarma's response, Annex 1A, Introduction, to the ACM's request for information dated 10 October 2017.
[171] Document FLC1981, page 10, line 25 to page 11, line 2, and page 31, lines 8 to 17, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017. Document FLC4925, page 82, lines 1 to 5, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018: '*it's just not the way we worked. We worked for ten years* […] *It was purely on trust. For many years, they made product for me without even a contract.'*
[172] Document FLC1981, page 49, lines 2 to 7, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.

(ii) planning for, and then manufacturing Fludrocortisone, and (iii) discussing the costs at which Tiofarma would manufacture the drug for Amilco.

i. Tiofarma applies for an MA on behalf of Amilco

4.21. Tiofarma notified the MHRA on 10 December 2014 that it had authorised [Person 4 acting for Amilco] '*to deal with all future communication on behalf of Tiofarma B.V.*'[173] [Person 4 acting for Amilco] was, at the time, [✂] (see paragraph 3.11 above). [Person 4 acting for Amilco] submitted an application to the MHRA for an MA on 23 December 2014.[174] All communications with the MHRA, including the preparation of responses to a request for information from the MHRA, were undertaken by [Person 4 acting for Amilco].[175] The MA was granted to Tiofarma by the MHRA in November 2015.[176]

4.22. Tiofarma explained that the dossier submitted to the MHRA was essentially put together by Amilco.[177] [Tiofarma Employee 1] also noted that '*The dossier was ready when it was handed to us* […].'[178] The nominal nature of Tiofarma's involvement continued throughout the application process.[179]

ii. Tiofarma and Amilco plan for manufacturing and Tiofarma commences manufacturing

4.23. On 15 September 2015, [Person 2 acting for Amilco] set out in detail to [Tiofarma Employee 2] the tasks to be undertaken by Amilco and Tiofarma respectively in order to start supplying Ambient Storage Fludrocortisone on

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[173] Document FLC3144, letter from Tiofarma to MHRA dated 10 December 2014.
[174] Document FLC2074.2, Tiofarma's Introduction and response to question 17 b, of the ACM's request for information dated 10 October 2017. See also for one module of the application itself: Document FLE0816, Tiofarma's MA application for Fludrocortisone Acetate 0.1mg Tablets (PL 17507/0058) CTD MODULE 2.5: Clinical Overview.
[175] Document FLC2074.2, Tiofarma's response to question 17 b, Annex 1A, of the ACM's request for information dated 10 October 2017.
[176] Document FLC0028.1 and its attachment Document FLC0036.2 (excel spreadsheet), MHRA's response to question 1, of the CMA's section 26 notice dated 3 May 2017. Prior to transferring the dossier to Tiofarma, [Pharmaceutical Company 2] made two abortive attempts to apply for an MA for Fludrocortisone Acetate Tablets: in September 2014, [Pharmaceutical Company 2] submitted an MA application. A month later, this application was withdrawn and resubmitted under [Pharmaceutical Company 1]. See Document FLE0753, email from [Person 4 acting for Amilco] to [✂] dated 20 October 2014. See also Document FLE0755 and its attachment Document FLE0756 ([✂]), email from [✂] to [MHRA] dated 22 October 2014. See also Document FLC1666.2, page 31, lines 12 to 26, and page 33, lines 13 to 16, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2016.
[177] Document FLC2074.2, Tiofarma's response to question 17 d, Annex 1A, of the ACM's request for information dated 10 October 2017: '*Amilco provided the dossier to Tiofarma. Tiofarma did not modify the dossier other than to make changes to the artwork (relating to the Tiofarma branding).*'
[178] Document FLC1981, page 29, lines 22 to 25, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[179] Document FLC3250, email from [Person 4 acting for Amilco] to [Tiofarma Employee 3] and others dated 1 December 2015; Document FLC3193, email from [Tiofarma Employee 5] to [Person 4 acting for Amilco] dated 8 October 2015.

the UK market, including in relation to [✂].[180] Updates were circulated on 29 September 2015[181] and 16 October 2015.[182]

4.24. On 17 September 2015, [Tiofarma Employee 2] emailed a number of colleagues at Tiofarma giving instructions in relation to the tasks incumbent on Tiofarma, including inter alia ordering '[✂]*'* of API*,* carrying out checks and testing (micro-validation, stability checks) and setting up the packaging.[183]

4.25. The updated task list of 29 September 2015 stated that Amilco planned to *'*[o]*rder sufficient API to cover 1 year worth of supply (approx. 2kg)'*.[184] Those plans also indicated that all preparatory regulatory steps for market entry were expected to be completed [✂].[185]

4.26. From November 2015, Amilco and Tiofarma started to discuss concrete plans to manufacture the drug.[186] Tiofarma's expectation was to manufacture between 10 and 20 million tablets per year, subject to '*developments in the market*', and to manufacture [✂] tablets per run.[187] On 18 November 2015, Tiofarma received the [✂] of API, in line with [Tiofarma Employee 2]'s instructions of 17 September 2015.[188]

4.27. The manufacturing of Fludrocortisone Acetate Tablets started in December 2015.[189] By 12 January 2016, shortly before the term sheet in relation to the

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[180] Document FLC3165 and its attachments Document FLC3166 ('*Gantt chart'*) and Document FLC3167 ('*Overview*'), Tiofarma's internal email from [Tiofarma Employee 2] to [Tiofarma Employee 3], dated 17 September 2015, forwarding an email from [Person 2 acting for Amilco] on 15 September 2015. These documents provide a breakdown of responsibilities between Amilco and Tiofarma for the purposes of obtaining regulatory approvals and scaling up production.
[181] Document FLC3172 and its attachments Document FLC3173 ('*Gantt chart'*) and Document FLC3174 ('*Overview*'), email from [Person 2 acting for Amilco] to [Tiofarma Employee 2] and [Tiofarma Employee 3], dated 29 September 2015.
[182] Document FLC3195 and its attachment Document FLC3196 (an updated Gantt chart entitled '*Overview – 16.10.15'*), email from [Person 2 acting for Amilco] to [Tiofarma Employee 2] and others, dated 16 October 2015.
[183] Document FLC3168, Tiofarma's internal email chain between [Tiofarma Employee 2] and [Tiofarma Employee 6] and others dated 17 September 2015 (see English translation in Document FLC3168.1).
[184] Document FLC3174 ('*Overview*').
[185] Document FLC3173 ('*Gantt chart*').
[186] Document FLC3238, email from [Person 3 acting for Amilco] to [Tiofarma Employee 2] dated 17 November 2015: [Person 3 acting for Amilco] summarised a call between Amilco and Tiofarma staff as follows: '*Manufacturing of the 4 batches will be in the first 3 weeks of December* [2015]*,* […] *and packing will be complete by the 2nd week of Jan* [2016]*'.*
[187] Document FLC3226 (see English translation in Document FLC3226.1), email from [Tiofarma Employee 2] to [✂] (trading partner of Tiofarma), dated 12 November 2015.
[188] See Document FLC3238, email from [Tiofarma Employee 2] to [Person 3 acting for Amilco] on 18 November 2015: [Tiofarma Employee 2] confirmed that Tiofarma had received '*5 x 425 grams of API*'.
[189] Document FLE0189, email from [Aspen Employee 21] of Aspen to [Person 2 acting for Amilco] dated 25 January 2016: '*Tiofarma manufactured* [✂] *in Dec-2015 - this will cover from Apr- 2016 to mid-Jun 2016 based on our forecast in the termsheet'*. In reply, [Person 2 acting for Amilco] commented in red in an email dated 25 January 2016: '[…] *all* [✂] *batches have been manufactured and packed* […] *the packs available for sale are likely to be in the region of* [✂].'

supply of Fludrocortisone Acetate Tablets was signed on 19 January 2016 (the '**Term Sheet**'), [✂] batches of Ambient Storage Fludrocortisone had been manufactured and were being prepared to be supplied on the UK market.[190] The next [✂] batches began production on 15 January 2016.[191]

iii. Discussion around the costs at which Tiofarma would manufacture the drug

4.28. From September 2015, Tiofarma started to discuss internally how to respond to Amilco's request to have Tiofarma's proposed cost of goods ('**COGs**').[192] On 7 October 2015, Tiofarma proposed COGs for the product to [Person 2 acting for Amilco].[193] In an email of 21 October 2015, [Person 2 acting for Amilco] requested that the COGs quoted by Tiofarma be reduced. [Person 2 acting for Amilco] justified this request by the need '*to ensure* [they] *remain competitive in the market'*, and noted that '*We hopefully should be in a position to review the costs about* [✂] *after launch'*.[194] The next day (22 October 2015), Tiofarma sent a response containing a calculation sheet proposing a price, premised on a minimum batch size of [✂] tablets, of €[✂] and €[✂] (or lower for batches of [✂] tablets).[195] Tiofarma was therefore willing to offer Amilco a lower price in order to facilitate entry in the market independently of the incumbent, Aspen. These figures were restated by [Tiofarma Employee 1] to [Person 1 acting for Amilco] by email on 22 December 2015.[196]

C. The Parties negotiate and agree the SDA

4.29. In parallel with the above developments, the Parties negotiated and agreed the terms of the SDA. The first step was taken by Amilco, which approached Aspen's [✂] team in August 2015 to offer an exclusive licence over Ambient

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[190] Document FLC3316 (see English translation in Document FLC3316.1), email from [Tiofarma Employee 2] to [Person 2 acting for Amilco] dated 12 January 2016 at 13:40. See also Document FLE0189 referenced above, email from [Person 2 acting for Amilco] to [Aspen Employee 21] dated 25 February 2015 with a table related to the four next batches.
[191] Document FLE0189, email from [Person 2 acting for Amilco] to [Aspen Employee 21] dated 25 January 2016.
[192] Document FLC3157, (see English translation in Document FLC3157.1), Tiofarma's internal email from [Tiofarma Employee 1] to [Tiofarma Employee 2] and [Tiofarma Employee 3], dated 10 September 2015, at 08:10.
[193] Document FLC3217 (see English translation in Document FLC3217.1), email exchange between [Person 2 acting for Amilco] and [Tiofarma Employee 2], and subsequently between [Tiofarma Employee 1] and [Tiofarma Employee 2], dated 7 to 21 October 2015.
[194] Document FLC3217 (see English translation in Document FLC3217.1), email exchange between [Person 2 acting for Amilco] and [Tiofarma Employee 2], and subsequently between [Tiofarma Employee 1] and [Tiofarma Employee 2], dated 7 to 21 October 2015.
[195] Document FLC3258 (see English translation in Document FLC3258.1), email from [Tiofarma Employee 2] to [Person 2 acting for Amilco] dated 22 October 2015.
[196] Document FLC1143.280, email from [Tiofarma Employee 1] to [Aspen Senior Executive 1] dated 22 December 2015.

Storage Fludrocortisone, but discussions with the [✂] team did not progress. [Person 1 acting for Amilco] then directly approached [Aspen Senior Executive 1] ([✂]) in December 2015, following which the key principles of a deal were agreed quickly as a result of negotiations between [Person 1 acting for Amilco], [Aspen Senior Executive 1], and [Aspen Senior Executive 2] ([✂]). After those principles were agreed, Aspen's [✂] team, Tiofarma, and other Amilco representatives became involved in negotiations that focussed on the details of implementation and the drafting of the contracts (as the key principles agreed at the outset were largely unchanged) which led to the Term Sheet (dated 19 January 2016) and the SDA that came into effect on 1 March 2016.

I. Amilco approaches Aspen's [✂] team to offer an exclusive licence on Ambient Storage Fludrocortisone

e. Initial approach by Amilco through a consultant

4.30. In August 2015 or slightly earlier, [Person 1 acting for Amilco] contacted [External Consultant 2],[197] a pharmaceutical consultant, with a view to discussing commercialisation of the new Fludrocortisone Acetate Tablets product. [External Consultant 2] had previously advised [Person 1 acting for Amilco] in relation to his pharmaceutical business activities.[198] This approach took place three months before an MA was granted by the MHRA to Tiofarma in relation to the new Fludrocortisone Acetate Tablets.

4.31. [External Consultant 2] undertook some consultancy work for [External Consultant 1]'s firm, [Healthcare Business Consultants].[199] [External Consultant 1] specialised in matters relating to the PPRS and was engaged by Aspen at the time to provide advice on PPRS matters.[200] [Healthcare Business Consultants] was therefore well positioned to act as an intermediary between Amilco (due to [External Consultant 2]'s existing connection with [Person 1 acting for Amilco] and Amilco) and Aspen (due to [External Consultant 1] consultancy work for Aspen).

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[197] Document FLC1538, page 1 of [External Consultant 2]'s response to the CMA's section 26 Notice dated 20 April 2018, Document FLC1143, Amilco's response to question 17, of the CMA's section 26 notice dated 12 February 2018.
[198] Document FLC1774, page 12, lines 5 to 16, Transcript of interview with [External Consultant 2] on 6 March 2018.
[199] Document FLC1774, page 8, lines 16-20, Transcript of interview with [External Consultant 2] on 6 March 2018.
[200] Document FLC1665, page 11, lines 1 to page 12, line 9 and page 15, lines 24 to 26, Transcript of interview with [External Consultant 1] on 6 March 2018.

4.32. [External Consultant 2] [201] and [External Consultant 1] [202] stated that [Person 1 acting for Amilco] approached them in relation to Fludrocortisone Acetate Tablets because of [Healthcare Business Consultants]' existing commercial relationship with Aspen, while [Person 1 acting for Amilco] claims that he approached [External Consultant 2] simply because he needed general advice about how to commercialise the product.[203]

4.33. Following a meeting with [Person 1 acting for Amilco], [External Consultant 2] discussed the matter with [External Consultant 1]. [External Consultant 2] and [External Consultant 1] agreed that [External Consultant 2] would prepare an introductory paper about the product that [External Consultant 1] could then send to Aspen.[204] [External Consultant 2] informed [Person 1 acting for Amilco] by email that he was preparing such a paper.[205] In the cover email to the introductory paper to be sent on behalf of Amilco to Aspen, [External Consultant 2] stressed to [External Consultant 1] that '*This should be seen by Aspen as an opportunity, should they choose not to participate, it will happen anyway*'.[206]

4.34. This introductory paper contained two sections: a first section (under the heading '*Background*') setting out some background information relating to the Relevant Market, and a second section (under the heading '*Opportunity*') describing Ambient Storage Fludrocortisone and raising the possibility of granting to Aspen an exclusive licence on the new product. [207]

4.35. Under the heading '*Background*', the paper noted that the '*NHS list price*' of Aspen's Florinef product at the time was £5.05 for 100 tablets, and that *'Florinef is a Category C reference product and the only solid dose formulation available*.' It further stated:

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[201] Document FLC1774, page 16, lines 19 to 24 Transcript of interview with [External Consultant 2] on 6 March 2018. See also page 19, line 26 to page 21, line 7. See also Document FLC1538, page 1 of [External Consultant 2]'s response to the CMA's section 26 Notice dated 20 April 2018.
[202] Document FLC1531, Chronology of Florinef [Healthcare Business Consultants] Involvement/Correspondence, [Healthcare Business Consultants]' response to the CMA's Section 26 Notice dated 19 April 2018. See also Document FLC1665, page 15, lines 16 to 26, Transcript of interview with [External Consultant 1] on 6 March 2018: *'So* [[Person 1 acting for Amilco]] *told* [External Consultant 2] *that he wanted someone to licence this product to because he did not have the infrastructure so to do it himself and Tiofarma has no UK presence. And he said Aspen are the leaders in this market, they have a global presence in Fludrocortisone with a product called Florinef* […]*'.*
[203] Document FLC1666.2, page 49, lines 6 to 18, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.
[204] Document FLC1774, page 18, lines 13 to 16, and line 22, Transcript of interview with [External Consultant 2] on 6 March 2018.
[205] Document FLC1143.3, email from [External Consultant 2] to [Person 1 acting for Amilco] on 21 August 2015.
[206] Document FLC1532, email from [External Consultant 2] to [External Consultant 1] dated 21 August 2015.
[207] Document FLC1531, page 5, Paper prepared by [External Consultant 2] on 21 August 2015, [Healthcare Business Consultants]' response to the CMA's section 26 response notice dated 19 April 2018.

'Florinef may be considered to be underpriced when compared to similar types of steroidal products available in the UK:

Product	*Category*	*Presentation*	*NHS List Price*[3]
[✂]	*Category A*	*(50s)*	£[✂]
[✂]	*Category M*	*(30s)*	£[✂]
Fludrocortisone tablets 100mcg	*Category C*	*(100s)*	*£5.05*

[3] *Drug Tariff July 2015'*

4.36. The paper then described the '*Opportunity*' as follows:

'A successful entrepreneur will obtain a UK licence for a Fludrocortisone 100mcg tablet in 60 days (circa October 2015). All MHRA assessments have been completed and the remaining time will be taken up with packaging finalisation and paperwork.

The main feature of this new product is that it can be stored at room temperature and hence there is no need for cold storage conditions. This is a significant improvement on the existing product benefiting patients, prescribers and pharmacists.

The Principal would be prepared to grant an exclusive licence to Aspen. Terms are subject to negotiation but the Principal would wish to retain manufacture […].

As the granted licence would be a generic without brand name, the pricing would be free of any DOH control.'[208]

4.37. [Person 1 acting for Amilco] claims that he was not aware of, and had not discussed, the content of the paper with [External Consultant 2] before it was sent to Aspen.[209] By contrast, [External Consultant 1] submitted to the CMA

[208] Document FLC1531, page 6, Paper prepared by [External Consultant 2] on 21 August 2015 headed *'Fludrocortisone Acetate Tablets'*, Document FLC1530, [Healthcare Business Consultants]' response to the CMA's section 26 notice dated 19 April 2018.
[209] Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 48 lines 23 to page 49 line 5: *'I have never seen* [this paper] *during that period'*. [Person 1 acting for Amilco] told the CMA that he had not discussed with [External Consultant 1] the fact that he would be prepared to grant an exclusive licence (Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 51 line 3 to 4, and page 54 lines 11 to 15).

that he '*understand*[s] *that* [✂] [[External Consultant 2]] *discussed the "Opportunity" Section (Page 2) with* [✂][[Person 1 acting for Amilco]] *so as to accurately represent the opportunity*.'[210] The CMA considers that [External Consultant 1]'s version of events is more plausible. In particular, it is likely that [Person 1 acting for Amilco] would have specified, discussed and been made aware of the terms (including the exclusive nature of the licence) on which Aspen would be approached, given that [External Consultant 2] was representing [Person 1 acting for Amilco]'s ownership interest in finding a licensee for Ambient Storage Fludrocortisone. The CMA's view is that it is implausible that [Person 1 acting for Amilco] would not want to influence, or even have sight of, such fundamental terms in relation to a valuable product owned by him before they were put to an important potential business partner. This view is further supported by [Person 1 acting for Amilco]'s active role in negotiating the Term Sheet and SDA, as discussed in the next section, and the fact that nothing in those negotiations and the actual terms of the Term Sheet and SDA contradicts the '*Opportunity*' section of [External Consultant 2]'s paper.

4.38. On 24 August 2015, [External Consultant 1] contacted [Aspen Employee 1], [✂] by email, attaching the paper prepared by [External Consultant 2] and noting in the cover email that '*It's clear that the current brand is massively underpriced! The new generic also seems to have some significant benefits in terms of temperature controlled storage.*'[211]

f. Aspen's initial reaction to Amilco's approach and continued plan for the debranding of Florinef

4.39. [Aspen Employee 1] replied to [External Consultant 1]'s email of 24 August 2015, apparently referring to Aspen's ongoing plan to de-brand Florinef in the UK and increase its price: '*We have talked about de-branding this product. Any immediate thoughts on pricing uplift?*'[212]

4.40. The following day, an internal Aspen presentation outlining Aspen's strategy in the UK identified Fludrocortisone Acetate Tablets as a potential priority

[210] Document FLC1530, [Healthcare Business Consultants]' response to part 1, Annex 1, of the CMA Section 26 Notice of 19 April 2018. See also Document FLC1143.3, email from [External Consultant 2] to [Person 1 acting for Amilco] dated 21 August 2015.
[211] Document FLC1531, email from [External Consultant 1] to [Aspen Employee 1] dated 24 August 2015, [Healthcare Business Consultants]' response to the CMA's section 26 response notice dated 19 April 2018.
[212] Document FLE0085, email from [Aspen Employee 1] to [External Consultant 1] dated 24 August 2015.

debranding project, and proposed to adopt [✂] as a benchmark for increasing its price: '*Florinef? Underpriced relative to value £5.05 versus* [✂]*'*.[213]

4.41. [✂], a consultant working for Aspen's [✂] team, told the CMA that [Person 1 acting for Amilco] contacted him about Ambient Storage Fludrocortisone.[214] An email from [Aspen Employee 1] to [Consultant to Aspen] on 1 September 2015, in which [Aspen Employee 1] referred to '*your contact'*, suggests that the contact between [Person 1 acting for Amilco] and [Consultant to Aspen] took place within a few days of the contact via [External Consultant 1]: '*Regarding the 2nd Florinef brand – I am happy for us to discuss further with your contact – but given our storage conditions is the ambient storage a massive concern for this brand? Or can we go alone?*'[215]

4.42. [Consultant to Aspen] arranged a meeting with [Person 1 acting for Amilco] and [Aspen Employee 1] of Aspen UK in Windsor on 15 September 2015.[216] However, [External Consultant 1] told the CMA that the meeting may not have gone ahead.[217]

4.43. It appears from the evidence on the CMA's file that there were no further discussions between Amilco and Aspen's [✂] team concerning Ambient Storage Fludrocortisone for a few months after the approach in August and the communication in September. As described further below, those discussions were restarted in December 2015, after [Person 1 acting for Amilco] approached Aspen's [✂] management directly.

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[213] Document FLE0087 and Document FLE0088, email from [Aspen Employee 1] to [Aspen Senior Executive 1] dated 25 August 2015. The price identified in this internal presentation is incorrect and appears to relate to the price of [✂] tablets 10mg, correctly reported in the paper prepared by [External Consultant 2] referred to above.
[214] Document FLC1991, pages 30, line 15, to page 32, line 26, Transcript of interview with [Consultant to Aspen] on 25 October 2017. [Consultant to Aspen] stated at interview that '[w]*e received an approach from Amilco saying* […] *that they had a product* [...] *there was an approach to me and I believe there was an approach to another Aspen consultant as well.* […] *It was* [Person 1 acting for Amilco] *who let me know in the first place.* […] [H]*e* […] *said* […] *we've got a registration for* […] *Tiofarma BV* […] *And it's an ambient product.* […] [I] *fed back* [the information] *to* [Aspen Employee 1] *and* […] *it went* […] *through the Aspen management tiers*.' See also Document FLC1992, Transcript of interview with [Aspen Employee 1] on 19 October 2017, page 27, line 25 to page 28, line 7.
[215] Document FLE0094, Email from [Aspen Employee 1] to [Consultant to Aspen] on 1 September 2015 headed '*FW: Florinef De-branding UK*'.
[216] Document FLE0095, Email from [External Consultant 1] of [Healthcare Business Consultants] to [Aspen Employee 1] on 5 September 2015 headed '*Re: 2014 PPRS – Acquisition of Florinef Tablets'*: '*I heard from* [External Consultant 2] *today who had spoken to* [Person 1 acting for Amilco]. [External Consultant 2] *tells me that a meeting has been arranged in Windsor on the 15th by* [Consultant to Aspen]*, and* [Person 1 acting for Amilco] […] *has asked* [External Consultant 2] *to attend with him.'* [Aspen Employee 1] then asked [Consultant to Aspen] if [External Consultant 1] could join them at the meeting.
[217] Document FLC1665, page 16, lines 17 and 18, Transcript of interview with [External Consultant 1] on 6 March 2018.

4.44. In the meantime, Aspen's [✂] team continued to plan for the debranding of Florinef and, as described above, Amilco and Tiofarma took steps to prepare for entry into the Relevant Market with their own product, including discussing cost of goods in October and starting up manufacturing in November 2015.

4.45. In October 2015, Aspen's [✂] team was considering the potential implications of a third party entering the market with Ambient Storage Fludrocortisone in the context of Aspen's unilateral debranding project. On 6 October 2015, [Consultant to Aspen] prepared a sales forecast including the following notes:

'[…] *Margin split TBC circa* [✂]

Existing position at no change in price[218] *would loose* [sic] *circa* [✂]*% or more to Ambient product*

Ambient prouct [sic] [✂] *easier to store* [✂]*.*

Caution Old price £0.05 per tablet, new price at £[✂] *pack £*[✂]*p tablet* […]*'.*[219]

4.46. Aspen continued to pursue a unilateral strategy of de-branding until January 2016.[220]

g. Amilco does not approach other potential partners in relation to Fludrocortisone Acetate Tablets

4.47. As noted above in paragraphs 4.12 and 4.13, during the negotiations around the proposed sale of [Pharmaceutical Company 2] to [Pharmaceutical Company 3] (from late 2014 to early 2015), [Person 1 acting for Amilco] did not mention to [Pharmaceutical Company 3] that [Pharmaceutical Company 2]

[218] Aspen explained to the CMA that the 'price' referred to in this correspondence is that of Cold Storage Fludrocortisone (Florinef): Document FLC1834, Aspen's response to question 38, of the CMA's section 26 notice of 19 April 2018 (s.26 notice provided in Document FLC1496).
[219] Document FLE0104 and its attachment Document FLE0105, email from [Consultant to Aspen] to [Aspen Employee 1] dated 6 October 2015.
[220] Document FLE0133, email from [Aspen Employee 11] to [Consultant to Aspen] on 6 January 2016 noting the potential '*impact due to Competitor ambient product vs Aspen refrigerated product*' on '*the likely volumes* [of debranded Florinef] *post launch of generic'*. See also Document FLE0142, email conversation between [Aspen Employee 13] and [Aspen Employee 1] on 11 January 2016 headed 'Florinef debranding': '*you mentioned in today's call that the Floronef* [sic] *debranding is superceded by another project/acquisition?* [...]' [Aspen Employee 1] replied, '*The project continues, but we have availability of a licensing agreement with an ambient competitor*.' This statement was reported in the debranding tracker as of 12 January 2016, which notes that an approach had been received from an *'external company for in-licensing a generic product* […]', but that '*Till official information we will continue according to the plan*' (Document FLE0148, internal email from [Aspen Employee 16] to various Aspen personnel, including [Aspen Employee 1], on 12 January 2016 headed *'UK debranding project – follow-up')*.

had prepared a dossier for Fludrocortisone Acetate Tablets. He therefore did not gauge whether [Pharmaceutical Company 3] would have had an interest in purchasing that dossier as part of the proposed acquisition. [Person 1 acting for Amilco] told the CMA that he had never considered doing so because the data had already been earmarked for Tiofarma.[221]

4.48. [Person 1 acting for Amilco] also told the CMA that he did not approach any other businesses in late 2014 or early 2015 to gauge their interest in the fludrocortisone acetate data. He explained that he did not do so because it was too early in the process and it was not possible to tell whether it would result in a marketable product.[222]

4.49. However, notwithstanding [Person 1 acting for Amilco]'s decision not to approach any potential partners other than Aspen, both [Company 1] and [Company 2] made separate, unsolicited approaches to Tiofarma in November 2015 to express their interest in the new fludrocortisone product, but were turned down. These approaches are discussed further in paragraphs 4.150 to 4.153 below.

II. [Person 1 acting for Amilco] approaches Aspen's [✂] management [✂], leading to the Term Sheet and the SDA

4.50. [Person 1 acting for Amilco] approached the [✂] management of Aspen (principally [Aspen Senior Executive 1] and [Aspen Senior Executive 2]) to discuss a potential deal relating to Ambient Storage Fludrocortisone in December 2015. Discussions between those three individuals led to the key terms of a potential term sheet (which were then largely replicated in the SDA) being agreed within two weeks.

a. Negotiations between [Aspen Senior Executive 2], [Aspen Senior Executive 1] and [Person 1 acting for Amilco] between 10 December and 22 December 2015

4.51. Between 10 December and 22 December 2015, [Person 1 acting for Amilco] discussed the key principles of the deal with [Aspen Senior Executive 2] and [Aspen Senior Executive 1].

[221] Document FLC1666.2, page 45, lines 12 to 23 Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.
[222] Document FLC1666.2, page 43, lines 15 to 25, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.

4.52. [Person 1 acting for Amilco] approached [Aspen Senior Executive 1], the [✂], through a common acquaintance[223] (apparently an approach made independently from the previous approach to Aspen's [✂] team through [Healthcare Business Consultants] described above) and spoke to him for the first time on 10 December 2015.[224] While no record of that conversation is available, four days later, on 14 December 2015, [Aspen Senior Executive 1] sent an email to [Aspen Senior Executive 2] about the potential benefits arising from the opportunity to in-license Ambient Storage Fludrocortisone (ie the product developed by Amilco and Tiofarma) versus debranding Florinef. Given the timing, and the fact that there is no previous record of [Aspen Senior Executive 1] being aware of that product, the CMA infers that this email was based on his earlier conversation with [Person 1 acting for Amilco]:

'A few issues for consideration on our debranding of florinef

We have the option to acquire/license a product from a Dutch company- tiofarma

It will mean less dependence on [✂] *supply from haupt*
Their product also can be stored at room temperature versus ours which needs refrigeration
If you believe, the above are worth considering we will need to agree a supply price with them
I would think it best to lock in a gross margin*'* (emphasis added)[225]

4.53. Three days later, on 17 December 2015, [Aspen Senior Executive 2] set out to [Aspen Senior Executive 1] the following basic terms that she wanted to record in a potential term sheet:

'Aspen will be the exclusive distributor for fludrocortisone 30's pack […]

[223] Document FLE0964, email from [✂] to [Aspen Senior Executive 1] dated 8 December 2015: '[Person 1 acting for Amilco] *called* – [✂] *would like to chat to you about a product. Says* [✂] *had connected you both a while back'.* N.B.: [✂].
[224] Document FLE0966, Text message from [Aspen Senior Executive 1] to [✂] dated 9 December 2015. The subject of this message was '*please arrange a call with* [Person 1 acting for Amilco] *tomorrow*'. At interview, [Person 1 acting for Amilco] explained that his main contact at Aspen [✂] in relation to the potential deal for Ambient Storage Fludrocortisone was in fact [Aspen Senior Executive 2]. Document FLC1666.2, page 53, lines 6 to 9, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.
[225] Document FLE0968, email from [Aspen Senior Executive 1] to [Aspen Senior Executive 2] dated 14 December 2015.

Aspen agrees to a minimum supply quantity which is based on IMS and reviewed 6 monthly or on the introduction of an additional product with this active ingredient (suggest 90% of the volume)

The supply price from TioPharm [sic] *will be* [✂]*% of the retail selling price before discounts, rebates etc (Please check my notes have* [✂]*% =* [✂]*c per tablets as well as* [✂]*%)*

Proposed retail selling price agreed 30 pounds per pack […][226]

4.54. This email appears to be based on the prior [Aspen Senior Executive 1] email of 14 December 2015, which was in turn based on the conversation [Aspen Senior Executive 1] had with [Person 1 acting for Amilco] on 10 December 2015 concerning *'the option to acquire/license a product from a Dutch company-tiofarma'*. This is clear from the fact that [Aspen Senior Executive 2] asks [Aspen Senior Executive 1] to '*please check'* the supply price from Tiofarma, which demonstrates that [Aspen Senior Executive 2] was checking her understanding of [Aspen Senior Executive 1]'s intentions was accurate. It is clear from [Aspen Senior Executive 2]'s proposal that the proposed retail selling price was already '*agreed'* at £30 per pack of 30 tablets.

4.55. [Aspen Senior Executive 1] confirmed later the same day that he was happy with [Aspen Senior Executive 2]'s proposal and for Tiofarma's commission to be £[✂] per tablet, on the assumption that the future retail List Price would be £1 per tablet (ie £[✂] taking into account a wholesale discount of [✂]%): '*On a wholesale discount of say* [✂] *pc then the price is* [✂] *pc of that is* [✂]*c*'.[227] Given that the pack size in [Aspen Senior Executive 2]'s proposal is 30 tablets, this equates to a commission of £[✂] per pack and a retail selling price of £30 per pack.

4.56. On 18 December 2015, [Aspen Senior Executive 2] sent [Person 1 acting for Amilco] an email proposing an '*exclusive distribution agreement*' using the

[226] Document FLE0970, email from [Aspen Senior Executive 2] to [Aspen Senior Executive 1] dated 17 December 2015.
[227] Document FLE0970, email from [Aspen Senior Executive 1] to [Aspen Senior Executive 2] dated 17 December 2015. In addition, in that chain of email, [Aspen Senior Executive 1] asked [Aspen Senior Executive 2] to change the wording in the draft Term Sheet so that the exclusivity granted to Aspen would cover any formulation of Ambient Storage Fludrocortisone and would not be limited to packs of 30 tablets. (Document FLE0972, email from [Aspen Senior Executive 1] to [Aspen Senior Executive 2] dated 18 December 2015). See also Document FLE0975, email chain between [Aspen Senior Executive 2] and [Aspen Senior Executive 1] dated 21 December 2015 commenting on [Person 1 acting for Amilco]'s email of the same day. This chain of emails shows that [Person 1 acting for Amilco] settled on a percentage of 30 per cent.

same key terms as previously agreed following her discussions with [Aspen Senior Executive 1]:

'As promised please see a list of items to be included in the term sheet. Once you confirm I will formalise this for a document for signature.

Exclusive Distribution agreement
Tio Pharm [sic] *and AGI (APIL will distribute in UK as an affiliate of AGI)*
Aspen will be the exclusive distributor for Tiopharm [sic] *flurdrocortisone which will be made available in a 30's pack*
TioPharm [sic] *will be the MA Holder*
Aspen can at its own election sell an Aspen branded pack
Aspen agrees to a minimum sales quantity which is based on IMS and reviewed 6 monthly or on the introduction of an additional product with this active ingredient (90% of the volume)
Proposed retail selling price agreed 30 pounds per pack of 30 tablets
[…]
Term will be 5 years with automatic 2 year renewals
[…]
Territory = UK, other countries can be considered
Start date 1/3/2016 based on a notification of the launch to the relevant authorities at the end of January'.[228]

4.57. [Aspen Senior Executive 2]'s comment that '*Once you confirm I will formalise this for a document for signature on Monday*'[229] indicates that either she or [Aspen Senior Executive 1] had already discussed some or all of these terms with [Person 1 acting for Amilco] and that she was confident that he would accept them swiftly. This is consistent with the CMA's analysis of the emails between [Aspen Senior Executive 1] and [Aspen Senior Executive 2] that [Aspen Senior Executive 2]'s proposal was based on the conversation [Aspen Senior Executive 1] and [Person 1 acting for Amilco] had on 10 December 2015 (see paragraph 4.54 above) and that the £30 per pack proposed retail selling price had already been agreed.

4.58. Following [Aspen Senior Executive 2]'s email, [Person 1 acting for Amilco] and [Aspen Senior Executive 1] negotiated the specific amount of Amilco/Tiofarma's commission by way of text messages. In an email of 21 December 2015 to [Aspen Senior Executive 2], [Person 1 acting for Amilco]

[228] Document FLC1143.13, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] on 18 and 22 December 2015.
[229] Document FLC1143.13, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 18 December 2015.

referred to the chain of previous text messages that he had exchanged with [Aspen Senior Executive 1], showing that the two sides were negotiating an absolute value for Amilco's commission of between £[✂] and £[✂] per tablet (with both sides appearing to consistently assume a future retail List Price of £1 per tablet, ie £30 per pack):

'Dear [✂],

Further to our various communications, I have meet with the Tiofarma people today in London.

Firstly I am aware of what terms we discussed via text messages, but the Tiofarma people have confirmed their proposals which are in line with the following text messages between [Aspen Senior Executive 1] *and myself.*

[[Person 1 acting for Amilco]] *to* [Aspen Senior Executive 1] *" Spoken to them about the* [✂] *pence been unacceptable. They said the best they can do is* [✂] *pence ([✂]%), let me know if that works and you still want to talk at 2 pm"*

[Aspen Senior Executive 1] *to* [Person 1 acting for Amilco] *" you said* [✂]*pc share of* [✂] *afterwards., that is* [✂]*, I am offering* [✂]*.*

I then clarified in a telecom they want [✂]*% of* [✂] *+ cogs ([✂] pence + cogs)*

Then [Person 1 acting for Amilco] *to* [Aspen Senior Executive 1] *"I am meting the Tio guys tomorrow and need to know if the commercials we discussed are broadly acceptable and if we are moving forward"*

[Aspen Senior Executive 1] *to* [Person 1 acting for Amilco] *"All ok. would have preferred* [✂]*c but at least we are still positive. we are still waiting your timing on the 30s"*

So Tio want [✂] *% Of* [✂] + [✂][230] *pence + cogs (pending confirmation that aspen will actually give* [✂]*% discount to wholesalers)"*[231]

[230] In the CMA's view, '+' is a typo and should be replaced with '='.
[231] Document FLC1143.94, email chain between [Person 1 acting for Amilco] and [Aspen Senior Executive 2] dated 21 December 2015. Interviewed by the CMA, [Person 1 acting for Amilco] submitted that he had no control over the List Price and that Amilco's commission could fluctuate (see Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 131 line 24 to page 132 line 16). However, in the CMA's view, the email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 21 December 2015 demonstrates that [Person 1 acting for Amilco] was effectively requesting that Aspen pay Amilco a fixed commission of [✂] pence / tablet. The mechanism protecting Amilco from fluctuations in Aspen's discount policy would be of limited value if Aspen were free to flex its retail price instead.

4.59. Later the same day, [Aspen Senior Executive 2] emailed [Person 1 acting for Amilco] a counterproposal offering '*If the wholesale discount is* [✂]*% or more then Tiopharm* [sic] *will get the* [✂]*% they asked for. If the wholesale discount is less than* [✂]*% then they will get* [✂]*%.*'[232]

4.60. In a subsequent email on 22 December 2015, [Aspen Senior Executive 2] wrote to [Person 1 acting for Amilco] in the same vein, indicating that the percentage of the retail selling price that would be paid to Amilco/Tiofarma under the SDA would increase in the event that the wholesaler discount was greater than [✂]% and providing the following worked examples:

'Where the wholesaler discount is between 0 and [✂]*%*
The supply price from TioPharm [sic] *will be 30% of the pre-wholesale discount price*
EXAMPLE
Retail selling price – wholesaler discount = pre-wholesale discount price.
Price = 1
Wholesaler discount is for example = [✂]*%*
Pre-wholesale discount price = [✂]
30% of [✂] = [✂]

Where the wholesaler discount is greater than [✂]*%*
The supply price from TioPharm [sic] *will be* [✂]*% of the pre-wholesale discount price*
EXAMPLE
Retail selling price – wholesaler discount = pre-wholesale discount price.
Price = 1
Wholesaler discount is for example = [✂]*%*
Pre-wholesale discount price = [✂]
[✂]*% of* [✂] = [✂][233]

4.61. Later the same day, [Person 1 acting for Amilco] confirmed in an email to [Aspen Senior Executive 2] and [Aspen Senior Executive 1] his agreement on the working example set out above. He added a calculation of the exact amount of the profit share element:[234]

[232] Document FLE0976, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 21 December 2015.
[233] Document FLC1143.13, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] on 18 and 22 December 2015.
[234] Document FLC1143.13, email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] (cc [Aspen Senior Executive 1]) dated 22 December 2015.

'[✂]

so the supply price to aspen is [✂] *x 30 = £* [✂]

Total = £ [✂]

The 2 variables are the actual amount of discount to wholesalers and the exchange rate from Euro to Pounds.' [235]

4.62. [Person 1 acting for Amilco]'s email is clear that the two variables in his calculation were the wholesaler discount and the Euro/GBP exchange rate. At that stage, the Parties did not appear to have contemplated the retail selling price as a possible variable.[236]

4.63. The key financial parameters discussed between the Parties in the correspondence outlined above prior to the SDA being finalised are summarised in the first table below. As shown by the second table below, the retail price and profit share element (in absolute terms) that were eventually included in the SDA were substantially identical to the figures discussed in that correspondence (the profit share element, expressed as a percentage, was amended to reflect the actual discount applied by Aspen in the UK):

Figure 3: Calculation of the Supply Price in the negotiation leading up to the SDA, assuming a commission level at [✂]***%***

Unit	Wholesale Discount	Retail Price	Wholesalers Price (post wholesale discount)	Profit share element (30%, 35% or 40%) = Amilco's commission	COGs	Supply Price (Profit share element + COGs)
Tablet	[✂]%	£1	£[✂]	£[✂] or [✂]p (with a commission at [✂]%) £[✂] or [✂]p (with a commission at [✂]%)	£[✂]	£[✂]

[235] Document FLC1143.13, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] on 18 and 22 December 2015.
[236] In interview with the CMA, [Person 1 acting for Amilco] confirmed this interpretation (see Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 125, line 23 to page 128, line 17).

				£[✂] or [✂]p (commission at [✂]%)		

Figure 4: Calculation of the Supply Price under the SDA

Unit	Wholesale Discount	Retail Price	Wholesalers Price (post wholesale discount)	Profit share element (30%) = Amilco's commission	COGs	Supply Price (Profit share element + COGs)
Tablet	[✂]%	£1	£[✂] (rounded to £[✂] in the SDA)	£[✂] (ie [✂]% of £[✂])	£[✂]	£[✂]
Pack of 30	[✂]%	£30	£[✂]	£[✂] (rounded to £[✂] in the SDA, this was obtained by multiplying £[✂] by [✂])	£[✂]	£[✂]

b. Term Sheet of 19 January 2016

4.64. After the initial discussions outlined above, Aspen prepared a draft of the Term Sheet which it shared with Amilco on 8 January 2016.[237]

4.65. Before finalising the Term Sheet, Aspen's [✂] management engaged colleagues within Aspen, including the [✂] team, to prepare certain details of the Term Sheet to allow that agreement to be finalised.

4.66. In an email of 8 January 2016, [Aspen Employee 1] sent [Aspen Senior Executive 2] and [Aspen Senior Executive 1] a likely forecast for the volume of Fludrocortisone on the basis of a future retail List Price of £1 per tablet.[238]

[237] Document FLE0981, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 8 January 2016, headed '*for release term sheet – AGI/Tiopharma* [sic]'.
[238] Document FLE0139 and its attachment Document FLE0140 ('*UK Fludrocortisone 30 Forecast*'), email from [Aspen Employee 1] to [Aspen Senior Executive 2] and [Aspen Senior Executive 1] dated 8 January 2016.

4.67. At this time, Amilco and Aspen were not in full agreement about the size of the market following the price increase, and therefore the forecast volumes that should be used as the basis for Aspen's minimum supply commitment. Aspen considered the appropriate monthly number should be around 38,000 packs/month and therefore sought to link the minimum purchase volumes to that figure.[239] Amilco considered that a much higher number of around 61,000 packs/month was appropriate.[240] Amilco made clear that the forecast needed to reflect the actual sales by Aspen and would need to increase if sales were to pick up, stating: '[…] *Aspen will have to amend this forecast fairly early on if sales are higher then* [sic] *you expect'*.[241]

4.68. As a result of this disagreement, the Term Sheet, and subsequently the SDA, specified that Aspen's minimum sales commitment would only be triggered after a period of seven months,[242] ie following a review of the forecast.

4.69. Meanwhile, [Person 1 acting for Amilco] arranged for [Tiofarma Employee 1] ([✂]) to have the opportunity to comment on the near-final Term Sheet, with a draft of that document being sent to him on 15 January 2016.[243] [Tiofarma Employee 1] told the CMA that he had no substantive input into the Term Sheet prior to signing it.[244]

4.70. On 19 January 2016, [Aspen Senior Executive 3] (for Aspen Global Inc.), [Tiofarma Employee 1] (for Tiofarma BV) and [Person 1 acting for Amilco] (for

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[239] 38,000 packs/month was calculated on the basis of an average of Aspen's sales of Fludrocortisone over certain months (when no promotion took place) in 2015. Document FLE0981, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 8 January 2016.
[240] Document FLC1143.14 and its attachment Document FLC1143.15, email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] dated 11 January 2016.
[241] Document FLC1143.18, email chain between [Person 1 acting for Amilco] and [Aspen Senior Executive 2] dated 11 January 2016.
See also Document FLC1143.25, email from [Person 2 acting for Amilco] to [Aspen Employee 21] (Aspen) cc [Person 1 acting for Amilco] dated 22 January 2016: *'The forecast in the term sheet averages out to be c. 46k per month* […] *If sales were to pick up and stabilise at 70k per month we will need to be very swift in informing Tiofarma so that they can increase their production planning to meet demand and to ensure that there are no stock shortages in the market.'*
[242] Document FLC1143.18, email chain between [Person 1 acting for Amilco] and [Aspen Senior Executive 2] dated 11 January 2016: '[…] *as discussed the 90% compliance with forecast in the term sheet will only kick in from month 7'*. See also Document FLE0304, email from [Aspen Employee 1] to [Aspen Employee 2] dated 29 April 2016. The revisions to the Term Sheet reflecting the delayed implementation were made on 12 January 2016 (Document FLC1143.109, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] and others dated 12 January 2016 and its attachment Document FLC1143.110, draft term sheet (rev 12/01/2016).
[243] Document FLC3263, email from [Assistant to Person 1 acting for Amilco] to [Tiofarma Employee 1] on 15 January 2016 and its attachment Document FLC3264, draft term sheet (rev 12/01/2016).
[244] Document FLC4907, page 92, lines 12 to 16, Transcript of interview with [Tiofarma Employee 1] on 24 July 2018.

Amilco) signed the Term Sheet in relation to the supply of Fludrocortisone Acetate Tablets.[245]

4.71. The key terms set out in the Term Sheet were substantially similar to the terms previously set out and agreed in the emails exchanged between [Person 1 acting for Amilco], [Aspen Senior Executive 1] and [Aspen Senior Executive 2] on 22 December 2015 (see paragraphs 4.60 and 4.61 above),[246] with the exception of the following aspects:

(a) It was formally stated that 'Neither party shall have the right to terminate the agreement without cause'.[247]

(b) The minimum supply quantity (previously agreed as being 90% of total volumes) was qualified as having 'effect from the 7th month after launch'.[248]

(c) Schedule 1 to the Term Sheet (which concerned the supply price from Tiofarma) stated: 'Fluctuations in the wholesaler discount, retail selling price or exchange rate that results in price changes up or down shall be taken into account when calculating the supply price.' This sentence mirrors the email of 22 December 2015[249] from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] and [Aspen Senior Executive 1], the only exception being the addition of 'the retail selling price' as a variable in the supply price[250] (see paragraphs 4.61 to 4.62 above).

(d) Schedule 2 to the Term Sheet provided a forecast for the remaining 10 months in 2016 (ie from March 2016 to December 2016). This was

[245] Document FLC1143.122, Term sheet between Aspen Global Incorporated, Tiofarma BV and Amilco Limited, dated 19 January 2016.
[246] The profit share and the List Price in the Term Sheet was based on what was previously agreed between [Person 1 acting for Amilco] and [Aspen Senior Executive 2]. For example, in an email to [Aspen Senior Executive 3] dated 13 January 2016, [Aspen Senior Executive 2] stated that '*the calculations in the attachment* [the term sheet] *reflect what has been agreed between* [Aspen Senior Executive 1] *and* [Person 1 acting for Amilco]*'* (Document FLE0983, email from [Aspen Senior Executive 2] to [Aspen Senior Executive 3] dated 13 January 2016). The calculations in the draft Term Sheet were based on a List Price at £1 per tablet (Document FLE0151 headed 'term sheet – rev 12012016').
[247] Document FLC1143.122, Term sheet between Aspen Global Incorporated, Tiofarma BV and Amilco Limited, dated 19 January 2016.
[248] Document FLC1143.122, Term sheet between Aspen Global Incorporated, Tiofarma BV and Amilco Limited, dated 19 January 2016.
[249] Document FLC1143.13, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] on 18 and 22 December 2015.
[250] This additional variable (also included in the SDA) followed an email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 13 January 2016 (see Document FLE0156 and Document FLC1143.108, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 13 January 2016).

replicated in its entirety in the SDA and is set out in full in paragraph 7.23 below.

4.72. Following signature of the Term Sheet, the negotiations between Amilco and Aspen focused on the specified forecast volumes. Meanwhile, Aspen began to take steps in preparation of implementing the SDA.

c. Finalisation of the SDA and remaining operational details

4.73. Between signing the Term Sheet on 19 January 2016 and the effective date of the SDA on 1 March 2016, the Parties discussed two aspects of their agreement relating to Ambient Storage Fludrocortisone, which are considered in turn below:

(a) the discounting strategy; and

(b) the drafting of Clause 3.3 of the SDA relating to Aspen's right to commercialise its incumbent Fludrocortisone Acetate Tablets product (ie Cold Storage Fludrocortisone).

i. Discounting strategy

4.74. In the Term Sheet, the Parties had already agreed to include a provision concerning the discounting strategy for Ambient Storage Fludrocortisone (see paragraph 4.71 above). Aspen and Amilco continued to discuss the details of how that strategy would work in practice in mid-February 2016.

4.75. In an email recording a meeting concerning that strategy between [Aspen Employee 1] and [Person 1 acting for Amilco], which appears to have taken place on 10 February 2016,[251] [Aspen Employee 1] reported the discussion as follows:

'[…] [Person 1 acting for Amilco] *and I met today to discuss specifically the question of:*

1. What would trigger a review of discounting strategy and

[251] [Aspen Employee 1] asked [Person 1 acting for Amilco] on 10 February 2016: '*Can you advise if you are available Wednesday 10th, to discuss the route for agreeing discounts*'. [Person 1 acting for Amilco] responded on the same day: '*I can do after 3pm on Wednesday*'. Document FLE0895, email chain between [Person 1 acting for Amilco] and [Aspen Employee 1] dated 9 February 2016.

2. How this would change section 15 – ie Commercialisation and Obligations of Aspen.

For 1 above, the trigger would be defined as the entry of 1 new competitor. The parties would then sit down to agree a discounting strategy – this would need to include a review of the contract commercials […]'[252]

4.76. Two days later, on 12 February, another Aspen employee ([Aspen Employee 4]) reported a conversation with [Person 1 acting for Amilco] to various Aspen staff, copying [Person 1 acting for Amilco], which showed that the agreed position at that time was that (i) Aspen would not be allowed to vary the discount without Amilco's approval; and (ii) Amilco's aim in drafting Clause 10.2 of the SDA was to protect Amilco's[253] commission in case of increased discounts:

*'**If the parties agree that additional discounts are necessary then Tiofarma's share of the net profit will be based on sales net of this discount**. This may have been fully understood but the agreement structure did not cater for it as the pre-wholesaler discount price would not cater for these off-invoice discounts. NB we will need to get agreement on these <u>in writing</u> as **unilateral discounting will not be allowed**'.*[254] (underlining in original, bold emphasis added)

4.77. Clauses 10 ('*Supply Prices and Payment*') and 15 ('*Commercialisation Obligations of Aspen*') of the finalised SDA are broadly consistent with the approach outlined above, although the prohibition on '*unilateral discounting*' referred to above is notable by its absence. The SDA also ensured that Amilco was protected, through the terms of Annexure B, from Aspen's apparent ability under the SDA to discount from the List Price (which in theory would reduce Amilco's margin). In line with the intention set out in the email from [Aspen Employee 4] quoted above, Annexure B ensured that any

[252] Document FLE0394, email from [Aspen Employee 1] to [Aspen Senior Executive 2], [Aspen Employee 4], [Person 1 acting for Amilco] and other Aspen employees dated 10 February 2016. [Person 1 acting for Amilco] told the CMA that Amilco would have no involvement in agreeing a discounting strategy and that they would just need to discuss Aspen's decision to amend its discounting strategy: '*it's not a question of us having to agree. They can do what they want to do. We would then discussion it, but we are not – they are not obligated to have us agree to anything*' (Document FLC4925, Transcript of Interview with [Person 1 acting for Amilco] on 6 December 2018, page 138, line 10 to 12).

[253] While the email from [Aspen Employee 4] refers to 'Tiofarma's share of the net profit', the profit share element went to Amilco.

[254] Document FLE0394, email from [Aspen Employee 4] to [Aspen Senior Executive 2], [Aspen Employee 1], [Person 1 acting for Amilco] and other Aspen employees dated 12 February 2016.

increase in Aspen's discount policy would not be passed on to Amilco, whose margin would not be adversely impacted (see further paragraph 7.54(a)).

ii. The drafting of Clause 3.3 of the SDA relating to Aspen's right to commercialise another Fludrocortisone Acetate Tablets product

4.78. Under Clause 3.3 of the SDA as signed by the Parties, Aspen remained entitled to '*source and commercialise alternate product in the event that there is a short supply in the market*' and '*commercialise its fludrocortisone acetate product in the UK*'.

4.79. A previous version of this clause was discussed between Aspen and Amilco: in the initial version of this clause, Aspen was allowed to commercialise its own version of fludrocortisone only '*in the event of Amilco and/or Tiofarma is unable to fulfil its supply obligations* […]*'*.[255] While this qualification was deleted, the steps taken by Aspen prior to entering the SDA (see paragraphs 4.91 to 4.104) and the intention of the Parties (see paragraphs 8.145 to 8.158) indicate that Aspen had no plans to continue selling Cold Storage Fludrocortisone in the UK provided that Tiofarma could supply sufficient volumes, and that Clause 3.3 was intended to be made a binding commitment in the SDA through the minimum sales quantity clause from late 2016.

4.80. This is supported by evidence relating to the negotiations of that clause.

4.81. The drafting of Clause 3.3 of the SDA was the subject of correspondence between Amilco and Aspen in February 2016. This correspondence includes various iterations of the draft SDA and comments on the various iterations of Clause 3.3 from Aspen and Amilco (and its external lawyers). As explained in further details below from paragraph 4.82, this correspondence shows that:

(a) In response to a draft SDA sent by Aspen which allowed Aspen to sell its own product, Amilco stated that it sought to limit absolutely Aspen's right to source and commercialise another Fludrocortisone Acetate Tablets product, while acting as the exclusive distributor of Ambient Storage Fludrocortisone in the UK;

(b) Following negotiations with Aspen, that limitation was relaxed to permit Aspen to source and commercialise another Fludrocortisone Acetate

[255] Document FLC1143.170, email chain between [Person 1 acting for Amilco] and [Aspen Employee 12] dated 12 February 2016. In that email, [Aspen Employee 12] sent [Person 1 acting for Amilco] a redraft of Clause 3.3 specifying that Aspen was allowed to commercialise its '*own branded pack of the Product'* only '*in the event of Amilco and/or Tiofarma is unable to fulfil its supply obligations* […]'.

Tablets product in the event that Tiofarma failed to supply the required quantity of the drug to Aspen;

(c) However, this restriction on Aspen's right to commercialise was eventually removed due to concerns raised by Amilco's external counsel in the context of the negotiations with Aspen relating to the compliance of such restriction with competition law. As a result, Clause 3.3 of the SDA was amended to purportedly allow Aspen to commercialise another Fludrocortisone Acetate Tablets product during that agreement without any express limitation.

4.82. On 8 February 2016, [Assistant to Person 1 acting for Amilco] sent to [Aspen Senior Executive 2] and [Aspen Employee 12] an email attaching a draft SDA annotated: '*Draft* […] *Amilco mark up 8 February 2016*'.[256]

4.83. This draft of the SDA included two clauses noting that Aspen commercialised Cold Storage Fludrocortisone and would remain entitled to continue to do so, subject to its obligation to purchase minimum sales quantities as per Clause 15.2:

(a) Clause 3.3: '[…] Aspen [and its affiliates] shall, subject to Aspen purchasing the minimum sales quantity in terms of clause 15.2, be entitled to also Commercialise its own branded pack of the Product in the Territory or any part thereof';

(b) Clause 19: 'Competitive Product: It is recorded that, as at the Effective Date, Aspen Commercialises the product (the "Competitive Product") which contain the same active pharmaceutical ingredients as the Product and/or which directly or indirectly compete with the Product, as recorded in paragraph 13 of Annexure A. Notwithstanding any other provisions of this Agreement, Aspen shall be entitled to Commercialise, in the Territory, the Competitive Product, subject to Aspen purchasing the minimum quantities in terms of Clause 15.2'.

4.84. In margin comments, Amilco's external counsel commented on both these clauses:

(a) On Clause 3.3: 'For discussion, Amilco's position is that Aspen should not be entitled to market their competing product while acting as exclusive

[256] Document FLE1811, email from [Assistant to Person 1 acting for Amilco] to [Aspen Senior Executive 2] and [Aspen Employee 12] dated 8 February 2016 and Document FLE1812, draft SDA annotated 'Amilco mark up 8 February 2016'.

distributor for the Tiofarma product unless Tiofarma materially fails to supply the Product to Aspen. Our legal team are advising on the potential competition law implication of such an approach, but in the meantime, this is a point for discussion on Tuesday';

(b) On Clause 19: 'see comment against clause 3.3'.

4.85. On 12 February 2016, [Aspen Employee 12] and [Person 1 acting for Amilco] discussed the drafting of Clause 3.3. [Aspen Employee 12], seeking to relax the absolute restriction as requested by Amilco, sent [Person 1 acting for Amilco] a redraft of Clause 3.3 specifying that Aspen was allowed to commercialise its '*own branded pack of the Product'* only '*in the event of Amilco and/or Tiofarma is unable to fulfil its supply obligations* […]'. [257]

4.86. On 14 February 2016, [Person 1 acting for Amilco] asked an external counsel to Amilco dealing with competition law matters to get in touch with [Aspen Employee 12].[258] On 15 February, [Aspen Employee 12] sent Amilco's external counsel a revised draft of the SDA annotated '*Aspen draft – 15 February'*. In this version of the SDA, Clause 3.3 was replaced with wording reflecting the correspondence set out in paragraph 4.81, giving Aspen the limited right to '*commercialise an alternate product* '*in the event of Amilco and/or Tiofarma is unable to fulfil its supply obligations*'. The Clause 19 contained in the previous drafts had been deleted.[259]

4.87. Following this, [Aspen Employee 12] told [Person 1 acting for Amilco] that the preference of Amilco's external competition counsel was to delete Clause 3.3, and added that Aspen needs to ensure continuity of supply:

'from a commercial perspective, Aspen does need to ensure continuity of supply to patients and so requires the right to source alternate supply in the event of non-supply by Amilco / Tiofarma. It is [✂] *and triggered only in the event of non-supply; perhaps Amilco can revise the wording for us to consider?'* [260]

[257] Document FLC1143.170, email chain between [Person 1 acting for Amilco] and [Aspen Employee 12] dated 12 February 2016, and FLE0903, email from [Person 1 acting for Amilco] to [Aspen Employee 12] dated 12 February 2016, in which [Person 1 acting for Amilco] noted '*So if Tio are unable to fulfil its supply obligations Aspen can seek alternative supplies for Fludrocortisone 100mcg tablets until Tio resume supplies. How does this sound?*'
[258] Document FLE1852, email chain between [Person 1 acting for Amilco], [✂](a competition lawyer at law firm [✂] acting for Amilco) and [Aspen Employee 12] dated 14 February and 15 February 2016.
[259] Document FLE2637, draft SDA annotated 'Aspen draft- 15 February 2016'.
[260] Document FLE1852, email from [Aspen Employee 12] to [Person 1 acting for Amilco] dated 15 February 2016.

4.88. On 16 February, Amilco's external legal counsel asked [Aspen Employee 12] if she would be available to discuss '*Proposed final draft: 25 Feb 2016'*.[261] The next iteration of the SDA came from Amilco and was sent by [Person 2 acting for Amilco] to [Aspen Senior Executive 2] (and others, copying [Person 1 acting for Amilco]) on 19 February ('*Amilco draft – 19 February 2016'*).[262] In this version of the SDA, the wording in Clause 3.3 that limited Aspen's right to commercialise a competing product was entirely deleted. Aspen, commenting on this version of the SDA requested the reinstatement of the previous wording of Clause 3.3 (enabling Aspen to commercialise *'in the event of Amilco and/or Tiofarma is unable to fulfil its supply obligations')* because *'Aspen has an obligation to ensure continuity of supply to patients'*.[263]

4.89. Finally, on 25 February 2016, Amilco's external counsel prepared a final version of the SDA that contains the final wording for Clause 3.3, as stated above in paragraph 4.78.[264]

4.90. The CMA considers that Amilco's intention is clear from Amilco's external counsel's comments on Clauses 3.3 and 19 of the 8 February 2016 draft of the SDA (set out above at paragraph 4.84): Amilco intended to prevent Aspen from selling Cold Storage Fludrocortisone while taking exclusive supply of Ambient Storage Fludrocortisone from Tiofarma. [Person 1 acting for Amilco] made no contemporaneous comment to qualify Amilco's external counsel's comment. In accordance with their respective settlement letters and the terms of settlement annexed to it, Aspen and Amilco have admitted the Infringement and have not contested the CMA's interpretation of the negotiations surrounding Clause 3.3 of the SDA, in particular as outlined in paragraph 4.79 above.

d. Aspen, assisted by Amilco, withdraws Cold Storage Fludrocortisone and replaces it with Ambient Storage Fludrocortisone

4.91. Following the Term Sheet, Aspen took steps to withdraw Cold Storage Fludrocortisone in preparation for replacing it with Ambient Storage

[261] Document FLE1867, email from [Amilco's External Legal Adviser] to [Aspen Employee 12] dated 16 February 2016.
[262] Document FLE1870, email from [Person 2 acting for Amilco] to [Aspen Senior Executive 2] and others dated 19 February 2016 and draft SDA annotated '*Amilco draft – 19 February 2016*' (Document FLE1871). The email of [Person 2 acting for Amilco] also attaches an excel spreadsheet showing a timeline with the various obligations in the Term Sheet (Document FLE1872).
[263] Document FLE1905, email from [Aspen Employee 12] to [✂] (a lawyer at law firm [✂] acting for Amilco), [Person 1 acting for Amilco] and [Person 2 acting for Amilco] dated 22 February 2016 and Document FLE1906, draft SDA annotated '*Aspen draft – 22 February 2016*'.
[264] Document FLE1917, email from [Amilco's External Legal Adviser] to [Aspen Employee 12] dated 26 February 2016, and Document FLE1918, draft SDA annotated '*Proposed final draft – 25 February 2016'*.

Fludrocortisone in the UK. At the same time, Amilco and Tiofarma scaled up the manufacturing of Ambient Storage Fludrocortisone to meet demand for Fludrocortisone Acetate Tablets as from March 2016, and assisted Aspen in communicating this withdrawal to wholesalers.

i. Aspen stops purchasing Cold Storage Fludrocortisone for the UK and places its first orders of Ambient Storage Fludrocortisone from Amilco/Tiofarma

4.92. In anticipation of an agreement being reached between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] concerning Ambient Storage Fludrocortisone, Aspen's [✂] team and [✂] management discussed the strategy to withdraw Cold Storage Fludrocortisone from the UK market and replace it entirely with Ambient Storage Fludrocortisone supplied by Tiofarma for the duration of the SDA.[265]

4.93. On 11 January 2016, [Aspen Senior Executive 3] informed [Aspen Employee 6]: '*The likelihood of signing Fludrocortisone is high. Based on this we will need to cancel the March order. Please let me know if this can be cancelled or allocated to another market*.'[266] Shortly after signing the Term Sheet, Aspen internally considered what to do with '*70k of UK orders we need to allocate elsewhere*'.[267]

4.94. One month later, Aspen placed its first three orders for Ambient Storage Fludrocortisone with Tiofarma, via Amilco. Each of these three orders, dated 19 February 2016 (under Aspen purchase orders MFT0444, MFT0449 and MFT0450), was for [✂] packs (meaning that the total volume ordered by Aspen on 19 February 2016 was some [✂] packs, equivalent to [✂] tablets).[268] The purchase orders were issued by Aspen with the supply price of £[✂],[269] that is, the price discussed between [Person 1 acting for Amilco] and [Aspen Senior Executive 2] in December 2015 (see paragraphs 4.51 to 4.63 above).

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[265] Document FLE0980, email from [Consultant to Aspen] to [Aspen Senior Executive 2] dated 8 January 2016: '*On Monday I think we need to make it clear that this is the only Fludrocortisone product we will market (reserving our rights as per term sheet)* […] *I will need some help from you in addressing Aspen stock delivery of Brand stock'*.
[266] Document FLE0982, email from [Aspen Senior Executive 3] to [Aspen Employee 6] dated 11 January 2016.
[267] Document FLE0985, email from [Aspen Senior Executive 3] to [Aspen Employee 6] and [Aspen Senior Executive 2] dated 20 January 2016.
[268] Document FLC1143.296, email from [Person 2 acting for Amilco] to [Tiofarma Employee 1] and [Tiofarma Employee 2] on 19 February 2016, headed *'Aspen – Fludrocortisone Purchase Orders'*.
[269] Document FLC1143.197, email from [Aspen Employee 19] to [Person 2 acting for Amilco] dated 26 February 2016, and purchase orders (Document FLC1143.198, Document FLC1143.199 and Document FLC1143.200).

4.95. One of these three orders (under Aspen purchase order number MFT0444) had already been manufactured by Tiofarma in December 2015.[270] It was planned for delivery by the end of February 2016 and was in fact delivered to [✂] (Aspen's logistics provider) within a few days of the commencement of the SDA on 1 March 2016. A second order of [✂] packs was planned for delivery on 15 April 2016, with the remainder planned for delivery by 15 June 2016.[271] These volumes are broadly in line with the figures set out in Annexure C of the SDA (also in the Term Sheet), as they are broadly equivalent to six months of anticipated demand.

ii. Aspen plans to sell off existing stocks of Cold Storage Fludrocortisone and to withdraw Florinef from the UK market

4.96. The [✂] team of Aspen planned to sell off existing stocks of Cold Storage Fludrocortisone.[272] Aspen's initial internal projections from that time indicated that it expected to be able to sell off all such stock by the end of February 2016 so as to sell only Ambient Storage Fludrocortisone from March 2016 onwards.[273] It later softened those expectations somewhat to reflect its uncertainties around [✂].[274] In its final budget, Aspen assumed zero sales of Ambient Storage Fludrocortisone in March, which gave it greater flexibility to sell the remainder of its Cold Storage Fludrocortisone stock during that month.[275]

4.97. Nevertheless, Aspen continued to work internally towards a goal of withdrawing Cold Storage Fludrocortisone on 29 February 2016 and launching Ambient Storage Fludrocortisone on 1 March 2016.[276] At the

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[270] Document FLC1981, page 40, lines 7 to 8, Transcript of CMA interview with [Tiofarma Employee 1] on 22 November 2017: *'We started producing in December'.* See also Document FLE0184, email from [Aspen Employee 21] to [Person 2 acting for Amilco] (cc [Person 1 acting for Amilco], [Aspen Senior Executive 2], [Consultant to Aspen] and others) on 25 January 2016: '*Tiofarma manufactured* [✂] *in Dec-2015'.*

[271] Document FLC1143.296, emails from [Person 2 acting for Amilco] to [Tiofarma Employee 1] and [Tiofarma Employee 2] on 19 February 2016 and 1 March 2016, headed *'Aspen – Fludrocortisone Purchase Orders'*.

[272] Document FLE0134, email from [Aspen Employee 11] to [Aspen Employee 1] dated 6 January 2016: '*Post launch of new ambient pack in March sales volume are zero as old stock is consumed*'.

[273] Document FLE0138, electronic text conversation between [Aspen Employee 2] and [Aspen Employee 1] dated 8 January 2016: '[Aspen Employee 2] *11:32:* [✂]- *is the proposal to discontinue Florinef, when we launch in March - will there be an residual sales?* [Aspen Employee 1] *11:33: Yes thats the point, we discontinue our de-branded fridge product and replace with this numbers are built into march sales ie we are selling out the current stocks. we think we have enough volumes for Feb and part march*'.

[274] [Aspen Employee 1] noted that, following an internal Aspen discussion, a revision of volumes was required during the transition to Ambient Storage Fludrocortisone, '*We have revised the volumes in the initial quarters to reflect, a) pipeline fill and b) a less aggressive decline in volumes, as we transition to the new pack and price offering*.' Document FLE0146, email from [Aspen Employee 1] to [Aspen Senior Executive 2] and others dated 11 January 2016.

[275] Document FLE0206, email from [Aspen Employee 1] to [Aspen Senior Executive 2] dated 12 February 2016.

[276] Document FLE0190, email chain between [Aspen Employee 1] and [Aspen Employee 16] dated 29 January 2016.

beginning of February 2016, in internal Aspen communication, [Aspen Employee 1] told [Aspen Employee 3] that the [✂] team was focused on '*selling through the existing brand to ensure we are out of stock this month'* and did not raise any potential issues with achieving that goal.[277] On 15 February 2016, Aspen received confirmation from the regulatory authorities that Florinef would be recorded as having been discontinued. [278] Despite Cold Storage Fludrocortisone being discontinued, the MA for Cold Storage Fludrocortisone remained in place, allowing for parallel imports of that drug.

4.98. On 23 February 2016, Aspen notified the NHSBSA of the introduction of Ambient Storage Fludrocortisone at a price of £30/pack.[279] On 24 February 2016, [Consultant to Aspen] told his Aspen colleagues that that NHSBSA did not object to the price of Ambient Storage Fludrocortisone.[280]

iii. Amilco's involvement in Aspen's withdrawal of Cold Storage Fludrocortisone

4.99. Amilco was not only aware of the withdrawal of Cold Storage Fludrocortisone by Aspen but actively monitored the implementation of the withdrawal and corresponded with Aspen on the text of the communication to wholesalers to announce the withdrawal of Florinef and introduction of Ambient Storage Fludrocortisone.

4.100. The discussions relating to the withdrawal of Cold Storage Fludrocortisone were taking place in parallel with the drafting of the SDA.

4.101. In late January 2016 [Person 2 acting for Amilco] and [Person 1 acting for Amilco] prepared a draft communication for Aspen to send to wholesaler customers[281] which stated that the withdrawal was occurring for the dual purpose of allowing Aspen to launch a new product with ambient features and

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[277] Document FLE0194, email from [Aspen Employee 1] to [Aspen Employee 3] dated 4 February 2016.
[278] Document FLE0206, email from [Consultant to Aspen] to [Aspen Senior Executive 2] and [Aspen Employee 1] dated 15 February 2016. See also Document FLC1834 and Document FLC1842, Aspen's response to question 40 of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).
[279] Document FLE0212, email from [Consultant to Aspen] to [NHSBSA] dated 23 February 2016.
[280] Document FLE0217, email from [Consultant to Aspen] to [Aspen Employee 1] and [Aspen Senior Executive 2] dated 24 February 2016 and its attachment Document FLE0219.
[281] Document FLE0174, email chain between [Person 2 acting for Amilco], [Consultant to Aspen], [Person 3 acting for Amilco] and [Person 1 acting for Amilco] dated 26 and 27 January. Aspen appears not to have sent a similar communication to some or all of its hospital customers. Internal Aspen emails reveal that it received complaints from at least one NHS Trust complaining about the lack of any prior notification of the change and the extent of the price increase. Document FLE0256, email chain from [Aspen Employee 17] to [Consultant to Aspen] dated 24 March 2016. [Aspen Employee 1] also separately noted in an update to the Aspen commercial team that '*Some customer complaints received into UK Office and pre-wholesaler on ++ price change – but nothing unexpected*.' Document FLE0264, email from [Aspen Employee 1] to [Aspen Senior Executive 2] and others dated 1 April 2016.

to address [✂] concerning the old product.[282] Aspen agreed to send a version of the communication without the reference to [✂][283] to wholesalers on 1 February 2016. [Person 2 acting for Amilco] agreed with the revised version of the communication.[284]

4.102. Amilco understood that the launch of Ambient Storage Fludrocortisone would coincide with the withdrawal of Florinef by Aspen, with a risk of sales of Ambient Storage Fludrocortisone being low in March 2016 due to residual stocks of Florinef working through the system. [Person 2 acting for Amilco] sent an email to [Consultant to Aspen] on 22 January 2016 stating:

'we are working towards a 1st March launch, although I do appreciate sales may not pick up to expected levels due to residual stocks of the brand being in the market. We would expect to see sales to start normalising from April onwards'.[285]

4.103. Towards the end of January 2016, [Person 2 acting for Amilco] sought confirmation from Aspen that the wholesalers had been notified of the discontinuation of Florinef and of the availability of the new Ambient Storage Fludrocortisone product.[286] In mid-February 2016, internal Aspen correspondence demonstrates that [Person 1 acting for Amilco] sought confirmation from both [Aspen Senior Executive 2] and [Aspen Employee 1] of Aspen that the relevant regulatory and clinical bodies such as the Directory of Medicines and Devices ('**DM&D'**) had been notified of the pending withdrawal of Cold Storage Fludrocortisone.[287]

4.104. In view of the above, Amilco actively assisted and monitored Aspen's withdrawal of Cold Storage Fludrocortisone and its replacement with Ambient Storage Fludrocortisone. Such withdrawal and replacement are consistent

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[282] See also Document FLE0886, email from [Person 2 acting for Amilco] to [Aspen Employee 20], cc [Person 1 acting for Amilco], dated 29 January 2016, mentioning that [Ambient Storage Fludrocortisone] is the only product on the market.
[283] Document FLE0188, email from [Person 2 acting for Amilco] to [Aspen Employee 1] dated 29 January 2016. Aspen's [✂] team rejected the draft communication on the basis that it appeared to contain unnecessary '*marketing'* (Document FLE0179, email chain from [Aspen Employee 1] to [Consultant to Aspen] dated 28 January 2016) and sought advice from Aspen's [✂] leadership (Document FLE0181, email chain from [Aspen Employee 1] to [Consultant to Aspen] dated 28 January 2016).
[284] Document FLE0188, email from [Person 2 acting for Amilco] to [Aspen Employee 1] dated 29 January 2016.
[285] Document FLC1143.29, email from [Person 2 acting for Amilco] to [Consultant to Aspen] dated 22 January 2016. See also Document FLE0886, email from [Person 2 acting for Amilco] to [Aspen Employee 20], cc [Person 1 acting for Amilco], dated 29 January 2016, mentioning that [Ambient Storage Fludrocortisone] is the only product on the market.
[286] Document FLC1143.39, email chain between [Person 2 acting for Amilco], [Aspen Employee 1] and [Consultant to Aspen] dated 1 February 2016.
[287] Document FLE0206, email from [Aspen Senior Executive 2] to [Aspen Employee 1] dated 12 February 2016 and from [Aspen Employee 1] to [Aspen Senior Executive 2] dated 12 February 2016.

with Amilco's position in the negotiation of the SDA that Aspen should not be entitled to market their competing product while acting as exclusive distributor for the Tiofarma product unless Tiofarma materially fails to supply the Product to Aspen (see paragraphs 4.79 to 4.90).

III. The key contractual terms of the SDA effective as of 1 March 2016

4.105. Aspen, Amilco and Tiofarma entered into the SDA with an effective date of 1 March 2016.[288] The key terms of the SDA are described in further detail below. They largely mirrored the terms set out in the Term Sheet previously agreed in January 2016.

e. Exclusive rights of commercialisation of Ambient Storage Fludrocortisone granted by Tiofarma to Aspen

4.106. Under Clause 6 of the SDA, Tiofarma granted Aspen the exclusive right to commercialise Ambient Storage Fludrocortisone in the UK and, to the extent required for that purpose, to use: (i) the data related to Ambient Storage Fludrocortisone (ie all proprietary information and material including but not limited to substances, formulations, techniques, methodology, manufacturing process, equipment, data reports, know-how, source of supply, related to Ambient Storage Fludrocortisone); (ii) the Tiofarma trademarks (since, under the licencing arrangement, Ambient Storage Fludrocortisone was sold under Tiofarma's brand); and (iii) the relevant MA.

4.107. The initial period of the SDA was three years (Clause 4.1), with the agreement automatically renewing for a single additional period of two years. This period allowed for an earlier termination than was originally contemplated in the Term Sheet (five years).

4.108. Under Clause 27.1 of the SDA, neither Tiofarma/Amilco or Aspen was entitled to terminate the SDA before the end of the initial three-year period except in the case of a breach of a material provision by the other party.

a. Aspen's obligation to order and sell minimum quantities of Ambient Storage Fludrocortisone

4.109. The SDA contained the following provisions requiring Aspen to order and sell minimum quantities of Ambient Storage Fludrocortisone under the SDA.

[288] Document FLE0225 and Document FLE0226 (signature page), Supply and Distribution Agreement between Tiofarma B.V., Aspen Global Incorporated and Amilco Limited, with an effective date of 1 March 2016.

i. Minimum sales quantity

4.110. The provisions of the SDA governing minimum sales quantity are considered in detail in paragraphs 7.22 et seq. In summary, Clause 15 of the SDA ('*Commercialisation Obligations of Aspen'*) establishes the basis for Aspen's minimum supply obligation for Ambient Storage Fludrocortisone. Under that clause, Aspen was required to purchase 90% of the minimum sales quantities recorded in an Annexure C. The quantities set out in Annexure C were to be periodically updated by agreement between Amilco and Aspen.

ii. Minimum order quantities

4.111. The SDA provided in Clause 8.3 that Ambient Storage Fludrocortisone was to be supplied by Tiofarma to Aspen '*in accordance with the minimum order quantities per delivery shipment ("MOQ's") as recorded in* ***Annexure B***.' Annexure B of the SDA provided that Aspen was required to purchase minimum order quantities of [✂] tablets (that is to say [✂] packs of 30 tablets).

iii. Rolling forecast

4.112. Clauses 9.1 and 9.2 of the SDA provided that, in order to allow Tiofarma to plan for the production of the drug, Aspen was required to provide Amilco with a rolling forecast of its requirements for the next 12 months, updated monthly. Clause 9.3 specified that the first four-month period included in each rolling forecast would '*constitute a binding commitment by Aspen'*.

iv. Aspen's commercialisation rights relating to Cold Storage Fludrocortisone

4.113. Under Clause 3.3, Aspen remained expressly entitled to '*source and commercialise alternate product in the event that there* [was] *a short supply in the market*' and '*in any event remain*[ed] *entitled to commercialise its fludrocortisone acetate product in the* [UK]'. (This clause is considered in more detail in paragraphs 4.78 to 4.90).

b. Payments to Amilco and Tiofarma under the SDA

4.114. Clause 10.7 of the SDA specifies that Amilco would invoice Aspen in respect of the supply of Ambient Storage Fludrocortisone from Tiofarma in full,[289]

[289] Clause 10.7 of the SDA holds that '*Amilco shall issue an invoice to Aspen in respect of all Product sold and supplied by Amilco to Aspen* [...]'

including profit share element and costs of goods.[290] There would therefore not be separate invoicing to Aspen by Tiofarma. As discussed below at paragraph 4.180, Aspen paid Amilco £[✂] under the SDA in the period from March 2016 to October 2016 (when the initial term of the SDA was cut short by Aspen and Tiofarma entering into the SAA).

i. The Supply Price

4.115. Clause 10.1 of the SDA states that '*the Product shall be sold and supplied by Amilco to Aspen at the Supply Price(s) as recorded in Annexure B*'. The supply price was defined in Clause 2.2.2.33 as '*the price recorded in column 5 of Annexure B* […] *which is/are payable by Aspen for each* [pack] *of the relevant Product as supplied by Tiofarma in accordance with the provisions of this Agreement, as may be adjusted by Tiofarma or Amilco pursuant to the terms of clause 10*' ('**Supply Price**').

4.116. Column 5 of Annexure B lists the Supply Price as £[✂] per pack, which was described in a note to column 5 as '[✂]'.

4.117. Under Annexure B, this Supply Price was calculated on the basis of a 'Proposed retail supply price' of '*£30.00 per pack of 30's*' (that is, a price per tablet of £1), and '*Cost of goods*' of '*€*[✂] *per 30 pack which is currently equal to £*[✂] *per 30 tablet pack*'.

4.118. The SDA therefore contains a clear link between the Supply Price and the price Aspen would charge in the market, as it envisages a future retail List Price of £1 per tablet or £30 per pack, of which Amilco would receive £[✂] per pack. This is in line with the communication between [Person 1 acting for Amilco] and Aspen [✂] management between 10 and 22 December 2015 (see paragraphs 4.51 to 4.63). The £30 per pack (or £1 per tablet) List Price equated to an increase in the price per tablet of over 1,800% (compared to the pre-SDA List Price of £0.05).

4.119. The SDA provided for changes to the Supply Price only in the context of an '*annual review'* of that price. Clause 10.5 stated that:

[290] Aspen's commercial team understood that Amilco's profit share would be paid upfront as part of the Supply Price and planned to budget accordingly. An email from [Aspen Employee 11] to a colleague in the Aspen commercial team noted: '*Further to conversation myself and* [Aspen Employee 1] *had this morning with* [Aspen Employee 4] *regarding florinef replacement from Tiopharma* [sic] *it appears that the profit share element will be paid as part of the product supply cost rather than paid retrospectively post the sale as a rebate*.' Document FLE0203, Email from [Aspen Employee 11] to [Aspen Employee 10] dated 11 February 2016.

'Unless otherwise agreed, the Parties shall meet in May of each year to review and, where appropriate, agree changes to the Supply Price ("Product Price Review"). Agreed changes shall take effect on 1 July of the same year, save where the Parties agree otherwise in writing. The first Product Price Review shall be held in May 2017, with the first change to take effect from 1 July 2017. In agreeing the Supply Price, the parties shall have regard to, inter alia, the following factors: changes to Tiofarma's costs of manufacturing the Products; the volumes of Products ordered by, and supplied to, Aspen; the Cost of Goods relative to the pre-wholesale discount price (after any further discounts) realised during the past three months; any cost reductions achieved by Tiofarma since the last Product Price Review [...]*'*

ii. The reconciliation mechanism in case of variation in the List Price, discount or GBP/EUR exchange rate

4.120. A balancing payment was due under the quarterly reconciliation provisions in the event of a variance between (i) Aspen's actual List Price or wholesale discount, and (ii) the List Price (ie £30 per pack) and the wholesale discount set out in Annexure B of the SDA. A separate quarterly reconciliation mechanism (set out in Clause 10.3 and not material for these purposes) applied in relation to variation to the GBP/EUR exchange rate so as to maintain a payment in pounds equal to €1.15 per pound.

4.121. Any variation of these elements affecting the calculation of the Supply Price would have led to payments between the Parties reflecting such variations. In addition, in the event that the wholesale discount exceeded [✂]%, the Parties agreed that the profit share element to be paid by Aspen would be increased to [✂]%. The adjusted Supply Price is referred to as the '*Reference Supply Price*' in the SDA.

4.122. Clause 10.2 states that:

'10.2.2 […] *The "Reference Supply Price" for a* [pack] *of* [Ambient Storage Fludrocortisone] *for the Relevant Calendar Quarter*[291] *shall be equal to:*

10.2.3 where the wholesaler discount is between 0% and [✂]*%:* [✂]*% of the pre-wholesaler discount price less any discounts agreed in writing between the Parties; or*

[291] Calendar Quarter means the respective periods of three consecutive calendar months ending on 31 March, 30 June, 30 September or 31 December.

10.2.4 where the wholesaler discount is greater than [✂]*%:* [✂]*% of the pre-wholesaler discount price less any discounts agreed in writing between the Parties;*

Plus, in both cases:

10.2.5 the Cost of Goods.

Where the total Supply Price for all Product supplied in the relevant Calendar Quarter is less than the Reference Supply Price for all such Product, Aspen shall make a balancing payment of the difference to Amilco within 14 days of receipt of Amilco's reconciliation calculation. Where the total Supply Price for all Product supplied in the relevant Calendar Quarter is more than the Reference Supply Price for all such Product, Amilco shall make a balancing payment of the difference to Aspen within 14 days of providing the reconciliation calculation to Aspen.'

iii. Worked examples in Annexure B of the SDA

4.123. Annexure B contained two worked examples of the calculation of the Supply Price, distinguishing between a wholesaler discount of [✂]% and of [✂]% (the latter leading to a higher Supply Price). Both examples are based on a '*proposed retail selling price*' of £1 per tablet (or £30 for a pack of 30 tablets) and a base GBP/EUR exchange rate of £1=€1.35:

'Where the wholesale discount is between 0 and [✂]*%*

Retail selling price less wholesaler discount = pre-wholesale discount price.

Price = £1.00

Wholesaler discount = [✂]*%*

Pre-wholesale discount price = £[✂]

30% of £[✂] = £[✂] *(profit share element per tablet)*

The supply price to Aspen is (£[✂]

Where the wholesaler discount is greater than [✂]*%:*

Retail selling price less wholesaler discount = pre-wholesale discount price.

Price = £1.00

Wholesaler discount = [✂]%

Pre-wholesale discount price = £[✂]

[✂]% *of* £[✂] = £[✂] *(profit share element per tablet)*

The supply price to Aspen is (£[✂] *x 30)* + [✂]

To the extent that the Parties all agree to grant further discounts beyond the pre-wholesaler discount, these shall also be deducted from the retail selling price prior to calculating the profit share element per tablet.

Fluctuations in the wholesaler discount, retail selling price or exchange rate that results in price changes (up or down) shall be taken into account when calculating the supply price.'

4.124. Therefore, the SDA reflects Amilco's objective that its commission under the SDA should be protected in case Aspen increased its wholesaler discounts (see paragraphs 4.76 to 4.77 above).

c. The role of Amilco under the SDA

4.125. The SDA described Amilco's role as follows:

(a) In Clause 3.4: 'Amilco as Tiofarma's local representative shall be responsible for the commercial arrangements in terms hereof.'; and

(b) In Clause 8.1: '[…] Amilco shall sell the Product to Aspen pursuant to orders placed by Aspen with Amilco. Aspen shall purchase all of its requirements of the Product only from Tiofarma via its local representative in the Territory, Amilco [...]'

4.126. In addition, under Clause 7.1, Aspen was subject to a monthly reporting requirement, allowing Amilco to monitor the sales made by Aspen (including volume; gross value; discounts, rebates and the like granted to customers; and current stock) and calculate its remuneration accordingly.

IV. Implementation of the SDA after 1 March 2016

d. Parties' ongoing discussions of minimum volume commitments under the SDA

4.127. In line with Aspen's contractual commitment to purchase minimum sales quantities from the 7th month of the SDA (ie from 1 September 2016), Aspen

and Amilco monitored Aspen's actual sales of Fludrocortisone Acetate Tablets during the first months of the SDA in order to set the applicable volumes.

4.128. Correspondence internal to Aspen shows concerns that these minimum sales quantities commitments might exceed Aspen's actual sales of Fludrocortisone Acetate Tablets in the UK. For instance, [Aspen Employee 1] explained to [Aspen Employee 2] in an email of 14 March 2016: '*This difference* [in forecast] *is why in the contract, the contracted volumes are not an obligation. UNTIL SEPTEMBER ie the 7th month. In April we will only have a few weeks of data to work with and therefore we think we should dig in on this number in our discussions with Durban'*.[292]

4.129. In an email to [Aspen Employee 2] of 29 April 2016, [Aspen Employee 1] noted that there had been a disagreement between the Parties as to the volume forecast for the period following the price increase of March 2016. Within this context, he noted that '*We will then meet in July, after 4 months of real sales to fix contract volumes for 6 months periods. We must be clever on this – the deal gives* [Amilco/Tiofarma] *their margin up front £*[✂]*/pack. If we get this massively wrong, we will have a significant issue'*.[293]

4.130. Contemporaneous evidence shows that, during the period of the SDA, Aspen regularly updated Amilco on sales volumes in accordance with Clause 7 of the SDA.[294] As contemplated in Clause 15.2 of the SDA, Aspen ([Aspen Employee 1] and [Consultant to Aspen]), Tiofarma ([Tiofarma Employee 1]) and Amilco ([Person 2 acting for Amilco]) met on 1 July 2016 to discuss the setting of the minimum volume commitments applicable to Aspen under the SDA from September 2016.[295] The minutes of the meeting recorded the following:

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[292] Document FLE0242, Email from [Aspen Employee 1] to [Aspen Employee 2] dated 14 March 2016.
[293] Document FLE0304, email from [Aspen Employee 1] to [Aspen Employee 2] dated 29 April 2016. [Aspen Employee 1] confirmed in interview that there was a disagreement on the volume forecast (Document FLC4896, Transcript of Interview with [Aspen Employee 1] on 6 December 2018, page 29, lines 3 to 4). He also confirmed to the CMA that his expectation, when reporting on the monthly sales volumes of Aspen, was that those volumes would then translate into the minimum sales commitment that would subsequently be agreed with Amilco (Document FLC4896, Transcript of Interview with [Aspen Employee 1] on 6 December 2018, page 30, lines 1 to 8).
[294] Document FLE0372, email from [Aspen Employee 1] to [Aspen Employee 6] and others at Aspen, dated 4 July 2016, headed *'Review of Commercial Forecast – Aspen/Tiofarma/Amilco'*. [Aspen Employee 6]: *'is the monthly sales data currently being supplied as per Clause 7 of the Agreement to Amilco?'* [Aspen Employee 1]: *'we have a monthly discussion with them on the performance for that month, and year to date as per the contract, and the directions we took from the telcons with them when completing the contract. The data is cut from the* [Logistics Provider] *sales report, and they are happy it gives them all the information they need.'*
[295] Document FLE0372, email from [Aspen Employee 1] to [Aspen Employee 6] and others dated 1 July 2016.

*'**Sales forecast***
Agreed that we will wait until July data is released to make a decision on the sales forecast for the period September 16 to February 17. A decision will be made in early August.'[296]

4.131. A few weeks later, [Aspen Employee 1] told [Person 2 acting for Amilco] that Aspen would send Amilco its sales data over the past 4.5 months in order to finalise the forecast.[297]

4.132. [Aspen Employee 1] sent an email to [Person 2 acting for Amilco] on 1 September 2016 regarding the commercial forecast to be included in the SDA for September 2016 to February 2017:

'Hi [Person 2 acting for Amilco]

For the agreed 6 month commercial forecast – can you confirm you are happy with the 'early 40k' quoted by [Consultant to Aspen] *to go into the contract, for the period Sep to Feb?'*[298]

4.133. [Person 2 acting for Amilco] replied '*Before we confirm please could you confirm the sales for last month?*'[299] [Aspen Employee 1] responded on the following day with the sales volumes of Ambient Storage Fludrocortisone for the period from March to August 2016, concluding:

'The mean PROPOSED commercial forecast therefore for September to February would be 40,532 units. Are you happy for this number to added [sic] *to the contract as the forecast addendum for the period Sep-Feb?'*[300]

e. Aspen's prices for Ambient Storage Fludrocortisone after entering into the SDA

4.134. Immediately after entering into the SDA, Aspen increased its List Price to £30/pack and maintained that List Price while the SDA was in force, in line with the worked example set out in Annexure B of the SDA. Similarly, it

[296] Document FLC1143.26, Minutes of meeting held on 1 July 2016 between Aspen, Amilco and Tiofarma. See also Document FLE0377, email from [Person 2 acting for Amilco] to [Aspen Employee 1] and others at Aspen, [Tiofarma Employee 1], [Person 1 acting for Amilco] and [Person 3 acting for Amilco] dated 10 July 2016 headed *'Minutes of Meeting – 01.07.16'*.
[297] Document FLC1143.44, email from [Aspen Employee 1] to [Person 2 acting for Amilco] dated 25 July 2016.
[298] Document FLE0402, email from [Aspen Employee 1] to [Person 2 acting for Amilco], dated 1 September 2016.
[299] Document FLE0402, email from [Person 2 acting for Amilco] to [Aspen Employee 1], dated 1 September 2016.
[300] Document FLE0402, email from [Aspen Employee 1] to [Person 2 acting for Amilco], dated 2 September 2016.

applied a wholesaler discount of [✂]%, subject to minor variations which were not taken into account for the purpose of the reconciliation mechanism.

4.135. It is clear from an email from [Aspen Employee 1] to [Aspen Employee 3] of 7 November 2016 that this pricing behaviour was linked to the SDA. [Aspen Employee 1] asked [Aspen Employee 3] to enquire with [Aspen Employee 5] ([✂]) whether Aspen had become free to set wholesaler discounts following the termination of the SDA and the conclusion of the SAA:

'Questions for [Aspen Employee 5]*. The Tiopharm* [sic] *contracts dictates that any price change ie Discounts or promotional activity is 'agreed between the parties'. Presumably now. We have a free reign to grow further the volumes? I have some ideas to get this moving faster'.*[301]

4.136. Two days later, on 9 November 2016, [Aspen Employee 1] sent [Aspen Employee 3] a text message asking whether consent from Tiofarma and '*their broker'* (the CMA infers this is a reference to Amilco) was still required to change the price of Fludrocortisone:

'Hi [✂]*. On Tiopharm* [sic]*. It's important that we know from* [Aspen Employee 5] *if I can promote and freely price now, following purchase of fludro.*
We can initiate some hospital promotion in Dec and beyond -which could give us an upside in 16/17. But I need confirmation I don't need to agree everything with Tiopharm [sic] *and their broker. (They didn't want to touch price when I had mentioned previously)* [...]*'* [302]

4.137. Eventually, [Aspen Employee 3] forwarded the email of 7 November 2016 to [Aspen Employee 5] of Aspen stating:

'Following the Tiopharm [sic] *acquisition, which is great news,* [Aspen Employee 1] *has raised the below important clarifying questions, which we are hoping you can help us with?'.*[303]

[301] Document FLE0471, email from [Aspen Employee 1] to [Aspen Employee 3] dated 7 November 2016.
[302] Document FLE0866, Text message from [Aspen Employee 1] to [Aspen Employee 3], 9 November 2016. [Aspen Employee 1] told the CMA that the sentence '*I don't need to agree everything with Tiopharm* [sic] *and their broker*' means that he will not need to have '*these monthly meeting with* [Amilco/Tiofarma]*, I don't need to do this bureaucracy'* (Document FLC4896, Transcript of Interview with [Aspen Employee 1] on 6 December 2018, page 75, lines 4 to 13). [Aspen Employee 1] told the CMA that "they" in this passage is a reference to Aspen Global Inc (Document FLC4896, Transcript of Interview with [Aspen Employee 1] on 6 December 2018, page 76, lines 12 to 17).
[303] Document FLE0474, email chain between [Aspen Employee 3], [Aspen Employee 1] and [Aspen Employee 5] (cc [Aspen Employee 2]) dated 7 and 9 November 2016.

4.138. The response from [Aspen Employee 5] stated:

> *'Correct we are free to make any decision as from 1st October 2016 as we own the product.'*[304]

4.139. Following this positive response, [Aspen Employee 1] emailed a colleague in his commercial team planning to take advantage of this pricing freedom:

> *'We are free to price and promote as we wish. Lets discuss on Friday for a* [✂]*, and* [Consultant to Aspen] *can investigate its reaction to promotion in the key wholesalers.* [✂]*.'*[305]

4.140. It is clear from these contemporaneous documents that Aspen considered itself restricted in terms of setting its List Price and wholesaler discounts during the time the SDA was in place, and considered this restriction was removed when it entered into the SAA.

D. The SDA was terminated in October 2016 by the entry of Aspen and Tiofarma into the SAA, pursuant to which Aspen purchased the MAs for Ambient Storage Fludrocortisone

4.141. In June 2016, following press reports published in The Times criticising the actions of certain generics companies that increased prices of vital drugs,[306] [Tiofarma Employee 1] expressed concerns to [Person 1 acting for Amilco] that the magnitude of the price increase implemented by Aspen could be seen in the same light as the actions of the companies quoted in The Times article, with negative consequences for Tiofarma:

> *'With regards to the link you send me and in particular after looking up what the actual market price of Fludro in the UK is, I've done some thinking: Isn't*

[304] Document FLE0473, email from [Aspen Employee 1] to [Aspen Employee 5] and [Aspen Employee 3] (cc [Aspen Employee 2] and [Consultant to Aspen]) dated 9 November 2016.
[305] Document FLE0474, email from [Aspen Employee 1] to [Aspen Employee 14] dated 9 November 2016.
[306] The press reports criticized generics companies to exploit loopholes within the system of price regulation, leading to price increases. Document FLC2273, [✂] '*Extortionate prices add £260m to NHS drug bill',* dated 3 June 2016*';* Document FLC2272 *'Brothers cost NHS millions by exploiting drug price loophole',* dated 3 June 2016; Document FLC2274 '*Firm's £1.5bn drug profit is bitter pill for taxpayer',* dated 4 June 2016; Document FLC2276 '*Huge price rise forces NHS to ditch life-changing drug'* dated 6 June 2017; Document FLC2277 '*Lessons in exploiting a loophole to make millions out of the NHS',* dated 4 June 2016; Document FLC2278 '*Price rise loophole was approved by Whitehall',* dated 7 June 2016. These did not refer to Aspen, Tiofarma, Amilco or Fludrocortisone Acetate Tablets [✂].

there a chance that what Aspen has done to the Fludro [✂]*? And moreover that that might backfire on us.'*[307]

4.142. [Person 1 acting for Amilco] responded the next day by email, noting that he shared some of the same concerns about the pricing of Fludrocortisone and suggested that he would try speaking to Aspen.[308]

4.143. A few weeks after this exchange, on 20 August 2016, [Person 1 acting for Amilco] proposed to Aspen to purchase the MAs for Ambient Storage Fludrocortisone and associated rights worldwide.[309] In an email of 6 September 2016, [Person 1 acting for Amilco] spelled out the proposed key terms for the transaction. According to this initial offer, the proposed price would be based on the net present value of the SDA for 2.5 years or 3 years paid in a lump sum (on the basis of the same profit share) and Tiofarma and Aspen would enter into a new Supply Agreement contemplating an increase in the COGs to be paid to Tiofarma from €[✂] to €[✂].[310]

4.144. From this point onwards, at Aspen's request,[311] the negotiations of the terms of the SAA were led by [Tiofarma Employee 1] (and not [Person 1 acting for Amilco]).[312] Whilst [Person 1 acting for Amilco] was no longer directly involved

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[307] Document FLC1143.309, email chain between [Person 1 acting for Amilco] and [Tiofarma Employee 1] dated 8 and 9 June 2016, Amilco's response to question 26 c of the CMA's section 26 notice dated 12 February 2018. This exchange is also described by [Tiofarma Employee 1] in his statement to the CMA on 26 January 2018, Document FLC0818, paragraph 10: '*In June of 2016 I discussed with* [Person 1 acting for Amilco] *news coverage of the price increases for Fludrocortisone that Aspen had implemented, and expressed reservations about those increases and the potential for Tiofarma to be associated with them*.'

[308] Document FLC1143.309, email chain between [Person 1 acting for Amilco] and [Tiofarma Employee 1] dated 8 and 9 June, Amilco's response to the CMA's section 26 notice dated 12 February 2018. The methodology subsequently adopted for the calculation of the purchase price for the MA (the methodology was initially proposed by Amilco, see paragraph 4.143) was based on that very same price of £1 per tablet.

[309] [Person 1 acting for Amilco] to [Aspen Senior Executive 2] (20 August 2016): '*Just a quick note to see if you still interested in the Fludrocortisone worldwide rights. As Tio want to dispose by latest September 10th*.' Document FLC1670, messages tab, text messages between [Person 1 acting for Amilco] and [Aspen Senior Executive 2] dated 20 August and 22 August 2016, call logs for [Person 1 acting for Amilco]'s phone NKM009.

[310] Document FLC1143.250, email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] dated 6 September 2016.

[311] Document FLC1143.250, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] dated 6 September 2016. See also Document FLC1670, text messages between [Person 1 acting for Amilco] and [Aspen Senior Executive 1] dated 6 December 2016, messages tab, call logs for [Person 1 acting for Amilco]'s phone NKM009: *'When you did the deal to acquire the product*. [Aspen Senior Executive 2] *and you decided to deal direct with Tiofqrma* [sic] *and froze me out*. […] *Despite this I will try to speak to* [Tiofarma Employee 1] *and call you back. Tonight I am at a dinner so will try call him tomorrow'.*

[312] See for instance, Document FLC4897, page 41, line 18 to page 42, line 3, Transcript of interview with [Aspen Senior Executive 2] on 12 April 2018 and Document FLC2074.2 Tiofarma's response to Question 18.a.iii of the ACM's request for information dated 10 October 2017. The initial offer made by Amilco to Aspen is referred to in an email from [Tiofarma Employee 1] to [Aspen Senior Executive 2] of 19 September 2016 setting out the justification underpinning their negotiating position on price, which is introduced by this statement: '*We believe the offer initially made to you through our representative is a fair offer*.' Document FLC1143.321, email chain between [Aspen Senior Executive 2], [Aspen Senior Executive 1] and [Tiofarma Employee 1] between 15 September and 20 September 2016. In interview, [Tiofarma Employee 1] explained that [Person 1 acting for Amilco] '*might*' have given him a '*ballpark figure*' of about '[✂]', or a calculation method resulting in that figure, as

in the negotiations, [Tiofarma Employee 1] used the initial parameters set out in [Person 1 acting for Amilco]'s email of 6 September as the basis for the price being asked, and kept [Person 1 acting for Amilco] informed at every step of his discussions with Aspen.[313] Tiofarma explained to the CMA that, as Ambient Storage Fludrocortisone ultimately belonged to Amilco, *'*[i]*t was not a matter for Tiofarma to decide how to dispose of the asset*s.'[314]

4.145. On 19 October, following around one month of negotiation,[315] Tiofarma and Aspen entered into the SAA,[316] with a retroactive implementation date of 1 October 2016. The key terms of the SAA included:

(a) Under Clause 4 of the SAA, Tiofarma agreed to sell all rights in Ambient Storage Fludrocortisone MAs, and associated data, with effect from 1 October 2016;

(b) Under a non-compete clause (Clause 8), Tiofarma undertook for a period of five years not to 'directly or indirectly, manufacture, distribute, market or sell any product containing fludrocortisone in solid oral dosage form with similar therapeutic indications to the Product [worldwide]', or to 'knowingly assist a third party' to do so.[317]

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a starting point for the negotiations (Document FLC4907, page 218, lines 14 to 19, Transcript of interview with [Tiofarma Employee 1] on 24 July 2018).

[313] Document FLC1143.321, email from [Tiofarma Employee 1] to [Person 1 acting for Amilco] dated 20 September 2016, forwarding an email that he sent to [Aspen Senior Executive 2] with calculations for a sale price of [✂]. See also Document FLC1143.47, email from [Tiofarma Employee 1] to [Aspen Senior Executive 1] dated 26 September 2016, in which [Tiofarma Employee 1] said: '*Before sending you a proposal based on our discussion there is one person I would like to consult. Please give me another 24 hours'.* This email was forwarded by [Tiofarma Employee 1] to [Person 1 acting for Amilco]. Document FLC3465, email from [Aspen Senior Executive 2] to [Tiofarma Employee 1] dated 5 October 2016 attaching the draft SAA. This email was forwarded to [Person 1 acting for Amilco] with the comment: '*sorry for the hour. Didn't have access to email any earlier.* […] *Haven't read it myself yet, but will right now*'. Document FLC3466, email from [Tiofarma Employee 1] to [Person 1 acting for Amilco] dated 9 October 2016 enclosing a draft SAA with the following comment: *'*[…] *I don't think either of us would feel comfortable if I wouldn't. Please find enclosed the version I want to send to* [Aspen Senior Executive 2] *tomorrow at the end of the morning.'*

[314] Document FLC2074.2, Tiofarma's response to Question 18.b of the ACM's request for information dated 10 October 2017. See also response to Question 18.a.ii where Tiofarma explained that it was Amilco who directed Tiofarma to sell the rights over Ambient Storage Fludrocortisone.

[315] After Aspen initially tried to negotiate the price down, Tiofarma responded that it would consider other options for the sale of the MAs. Document FLC1143.321, email from [Tiofarma Employee 1] to [Aspen Senior Executive 2] dated 17 September 2016. However, the evidence shows that no other options were pursued, with [Tiofarma Employee 1] not following through any approaches by any companies expressing an interest in supplying Ambient Storage Fludrocortisone (see Section 4.E)

[316] Document FLC0344.6, Sale of Assets Agreement between Tiofarma BV and Aspen Global Incorporated, dated 19 October 2016.

[317] The restrictions on Tiofarma set out in the SAA were worldwide, and therefore represented a territorial extension of the corresponding terms of the SDA, which applied only to sales in the UK. The Product refers to '*fludrocortisone (for human use)*' and refers to the two UK MAs held by Tiofarma under PL numbers 17299/0001 and 17299/0002.

4.146. Aspen agreed to pay a purchase price of £[✂] or €[✂] (to be adjusted to take into account fluctuations in the exchange rate). This price was equivalent to the profit share element of the SDA that would have been paid by Aspen to Amilco over the remaining SDA period of 29 months, assuming that volumes and prices would remain at the level expected under the SDA (ie [✂] packs per month, a List Price of £30 per pack and a wholesale discount of [✂]%), after the application of a discount for upfront payment.[318] Effectively therefore, Aspen paid the outstanding monthly profit share element under the SDA in a single lump sum, a point confirmed in an internal Board paper of Aspen dated 12 October 2016.[319]

4.147. On 24 October 2016, Aspen made a payment of €[✂][320] to Tiofarma for the purchase of the MAs for Ambient Storage Fludrocortisone under the SAA.[321] On 21 December 2016, as agreed with Amilco,[322] Tiofarma transferred €[✂] to [✂].[323] [Person 1 acting for Amilco] explained that the proceeds went to this individual by virtue of '*an agreement* [✂]'.[324] Tiofarma explained that it retained only €[✂] to cover the costs it incurred in relation to the MA applications and the negotiation of the sale of the MAs.[325]

4.148. While the transfer of the MAs was effective as from 1 October 2016, these were only formally transferred to Aspen following approval from the MHRA in January 2017.

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[318] The fact that the SAA is based on the payments made under the SDA is also confirmed by later correspondence. In an email from [Aspen Senior Executive 2] to [Tiofarma Employee 1] dated 6 December 2016, [Aspen Senior Executive 2] noted that the purchase price paid under the SAA reflected Amilco's profit share element from October 2016 and therefore Aspen is entitled not to pay the profit share element in relation to volume purchased in advance for sale after October 2016. (see Document FLC1143.79, email chain from [Aspen Senior Executive 2] to [Tiofarma Employee 1] dated 15 November to 6 December 2016).

[319] Document FLE0456, paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016: '*This valuation is essentially the discounted value of the remaining 30% profit share Aspen is assumed to have paid over the remaining period of the initial term*'.

[320] The purchase price was reduced following fluctuations in the currency exchange, as per the contractual mechanism set out in the SAA.

[321] Document FLC2074.2, Tiofarma's response to Question 18.g of the ACM's request for information dated 10 October 2017. See also Document FLE2265, email chain between [Tiofarma Employee 1], [Aspen Employee 12] and others between 19 October and 24 October 2016.

[322] [Person 1 acting for Amilco] explained that, in advance of the negotiation with Aspen, he agreed with Tiofarma that [✂] would be the beneficiary of any revenues that would be generated by the sale of the MA. Document FLC1666.2, page 104, lines 24 to 26, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017. Document FLC1982, page 19, line 22, to page 23, line 4, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.

[323] [✂]. See Document FLC2088, [✂].

[324] Document FLC1666.2, page 109, lines 14 to 15, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017.

[325] Document FLC2074.2, Tiofarma's response to question 18.g of the ACM's request for information dated 10 October 2017.

4.149. Tiofarma and Aspen also entered into a new five-year Supply Agreement on 17 October 2016,[326] with a starting date of 1 October 2016. Under the new Supply Agreement, the supply price (ie €[✂] until March 2019 and €[✂] thereafter) did not include any profit share element (as this had been paid through the purchase price, as discussed below) nor any mechanism requiring Aspen to sell minimum quantities of Ambient Storage Fludrocortisone.

E. Third parties expressed an interest in MAs held by Tiofarma for Ambient Storage Fludrocortisone

4.150. Contemporaneous evidence shows that at least eight generic pharmaceutical companies approached Tiofarma between November 2015 and October 2016 to express their interest in partnering with Tiofarma to distribute Ambient Storage Fludrocortisone in the UK through various business models. Tiofarma, which communicated these approaches to [Person 1 acting for Amilco] in most cases, did not take up any of these partnership offers. These approaches are summarised below.

4.151. Tiofarma rejected or did not respond to approaches relating to Ambient Storage Fludrocortisone from the following two companies prior to the SDA:

(a) [Company 1],[327] on 11 November 2015[328] (two days after Tiofarma was granted its MA for Ambient Storage Fludrocortisone – information that would be publicly available); and

(b) [Company 2], On 16 November 2015[329] (a week after Tiofarma had obtained the MA for Ambient Storage Fludrocortisone). A call was arranged for 20 November 2015 and, in the meantime, [Tiofarma Employee 1] forwarded the email correspondence with [✂] of [Company 2] to [Person 1 acting for Amilco].[330]

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[326] Document FLC0344.5, Supply Agreement between Tiofarma BV and Aspen Global Incorporated, dated 17 October 2016.
[327] [Company 1] is a company with expertise in manufacturing, batch release, logistics and distribution in the UK pharmaceutical industry. See Document PD0022, [✂].
[328] Document FLC3225 (see English translation in Document FLC2837), email from [✂] to [Tiofarma Employee 4] ([✂]) dated 11 November 2015. Document FLC3225 (see English translation in Document FLC2837), email from [Tiofarma Employee 2] to [Tiofarma Employee 4] dated 12 November 2015.
[329] At that time, [Company 2] was apparently unaware that Amilco held the beneficial rights to the product underlying Tiofarma's MA. Document FLC1143.2, Email chain from [✂] to [Tiofarma Employee 1] dated 16 to 17 November 2015.
[330] Document FLC1143.2, Email from [Tiofarma Employee 1] to [Person 1 acting for Amilco] on 17 November 2015 headed *'Fludrocortisone'*. [Company 2] told the CMA that '[✂] *had a telephone call with* [Tiofarma Employee 1] *on 20 November 2015. During this call, it was made clear that Tiofarma would not be able to enter*

4.152. Tiofarma rejected or did not respond to approaches relating to Ambient Storage Fludrocortisone from the following five individuals and companies while the SDA was in effect (ie during the period from 1 March to 31 September 2016):

(a) [Pharmaceutical Operator], in March 2016;[331]

(b) [Company 3],[332] in April 2016;[333]

(c) [Company 4],[334] in May 2016;[335]

(d) [Company 5],[336] in August 2016;[337] and

(e) [Company 2], for a second time, in September 2016[338] (around the time Tiofarma was granted its second, duplicate, MA for Ambient Storage Fludrocortisone – information that would be publicly available).

4.153. Tiofarma rejected or did not respond to approaches relating to Ambient Storage Fludrocortisone from the following two companies after the effective date of the SAA (ie 1 October 2016):

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into an agreement to supply [Company 2] *with Fludrocortisone in the UK. This was because Tiofarma had, or was going to, enter into an agreement to manufacture Fludrocortisone for a third party, apparently as part of a wider European arrangement.* [✂] *believes that* [Tiofarma Employee 1] *stated during the call that this third party was Aspen*.' Document FLC2045, [Company 2] response to question 1 a (i) and (ii), of the CMA Section 26 notice dated 7 June 2018.

[331] Document FLC3486, email chain from [Pharmaceutical Operator] to [Tiofarma Employee 1] dated 8 to17 March 2016. Document FLC3481, email from [Tiofarma Employee 1] to [Person 1 acting for Amilco] dated 8 March 2016. Document FLC3486, email from [Tiofarma Employee 1] to [Pharmaceutical Operator] dated 17 March 2016.

[332] [Company 3] is a privately owned British pharmaceutical company. See Document PD0045, [✂].

[333] Document FLC3332, email from [Tiofarma Employee 2] to [Person 2 acting for Amilco] dated 14 April 2016.

[334] [Company 4] is a [✂] generic pharmaceutical company with a UK presence and active in the licensing and marketing of products from third parties. It specialises in the marketing and supply of generic pharmaceutical products through all major wholesale, retail and secondary care channels. See Document PD0023, [✂].

[335]Document FLC3344, email chain from [✂] ([Company 4]'s [✂]) to [Tiofarma Employee 1] dated 31 May 2016, and [Tiofarma Employee 1] to [Person 1 acting for Amilco], dated 31 May 2016. Document FLC1886, [Company 4]'s response to questions 1a of the CMA's section 26 notice dated 23 May 2018.

[336] [Company 5], [✂]. It holds a licence to parallel import Fludrocortisone Acetate Tablets. [✂]. See Document PD0024, [✂].

[337] Document FLC1868, [Company 5]'s response to questions 1a, of the CMA's section 26 notice dated 17 May 2018, email from [✂] to [Tiofarma Employee 2] dated 11 August 2016. See also, Document FLC2770 (see English translation in Document FLC2770.1), email chain between [✂], [Tiofarma Employee 2] and [Tiofarma Employee 1] dated 11 August 2016. The email was forwarded to [Person 1 acting for Amilco] on the same date.

[338] Document FLC3397 email dated 26 September 2016 from [✂] to [Tiofarma Employee 1] and related email chain; Document FLC1143, Amilco's response to question 16, of the CMA's section 26 notice dated 12 February 2018. See also Document FLC2045 [Company 2]'s response to question 2 of the CMA's section 26 notice dated 7 June 2018.

(a) [Company 6],[339] on 17 October 2016;[340] and

(b) [Company 7],[341] on 21 October 2016.[342]

4.154. Although the exact form of the relationship between Tiofarma, Amilco and Aspen changed over the course of the period spanning the SDA and the SAA, the relationship between the Parties remained in place, and approaches from third parties were not pursued. In what follows, the pricing of Fludrocortisone over that period is considered in further detail.

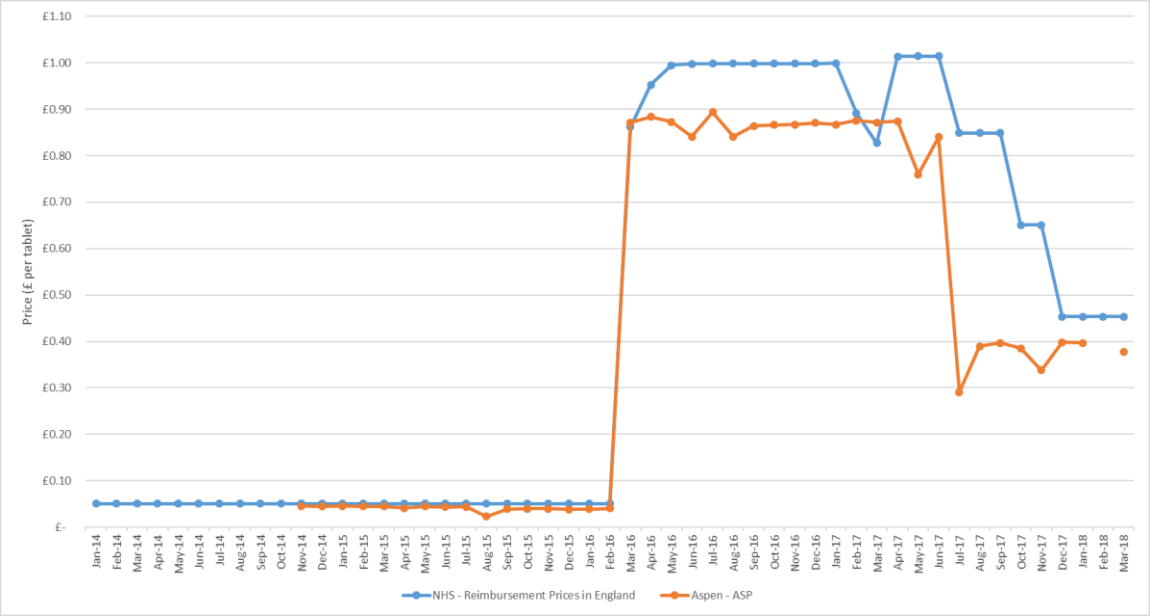
F. Overview of the pricing, cost, volume and revenues related to the supply of Fludrocortisone Acetate Tablets in the UK from 2014 to 2018

I. Aspen's pricing of Fludrocortisone Acetate Tablets in the UK and its impact on the NHS England Reimbursement Price

4.155. Figure 5 sets out, for Fludrocortisone Acetate Tablets in the UK from January 2014 to March 2018, Aspen's monthly Average Selling Price ('**ASP'**) per tablet, and the monthly NHS England Reimbursement Price.

[339] [Company 6] is a privately-owned British company offering a range of medicines, medical devices, diagnostics and OTC products. See Document PD0025, [✂].
[340] Document FLC3469, Email chain from [✂] to [Tiofarma Employee 2] and [Tiofarma Employee 1] dated 17 and 18 October 2016.
[341] [✂]. See Document PD0031, [✂].
[342] Document FLC3485, email chain from [✂] to [Tiofarma Employee 1] dated 21 and 22 October 2016.

Figure 5: ASP and NHS England Reimbursement Price of Aspen's Fludrocortisone Acetate Tablets (on a monthly basis, 2014-2018)



Source: Document FLC1834 and Document FLC1836, Aspen's response to question 1 of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496); Document PD0012, PCA data for England for months January 2014 to March 2018.
Notes:
[1] NHS England Reimbursement Prices are based on NHS England's PCA data for the period January 2014 to March 2018.
[2] 2018 data:
For Aspen, the data relate to the months January to March only.
For the NHS, the data relate to months January to March from England.
[3] Aspen monthly ASP for February 2018 is excluded from the graph as Aspen made no sales. Aspen noted: [✂]. Document FLC1836, Aspen's response to question 1 of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496).

4.156. Since November 2014, the NHS England Reimbursement Price for Fludrocortisone Acetate Tablets has reflected Aspen's List Price:

(a) Until August 2016, Fludrocortisone Acetate Tablets were listed in Category C of the Drug Tariff (those drugs not readily available as a generic, whose List Price is therefore based on a particular proprietary product – see further paragraph 3.64(a)). As a result, the Drug Tariff Price was based on Aspen's List Price, Aspen being the only supplier of Fludrocortisone Acetate Tablets in the UK.

(b) For the period from September 2016 to present, during which time Fludrocortisone Acetate has been in Category A, the Drug Tariff Price of Fludrocortisone Acetate Tablets has been based on the weighted average

of the List Prices of AAH and Alliance.[343] These have in turn been based solely on Fludrocortisone Acetate Tablets supplied by Aspen.[344]

(c) As noted above at paragraph 3.63, the NHS England Reimbursement Price is the Drug Tariff Price readjusted for any clawback discount[345] or concessions.[346]

a. Prices in the period prior to the SDA

4.157. From the time that Aspen acquired Florinef from BMS, until it began supplying Ambient Storage Fludrocortisone in March 2016, Aspen's monthly ASP was consistently around £0.04 per tablet. The NHS England Reimbursement Price during this time mirrored Aspen's List Price at £0.05 per tablet.[347]

b. Prices during the term of the SDA

4.158. Between March 2016 and October 2016, Aspen supplied Ambient Storage Fludrocortisone under the terms of the SDA at a List Price of £30 per pack (£1.00 per tablet) and Amilco received a commission of £[✂] per pack.[348]

4.159. The key price trends during the term of the SDA, as shown in Figure 5, were as follows:

(a) The NHS England Reimbursement Price per tablet rose to £1.00 by June 2016 reflecting the new List Price – an increase of more than 1,800% relative to the NHS England Reimbursement Price of Florinef until the end of February 2016.

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[343] Document FLC0017, NHSBSA's response to questions 1 and 4, of the CMA's information request dated 6 April 2017.
[344] Document FLC0046 and its attachment Document FLC0046.1, NHSBSA's response to the CMA's information request dated 7 June 2017; the Excel file supplied by the NHSBSA shows that the Drug Tariff calculation from September 2016 to May 2017 was based on a 30-pack supplied by AAH and Alliance, ie Ambient Storage Fludrocortisone supplied by Aspen, with one exception during this period: in March and April 2017, the calculation for the Drug Tariff Price was erroneously based in part on a parallel imported 100-pack of Fludrocortisone Acetate Tablets supplied by a wholesaler whose List Price was used for the Drug Tariff calculation. See also Document FLC0017, NHSBSA's response to question 4, of the CMA's information request of 6 April 2017.
[345] The clawback was designed to share with the NHS the profits pharmacies can make by purchasing drugs at below the price at which they are reimbursed. See *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 33.
[346] Concessions are variations of the Drug Tariff agreed between the DHSC and the PSNC, usually when pharmacies would make a loss on the product if reimbursed at the Drug Tariff Price.
[347] Document CMA002, CMA Fludro File.
[348] In November 2016, Aspen claimed money back in relation to stocks of Fludrocortisone Acetate Tablets acquired prior to October 2016 but for sale post October 2016. This led Amilco to issuing a credit note to Aspen of £[✂] in December 2016. See Document FLC1143.392, email from [Tiofarma Employee 1] to [Person 2 acting for Amilco] dated 16 December 2016.

(b) Similarly, Aspen's monthly ASP per tablet, reflecting the wholesaler price, rose to £0.87 per tablet in March 2016, reaching a peak of £0.89 per tablet in July 2016 – a price increase of 1,800% relative to the previous ASP of Florinef.

4.160. The average difference between Aspen's ASP and the NHS England Reimbursement Price (which is broadly equivalent to wholesaler discount) varied from month to month, ranging between [✂]% and [✂]% (although this had only a very minor impact on Aspen's total turnover for the sale of the product).[349] Despite these variations, the reconciliation mechanism set out in Clause 15.2 of the SDA was not used.[350]

c. Prices following the SDA

4.161. By entering into the SAA, the SDA was terminated. Aspen's List Price initially remained unchanged at £30 per pack (£1 per tablet), the NHS England Reimbursement Price remained around £1.00 per tablet,[351] and Aspen's monthly ASP remained around £0.87 per tablet,[352] as shown in Figure 5.

4.162. In April 2017, a few days after the European press reported on Aspen's attempt to impose large price increases in relation to certain cancer drugs,[353] [Aspen Senior Executive 1] asked [Aspen Employee 3] to reconsider Aspen's pricing strategy for Fludrocortisone Acetate Tablets in the UK.[354] Aspen's [✂] management instructed [External Consultant 1] to make a price recommendation for Ambient Storage Fludrocortisone '*in light of his experience, inter alia, of excessive pricing investigations'*, specifically

[349] Document CMA002, CMA Fludro File.
[350] Document FLE0225 and Document FLE0226 (signature page), Supply and Distribution Agreement between Tiofarma B.V., Aspen Global Incorporated and Amilco Limited, with an effective date of 1 March 2016. See paragraph 4.122, which describes the reconciliation mechanism applicable for wholesaler discounts of [✂]% or more.
[351] Except for February and March when it dipped below £0.90 per tablet. The NHSBSA explained that the fall in the NHS England Reimbursement Price in February and March 2017 was due to a parallel import product supplied by a pharmaceutical wholesaler erroneously having been taken into account for the purpose of the Drug Tariff calculation. See Document FLC0017, NHSBSA's response to question 4, of the CMA's information request dated 19 April 2017, 10:52 (CMA's information request provided in Document FLC0016, email chain between [CMA] and [NHSBSA], dated 6 and 19 April 2017).
[352] It fell to £0.76 per tablet in May 2017 before returning to £0.84 per tablet in June 2017.
[353] See Document PD0026, The Times article – Aspen's attempt to impose price increase in relation to certain cancer drugs, https://www.thetimes.co.uk/article/drug-giant-s-secret-plan-to-destroy-cancer-medicine-75rg6wt2n and see Aspen's official statement in response in Document PD0027, Aspen's statement in response to press reports of 14 and 15 April 2017, https://www.aspenpharma.com/2017/04/18/statement-in-response-to-press-reports-of-14-and-15-april-2017/ .
[354] Document FLE0593, email from [Aspen Employee 3] to [Aspen Employee 1] dated 21 April 2017 and Document FLE0599, electronic messaging between [Aspen Employee 3] and [Aspen Employee 1] dated 21 April 2017.

considering whether it would meet the CMA's cost-plus methodology.[355] Aspen's internal communication shows that its strategy was to '*justify'* the higher price possible under this methodology.[356]

4.163. On 26 April 2017, [External Consultant 1] sent Aspen his calculations for a price for Ambient Storage Fludrocortisone that purported to follow the CMA's methodology when assessing excessive pricing cases (ie a '*cost-plus analysis*', as applied in the CMA's *Phenytoin* decision).[357] Using this methodology, [External Consultant 1] calculated a '*CMA price*' (corresponding to Aspen's ASP) that would be less than 25% '*excessive'* based on a CMA methodology to assess pricing.[358] Having taken into consideration Aspen's reduced cost of goods following the purchase of the MAs held by Tiofarma, but also the need to amortise the purchase price,[359] [External Consultant 1] presented an '*aggressive case*' (where the SAA price was amortized over a period of three years) and a '*conservative case*' (where the SAA case was amortised over five years). His calculations provided '*CMA'* prices for 30 tablets of £[✂] and £[✂] (conservative and aggressive case respectively) for 2016/2017 and of £[✂] and £[✂] for 2017/2018.[360]

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[355] Document FLC1665, page 17, lines 14 to 17, Transcript of interview with [External Consultant 1] on 6 March 2018: '*Aspen asking me to look at the pricing of Fludrocortisone, and in particular, whether under the CMA's method of cost plus of which there is extensive record of my disagreement, but under your methodologies the price was above cost plus*'. See also Document FLC1531, [External Consultant 1]'s response (Chronology of events), Annex 1, to the CMA's section 26 notice dated 19 April 2018.

[356] [Aspen Employee 1] texted [Aspen Employee 3], noting that a higher price could be justified if the value transfer of the MAs was for the UK only: '*It is important that the full value was only for the UK MA transfer. We can then* ***justify a higher price point'.*** Document FLE0866, text message, Chats Tab, from [Aspen Employee 1] to [Aspen Employee 3] dated 25 April 2017.

[357] Document PD0032, Phenytoin sodium capsules: suspected unfair pricing https://www.gov.uk/cma-cases/investigation-into-the-supply-of-pharmaceutical-products.

[358] Document FLC1530, [External Consultant 1]'s response to question 3a, of the CMA's section 26 notice dated 19 April 2018 and Document FLC1533 (Fludrocortisone [Healthcare Business Consultants] *workings).*

[359] In an email of 17 May 2017, [Aspen Employee 3] explained his colleagues that the process undertaken to secure fair pricing can be summarized as follows: '*We have engaged* [External Consultant 1] *from* [Healthcare Business Consultants]*, who is well respected in the UK and both utilized by pharma companies for preparation of pricing dossiers to the DoH and by authorities (ie for expert opinion).*[…] *Through* [External Consultant 1]*, we have prepared the new pricing considering: Market conditions (medical criticalness, target audience, demand outlook, competition), Level of innovation (linking to the fact that the new Fludro does not require cold chain storage* […]*) COGS, Factored in that margin to Tiopharm* [sic] *falls out post acquisition and Acquisition price amortized over 3 years'*. (see Document FLE1067, email from [Aspen Employee 3] to [Aspen Senior Executive 4], [Aspen Senior Executive 1], [Aspen Senior Executive 2] and others dated 17 May 2017).

[360] Document FLC1530, [External Consultant 1]'s response to question 3a, of the CMA's section 26 notice dated 19 April 2018 and Document FLC1533 (*Fludrocortisone* [Healthcare Business Consultants] *workings)*. In a version circulated internally by Aspen, £[✂] became £[✂] (see Document FLC0464, [Healthcare Business Consultants] *recommended price of Fludro post Aspen acquisition* and Document FLC0463, email from [Aspen Employee 3] to [Aspen Senior Executive 4], [Aspen Senior Executive 1], [Aspen Senior Executive 2] and others, dated 17 May 2017). [External Consultant 1]'s calculations also show List Prices, corresponding to the 'CMA price' plus the wholesaler margin of [✂]%.

4.164. In May 2017, Aspen decreased the List Price of Fludrocortisone Acetate Tablets to £13.60 per pack of 30 tablets (approximately £0.45 per tablet).[361] This decision started to take effect from July 2017, when the ASP initially fell to £0.29 per tablet, before stabilising at around to £0.39 per tablet in August 2017, a price fall of 54% relative to the ASP of £0.84 in June 2017, and it largely remained at this level until March 2018[362] This lower price represented a price increase of around 800%, compared with the price of Florinef prior to the SDA.

II. The costs of supplying Fludrocortisone Acetate Tablets in the UK

4.165. Aspen submitted that '*Using Haupt as a benchmark, the direct costs of production of Cold Storage Fludrocortisone would be approximately €*[✂] *for a bottle of 100 tablets and the indirect costs of production, including freight and logistics would be approximately €*[✂] *per bottle of 100 (using Aspen's own freight and logistics costs as a benchmark)*.'[363]

4.166. This was not significantly different from the costs of Ambient Storage Fludrocortisone. According to Aspen, '*Using Tiofarma as a benchmark the direct costs of production would be approximately €*[✂] *per bottle of 30 tablets and the indirect costs of production, including freight and logistics would be approximately €*[✂] *for a bottle of 30*.'[364]

4.167. The direct and indirect costs of the two products are set out below. The prices below have been converted using an exchange rate of £1= €1.35, as included in the SDA.

Figure 6: Costs of Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone

Product	**Cold Storage Fludrocortisone**	**Ambient Storage Fludrocortisone**	
Number of tablets	100 tablets	30 tablets	100 tablet equivalents

[361] Document PD0047, NHSBSA - Amendments to the Drug Tariff April 2019 https://www.nhsbsa.nhs.uk/sites/default/files/2019-03/Drug%20Tariff%20April%202019.pdf .
[362] With the exception of November 2017, when it stood at £0.34, and in March 2018, when it stood at £0.38 per tablet.
[363] Document FLC1834, Aspen's response to question 31 of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496). Until the end of February 2016, Aspen obtained supplies of Cold Storage Fludrocortisone for sale in the UK from Haupt Pharma AG, a German manufacturer. The benchmark direct cost of production stated by Aspen is the supply cost paid to Haupt Pharma AG per pack of 100 tablets.
[364] Document FLC1834, Aspen's response to question 31 of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496). The Tiofarma benchmark cost of production stated by Aspen is the *'fully absorbed cost of goods per IFRS'* of EUR[✂] per pack of 30 tablets as per the SDA.

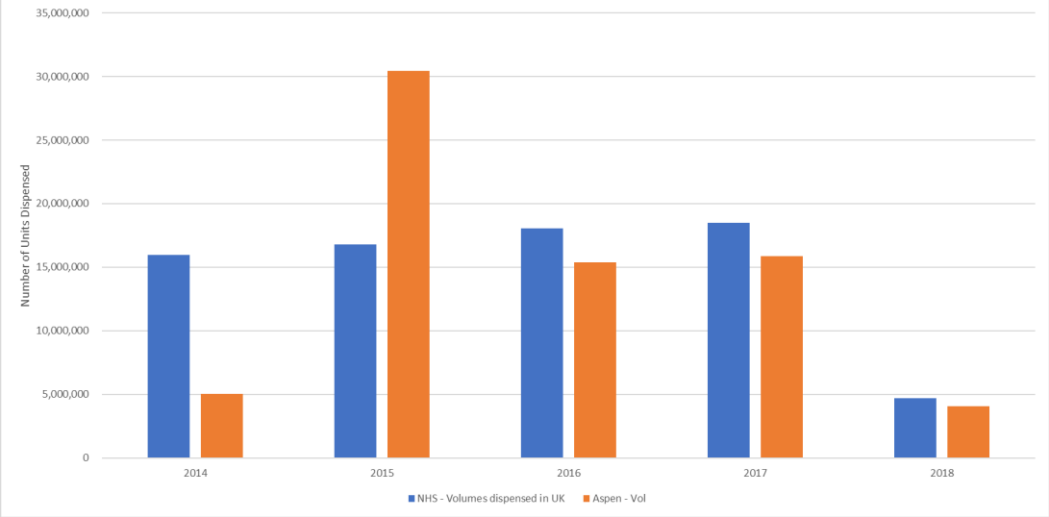
Direct Cost £	[✂]	[✂]	[✂]
Indirect costs (including freight and logistics) £	[✂]	[✂]	[✂]
Total Cost of Production £	[✂]	[✂]	[✂]
Cost of Production per tablet £	[✂]	[✂]	[✂]
Price per tablet	0.0505	1.000	1.000

4.168. Therefore, the price differential of over 1,800% between Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone cannot be explained by a significant increase in costs for producing the ambient product given the increase in costs was only [✂]%.

III. The volume of Fludrocortisone Acetate Tablets supplied in the UK

4.169. Figure 7 shows Aspen's tablet sales between January 2014 and March 2018 compared to NHS prescription cost analysis data ('**PCA data'**) on tablets dispensed for the same period. Given that Aspen only began selling Fludrocortisone Acetate Tablets towards the end of 2014, the CMA focuses its analysis on the period from 2015.

Figure 7: Annual volumes of Fludrocortisone Acetate Tablets (2014-2018)



Source: Document FLC1834 and Document FLC1836, Aspen's response to question 1, of the CMA's section 26 notice dated 19 April 2018 (s.26 notice is provided in Document FLC1496); Document PD0012, PCA data for England, Document PD0028, PCA data for Wales; Document PD0029, PCA data for Northern Ireland for months January 2014 to March 2018; Document PD0030, PCA data for Scotland for financial years 2014/15 to 2017/18.
Notes:
[1] 2014 data: Aspen data relate to months November 2014 and December 2014 only.
[2] 2018 data:
For Aspen, the data relate to the months January to March only.
For the NHS, the data relate to months January to March.

d. Aspen's sales in 2015

4.170. As shown in Figure 7, Aspen's total tablet sales in 2015 were more than 30 million tablets. The total number of tablets dispensed by the NHS in the UK in 2015 was approximately 16.8 million – this is roughly half the total number of tablets sold by Aspen for 2015. The additional sales from Aspen appear likely to relate to veterinary use[365] and exports.[366]

e. Aspen's sales in 2016

4.171. As shown in Figure 7, following the replacement of Cold Storage Fludrocortisone with Ambient Storage Fludrocortisone and the significant price increase effected by Aspen, the total number of tablets sold by Aspen in 2016 fell by roughly 50 per cent from 2015, to just under 15.4 million tablets. As the volumes dispensed by the NHS remained relatively constant (see paragraph 4.174 below), this reduction is likely due in part to falling sales to other customer groups, such as veterinary users and exports.

4.172. Estimates from Dechra indicate that in 2016, the number of Fludrocortisone Acetate Tablets used for veterinary supply fell from 6.6 million to 2.6 million (see paragraph 3.34).

4.173. In relation to the volume of Fludrocortisone Acetate Tablets exported from the UK, the CMA has attempted to obtain data on exports from IQVIA. This indicated that sell in units (packs sold from wholesalers to pharmacies) exceeded sell out units (packs dispensed by pharmacies) in most months until October 2016 and has done so again since September 2017. However, it is not clear what proportion of this is being sold for export compared to other explanations, such as stockpiling and resale to other pharmacies.[367] Therefore, the CMA has not been able reliably to identify the extent of export sales.

4.174. As shown in Figure 7, the total number of tablets dispensed by the NHS remained stable in 2016 at roughly 18.1 million tablets. In contrast to previous years, the total number of tablets dispensed by the NHS was higher than

[365] Around 6.6 million Fludrocortisone Acetate Tablets were used for veterinary supply in 2015, see paragraph 3.34.
[366] See paragraphs 4.172 to 4.173.
[367] Document FLC3672, email from [IQVIA] to [CMA] and Document FLC3673, spreadsheet provided to the CMA by IQVIA on 17 September 2018. IQVIA identified relatively few 'edits' to its data for exports in May and August 2015 and February 2018. However, this only identifies abnormally large usage at a pharmacy level (Document FLC4844A, email from [IQVIA] to [CMA] dated 20 November 2018).

Aspen's sales volumes. The difference, accounted for by parallel imports (see Figure 8), amounted to approximately 2.7 million tablets in 2016.

f. Aspen's sales in 2017

4.175. As shown in Figure 7, the total number of tablets sold by Aspen in 2017 remained stable at roughly 15.9 million tablets vis-à-vis 2016, and the total number of tablets dispensed by the NHS continued to remain stable in 2017, at roughly 18.5 million tablets.[368] The total number of tablets dispensed by the NHS was again higher than Aspen's sales volumes. The difference, accounted for by parallel imports (see Figure 8), amounted to approximately 2.6 million tablets.

4.176. The significant drop in Aspen's volumes in 2016 therefore did not continue in 2017, and was a one-off event as other customer groups than NHS patients (such as veterinary users) switched away from the product as a result of Aspen's higher prices and the introduction of a fludrocortisone acetate drug licensed for veterinary users. This option was not available to the NHS as Fludrocortisone Acetate Tablets are an essential medicine and Aspen and Tiofarma (and after the SAA only Aspen) were the only holders of MAs for this product in the UK.

IV. Aspen's revenues

g. Before the SDA

4.177. In the 12 months prior to the SDA, Aspen generated revenues of £1.3 million from the sale of over 30 million tablets of Cold Storage Fludrocortisone.[369]

h. During the period of the SDA and thereafter

4.178. Over the period of the SDA, between March and September 2016, Aspen achieved a total turnover for the sale of Ambient Storage Fludrocortisone in the UK of £6,615,000, ie approximately £1,000,000 per month (compared to c. £1,300,000 total annual turnover for the sale of Cold Storage Fludrocortisone

[368] In 2017, non-NHS volumes appeared to remain low. The number of Fludrocortisone Acetate Tablets for veterinary use in 2017 is estimated at 240,000 (see paragraph 3.34).
[369] See paragraph 4.170.

in the UK for the twelve months prior to the SDA).[370] This was despite the 50% drop in volumes discussed above.

4.179. During the 12 months following the entry into effect of the SDA (ie from March 2016), Aspen's annual revenues increased to £11.2 million due to the price increase.[371] Following the July 2017 price reduction, revenues decreased to c. £6.5-7.5 million per annum, still significantly higher than the pre-SDA levels.

V. The payments made by Aspen to Amilco under the SDA and by Amilco to Tiofarma

4.180. Amilco received £[✂] from Aspen under the SDA between March and October 2016 corresponding to the following invoices:

(a) 4 March 2016: £[✂];

(b) 5 April 2016: £[✂];

(c) 25 May 2016: £[✂];

(d) 27 September 2016: £[✂];

(e) 18 October 2016: £[✂] (currency fluctuation, as per the SDA); and

(f) 18 October 2016: £[✂] (currency fluctuation, as per the SDA).[372]

4.181. However, in December 2016, at Aspen's request, Amilco reimbursed Aspen £[✂] for the value of the order made by Tiofarma to Aspen in September

[370] Document FLC1834 and its attachment Document FLC1836 (Document 1), Aspen's response to Question 1 of the CMA' section 26 notice dated 19 April 2018. Turnover for the period of the SDA covers the period March-September 2016 (section 26 notice is provided in Document FLC1496). The turnover for the previous twelve months covers the period March 2015-February 2016.
[371] See paragraphs 4.170 to 4.175.
[372] Document FLC1143 and its attachment Document FLC1141 (Annex D), Amilco's response to question 25, of the CMA's section 26 notice dated 12 February 2018.

2016, deducted for the COGs.[373] This payment was requested by Aspen shortly after the implementation of the SAA [✂].[374]

4.182. Therefore, Amilco received £[0-5 million] from Aspen net of the stock adjustment.[375] Of this amount, it paid €[✂] to Tiofarma (see paragraph 4.183). This gave Amilco a net amount of approximately £[0-5] million under the SDA. In addition, [✂] received €[✂] (approximately £[✂] million at the exchange rate used in the SAA) from Tiofarma after that undertaking was paid the purchase price in the SAA by Aspen.[376]

4.183. Under the SDA, Tiofarma invoiced €[✂] to Amilco in relation to the COGs corresponding to the following invoices:

(a) 3 May 2016: [✂];

(b) 20 May 2016: [✂];

(c) 29 June 2016: [✂]; and

(d) 5 December 2016: [✂].[377]

G. Aspen's actions with respect to parallel imports of Cold Storage Fludrocortisone into the UK

4.184. Following entry into the SDA, Aspen regularly monitored parallel imports of Fludrocortisone Acetate Tablets into the UK. [378]

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[373] This amount corresponds to the price paid by Aspen for the [✂]. See Document FLC1143.257, email chain between [Aspen Senior Executive 2] and [Tiofarma Employee 1] dated 7 December to 20 December 2016. See also the invoice in Document FLC1143.258 and its attachment Document FLC1143.259, email from [Aspen Senior Executive 2] to [Tiofarma Employee 1], [Person 1 acting for Amilco] and [Person 2 acting for Amilco] dated 20 December 2016. Aspen initially requested Amilco to reimburse it for the stock available at Aspen in October 2016. See Document FLC1143.68, email chain between [Aspen Senior Executive 2], [Tiofarma Employee 1] and [Aspen Employee 5] dated 15 November to 17 November 2016. See also Document FLC1143.377, email from [Person 1 acting for Amilco] to [Tiofarma Employee 1] dated 17 November 2016 and Document FLC1143.79, email chain from [Aspen Senior Executive 2] to [Tiofarma Employee 1] dated 15 November to 6 December 2016.
[374] As part of the stock purchased under the SDA was expected to be used in the period after the completion of the SAA, it was included in the calculation of the purchase price of £[✂] million for the MA.
[375] As the Supply Price was set at £[✂], this level of payment corresponds to approximately [✂] tablets.
[376] See footnotes 322 and 323.
[377] Document FLC1143 and its attachment Document FLC1141 (Annex D), Amilco's response to question 25, of the CMA's section 26 notice dated 12 February 2018.
[378] See for instance: Document FLE0302, internal Aspen email chain dated 27 April 2016. See also Document FLE0305, email from [Aspen Employee 1] to [Aspen Senior Executive 2], [Aspen Employee 2], [Aspen Employee 3] and [Aspen Employee 10] dated 29 April 2016. Document FLE0317 and Document FLE0318, note prepared by [Aspen Employee 3] dated 3 May 2016 headed '*Europe CIS, Commercial Business Budget / 2016/2017 / Key take-aways from today's budget discussion'* and cover email of the same date from [Aspen Employee 3] to [Aspen Employee 10] and [Aspen Employee 2].

4.185. [Aspen Senior Executive 2] alerted [Person 1 acting for Amilco] to an apparent increase in parallel imports in April 2016, writing in an email:[379]

'We have started to see a number of parallel importations into the UK Can we possibly have a call to discuss the matter further'.

4.186. However, the minutes of a meeting between Aspen ([Aspen Employee 1] and [Consultant to Aspen]), Amilco ([Person 2 acting for Amilco]) and Tiofarma ([Tiofarma Employee 1]) on 1 July 2016 show that the level of parallel imports was below the 10% forecast:

'Initial assumption was that Parallel Imports would make up 10% of the total volume – but that was too high a level. Stock is coming in from the Netherlands @ Eur. 6 a pack. There are other sources of Florinef which are not under [Aspen Employee 1]*'s remit. Aspen will have more information on PI's over the next 6 months.'*[380]

4.187. In September 2016 [Aspen Employee 1] noted in an internal email, *'Our assumption of 10% of PI seems to be holding, but we are ever vigilant.'*[381]

4.188. The monitoring of parallel imports continued after the termination of the SDA.[382] Despite Aspen's attempts to control parallel imports of Florinef, [383] these continued to grow.[384]

[379] Document FLC1143.239, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 28 April 2016.
[380] Document FLC1143.26, Minutes of meeting held on 1 July 2016 between Aspen, Amilco and Tiofarma. See also Document FLE0377, email from [Person 2 acting for Amilco] to [Aspen Employee 1] and others at Aspen, [Tiofarma Employee 1], [Person 1 acting for Amilco] and [Person 3 acting for Amilco] dated 10 July 2016.
[381] Document FLE0402, email from [Aspen Employee 1] to [Aspen Employee 3], [Aspen Employee 2], [Aspen Employee 6] and [Aspen Senior Executive 2], dated 2 September 2016.
[382] Document FLE0528, email from [Aspen Employee 1] to Aspen employees dated 27 January 2017.
[383] See for instance: Document FLE0572, email from [Aspen Employee 14] to [Aspen Employee 25] dated 5 April 2017.
[384] Document FLE0532, email from [Consultant to Aspen] to [Aspen Employee 7] dated 6 February 2017: '*Notable is Fludrocortisone decrease as Pi bites*.'. See also Document FLE0541, email from [Aspen Employee 11] to [Aspen Employee 1] dated 13 February 2017: '*Fludro: …This is a constant worry for us to maintain the 38k/month. This was the 1st significant drop we have had since launch. PI is selling to retail at £17/pack of 30s versus our £30/pack. We cannot therefore equalise to this price if PIs is in sufficient quantities in the marketplace. We cannot see any significant changes in buying patterns from our other EU selling markets. Likely dutch pack is our best guess'.*

5. THE PARTIES ARE UNDERTAKINGS FOR THE PURPOSE OF COMPETITION LAW

5.1. For the reasons set out below, the CMA concludes that each of Aspen, Tiofarma and Amilco is an undertaking for the purposes of the Act and the TFEU.

A. Legal framework

5.2. The Chapter I prohibition and Article 101 TFEU apply to agreements between '*undertakings*'. The concept of an undertaking covers any entity engaged in an economic activity, regardless of the legal status of the entity or the way in which it is financed.[385] Economic activity has been defined as any activity *'of an industrial or commercial nature by offering goods and services on the market'*.[386] It is settled case law that: 'the term '*undertaking*' must be understood as designating an economic unit for the purpose of the subject-matter of the agreement in question even if in law that economic unit consists of several persons, natural or legal.[387]

B. Assessment

5.3. The CMA finds that each of Aspen, Tiofarma and Amilco was engaged in an economic activity and constitutes an undertaking for the purposes of the Act and the TFEU:

(a) Aspen supplied pharmaceutical products, including Fludrocortisone Acetate Tablets, to customers in the UK (see paragraphs 3.1 to 3.5).

(b) Amilco is a generics development intermediary; it specialises in providing advice and support for pharmaceutical companies seeking to obtain new generic product licences for the UK market (see paragraphs 3.6 to 3.13).

(c) Tiofarma manufactured a number of pharmaceutical products, including Fludrocortisone Acetate Tablets to Aspen, for sale in the UK (see paragraphs 3.14 to 3.17).

[385] T-117/07 and T-121/07 *Areva v* Commission, EU:C:2014:257, paragraph 124; see Case C-41/90 *Hofner and Elser v Macrotron* EU:C:1991:161, paragraph 21; Case C-205/03 P *FENIN* v *Commission* EU:C:2006:453, paragraph 25.
[386] Case C-118/85 *Commission v Italy*, EU:C:1987:283, paragraph 7.
[387] See (among other cases) C-516/15 *Akzo Nobel N.V. v Commission*, EU:C:2017:314, paragraph 48.

6. THE RELEVANT MARKET AND ASPEN'S POSITION ON THE MARKET

6.1. In this section, the CMA sets out:

(a) the market definition; and

(b) Aspen's position as the sole UK supplier of Fludrocortisone Acetate Tablets since November 2014.

A. Market definition

6.2. For the reasons set out below, the CMA concludes that the Relevant Market is the supply of Fludrocortisone Acetate Tablets in the UK, comprising both versions that have been authorised for supply for human use in the UK.[388]

I. Legal framework

6.3. Market definition is a key step in identifying the constraints acting on a supplier of a given product, including in identifying whether an undertaking has market power. The concept of the relevant market implies the existence of effective competition between the products forming part of it, which '*presupposes that there is a sufficient degree of interchangeability between all the products forming part of the same market in so far as a specific use of such products is concerned*'.[389]

6.4. Market definition is a tool to identify and define the boundaries of competition between undertakings. It is not an end in itself.[390] The purpose of defining the relevant market is '*to determine the competitive constraints on the product on the basis of which the market is defined*'.[391]

6.5. There are normally two dimensions to the definition of the relevant market: (i) a product dimension; and (ii) a geographic dimension. As such, the key question when assessing the relevant market is whether the products concerned are '*close enough*' substitutes to be sensibly regarded as being in the same market.[392]

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[388] This includes parallel imports.
[389] C-85/76 *Hoffman-La Roche v Commission*, EU:C:1979:36, paragraph 28.
[390] See, for example, *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 36, paragraph 90; and *European Commission Notice on the definition of the relevant market for the purposes of Community competition law*, OJ C 372, 9.12.1997, paragraphs 5 to 13.
[391] T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 174.
[392] OFT403 *Market definition* (December 2004), paragraph 2.5. A further possible dimension to market definition is time (paragraph 5.1).

6.6. According to the General Court, the test for defining the relevant product market is as follows:

'the relevant product market includes products or services which are substitutable or sufficiently interchangeable with the product or service in question, not only in terms of their objective characteristics, by virtue of which they are particularly suitable for satisfying the constant needs of consumers, but also in terms of the conditions of competition and/or the structure of supply and demand on the market in question'.[393]

6.7. The relevant product market '*is to be defined by reference to the facts in any given case, taking into account the whole economic context*'.[394] As the Competition Appeals Tribunal ('**CAT**')[395] has explained in the context of the Chapter II prohibition:

'Each case will depend on its own facts, and it is necessary to examine the particular circumstances in order to answer what, at the end of the day, are relatively straightforward questions: do the products concerned ***sufficiently compete with each other to be sensibly regarded as being in the same market? The key idea is that of a competitive constraint: do the other products alleged to form part of the same market act as a competitive constraint on the conduct of the allegedly dominant firm?'*** [396]

6.8. The process of defining a market typically begins by establishing the closest substitutes to the product that is the focus of the investigation ('**Focal Product**') followed by determining the scope of products or services that are interchangeable with the Focal Product.

6.9. Functional interchangeability or similarity of characteristics will not, in themselves, provide sufficient criteria to determine whether two products are demand substitutes because the responsiveness of customers to relative changes in price may be determined by other considerations as well.[397]

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[393] T-504/93 *Tiercé Ladbroke v Commission*, EU:T:1997:84, paragraph 81.
[394] *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 96.
[395] References to the CAT should be read as including reference to the Competition Commission Appeal Tribunal where appropriate. See section 12 of the Enterprise Act 2002.
[396] *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 97 (emphasis added).
[397] European Commission Notice *on the definition of the relevant market for the purposes of Community competition law*, OJ C 372, 9.12.1997, paragraph 36.

6.10. In this respect, the European Commission has repeatedly rejected the proposition that pharmaceutical products that are used to treat the same medical condition can necessarily be regarded as demand substitutes.

6.11. For example, in *AstraZeneca*, the European Commission noted that:

> *'In determining the functional substitutability of medicines it is not enough, for the purposes of product market definition, to state that different medicines are prescribed for the same general illness or disease'.*[398]

6.12. The key consideration is the extent to which different product types are capable of significantly constraining an undertaking's conduct:

> *'When products such as pharmaceutical products can be broadly used for the same purpose, but differ in terms of price, quality, consumer preferences or other significant attributes, the products are considered to be differentiated. Although differentiated products may 'compete' in some dimensions, a relevant market in competition cases should only include those products that are capable of significantly constraining an undertaking's behaviour and of preventing it from behaving independently of an effective competitive pressure'.*[399]

6.13. The competitive relationships and interactions between different products in pharmaceutical markets may differ from markets which face no, or lighter, regulation.[400] The General Court of the European Union ('**General Court**') has found that the pharmaceutical sector is '*atypical*' to the extent that the demand for prescription medicines is driven by prescribers (doctors) rather than consumers (patients). In so far as they determine doctors' choices, non-price factors, such as therapeutic use, therefore also constitute, alongside price-based indicators, a relevant factor for the purposes of market definition.[401] In *Servier*, the General Court found that when prescribing for treating the same condition, doctors have the choice between medicines, none of which is recognised or perceived as being superior to the others. Relevant factors will include their degree of therapeutic differentiation, their adequacy to the profile

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[398] Commission decision of 15 June 2005 in Case 37507 *AstraZeneca*, paragraph 381.
[399] Commission Decision of 15 June 2005 in Case 37507 *AstraZeneca*, paragraph 370.
[400] *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4. See also *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 97.
[401] T-321/05 *AstraZeneca*, EU:T:2010:266, paragraphs 183 to 187; T-691/14 *Servier and Others v Commission*, EU:T:2018:922 paragraph 1385. See also C-179/16 *Hoffmann-La Roche and others*, EU:C:2018:25, paragraph 65 : '*the relevant market for the purposes of the application of competition law is, in principle, capable of comprising medicinal products that may be used for the same therapeutic indications, since prescribing doctors are primarily guided by considerations of therapeutic appropriateness and the efficacy of medicines*'.

of the patients, the knowledge by the doctor of the different drugs or his personal experience and that of his patients, rather than being primarily a function of the respective cost of these treatments.[402]

6.14. In line with EU and UK jurisprudence, it is not necessary to reach a definitive view on market definition in order to determine whether there are agreements or concerted practices between undertakings which have as their object the appreciable prevention, restriction or distortion of competition.[403]

II. The relevant product market

6.15. As set out in more detail in paragraphs 3.18 to 3.23, Fludrocortisone Acetate Tablets is the first-line treatment for the replacement of mineralocorticoids[404] in human patients with primary adrenal insufficiency in the UK and it is the focus of the CMA's investigation.[405]

6.16. Therefore, for the analysis of the relevant product market, the CMA has used Fludrocortisone Acetate Tablets (including both Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone) licensed for human use as its Focal Product.

6.17. The CMA finds that the relevant product market is no wider than the supply of Fludrocortisone Acetate Tablets licensed for human use, and specifically that:

(a) other products for treating Addison's disease which are licensed for veterinary users are not part of the relevant product market; and

(b) there are no other products that exert a sufficient competitive constraint on the supply of Fludrocortisone Acetate Tablets to warrant widening the relevant product market.

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[402] T-691/14 *Servier and Others v Commission*, EU:T:2018:922, paragraphs 1393 to 1397. In Case 37507, *AstraZeneca*, paragraph 370, the European Commission noted that relevant factors in assessing interchangeability included price, quality, consumer preferences or other significant attributes.
[403] Case T-62/98 *Volkswagen AG v Commission* EU:T:2000:180, paragraph 230 and Case T-29/92 *SPO and Others v Commission* EU:T:1995:34, paragraph 74. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, in which the CAT held, at [176], that in Chapter I cases '*determination of the relevant market is neither intrinsic to, nor normally necessary for, a finding of infringement*'.
[404] Adrenal glands produce corticosteroids. Corticosteroids can be further subdivided into glucocorticoids (eg cortisol), mineralocorticoids (eg aldosterone) and sex hormones.
[405] Document FLC1571, response to question 1, Annex 1 of the Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018.

6.18. Further, the CMA finds that, despite their different storage conditions, Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone form part of the same relevant product market.

a. Products licensed for veterinary use

6.19. As set out in paragraphs 3.31 to 3.34, although Fludrocortisone Acetate Tablets are only licensed for human use, the product has in practice been used in treating primary adrenal insufficiency in both animals and humans.[406] However, the CMA finds that the relevant product market should be defined as sales for human use only.

6.20. Medicines licensed for veterinary use such as Zycortal, which was introduced in the UK in March 2016 for the treatment of Addison's disease, cannot in any circumstances be used for human use. Under UK regulations, veterinary users should not have been using Fludrocortisone Acetate Tablets to treat Addison's disease since the introduction of Zycortal unless there was specific need to do so (eg for patient safety).[407] The CMA therefore considers that the behaviour of suppliers of Fludrocortisone Acetate Tablets for human use is not constrained by products aimed at veterinary users, as these are not a substitute for human users.

6.21. Consistent with the above, Aspen's internal documents and actual behaviour demonstrate that its pricing strategy for Fludrocortisone Acetate Tablets was not constrained by the behaviour of veterinary users or those who supply veterinary licensed products. Aspen stated that it '*does not consider retailers or consumers in the veterinary channel as customers. Aspen's product is intended and regulated for human use only. Simply put, if Aspen did regard veterinary users as customers it would be breaching regulation.*'[408] Aspen further stated that it disregarded veterinary use when forecasting volumes of

[406] Document FLC1834 and Document FLC1496, response to Question 18b, Annex 1, Aspen's response to the CMA's section 26 notice dated 19 April 2018. Document FLC3490, response to question 1, Annex 1, British Small Animal Veterinary Association's response to the CMA's section 26 notice dated 11 May 2018. In 2015, Aspen's total sales volume for Fludrocortisone Acetate Tablets was 30.4 million tablets, while total NHS volume dispensed for the same product was 16.8 million. As set out in paragraph 4.170, the difference is likely due in part to use for veterinary purposes.
[407] Whilst veterinary surgeons' switch to Zycortal was accelerated due to the price increase of Fludrocortisone Acetate Tablets, evidence shows that such switching away from Fludrocortisone Acetate Tablets would have occurred anyway (albeit at a slower pace): Document FLC3490, response to question 10, Annex 1, British Small Animal Veterinary Association's response to the CMA's section 26 notice dated 11 May 2018. Document FLC1946, response to questions 6 and 7, Annex 1, Dechra's response to the CMA's section 26 notice dated 21 May 2018.
[408] Document FLC1834, response to question 16, Annex 1A, Aspen's response to the CMA's section 26 notice dated 28 February 2018.

sales for Ambient Storage Fludrocortisone for the purposes of the SDA.[409] Contemporaneous documents show that Aspen proceeded with its pricing strategy despite being aware its sales for veterinary use could fall significantly.[410]

6.22. Therefore, other products for treating Addison's disease which are licensed for veterinary users are not part of the relevant product market.

b. There are no other potential substitutes that exert sufficient competitive constraint on the Focal Product to be included in the relevant product market

6.23. The CMA finds that none of the other potential substitutes it has identified, namely other formulations of fludrocortisone acetate and other potential substitute products, exert a sufficient competitive constraint on the supply of Fludrocortisone Acetate Tablets for human use.

6.24. As set out at paragraphs 3.22 and 3.30, no other drug, including other corticosteroids, can be used as a suitable alternative for long term mineralocorticoid deficiency in primary adrenal insufficiency, so clinicians have no choice but to prescribe Fludrocortisone Acetate Tablets in order to treat that therapeutic indication. As a result, pharmacists and hospitals may not dispense any other product to fulfil a prescription.[411]

6.25. Other forms of fludrocortisone acetate (ie capsules or liquid forms) are not licensed for human use and can therefore only be prescribed where there is

[409] Document FLC1834 and Document FLC1496, response to question 19, Annex 1A, Aspen's response to the CMA's section 26 notice dated 28 February 2018. Amilco considered developing a veterinary-only licensed version of Fludrocortisone Acetate Tablets, which supports the view that having the proper regulatory authorisations is important to supply the product to veterinary users (Document FLE0377, minutes of meeting between Aspen, Amilco and Tiofarma dated 1 July 2016).
[410] Document FLE0304, email chain between [Aspen Employee 2], [Aspen Employee 10] and others dated 29 April 2016; Document FLE0141, email chain between [Person 1 acting for Amilco], [Aspen Senior Executive 2] and others dated 8 January 2016.
[411] None of the pharmacies or hospitals contacted by the CMA were able to identify a suitable alternative to which prescriptions for the Focal Product have switched in response to price changes: (pharmacies: [Pharmacy 1], [Pharmacy 2], [Pharmacy 7], [Pharmacy 10], [Pharmacy 6], [Pharmacy 5], [Pharmacy 9], [Pharmacy 11]. Document FLC1253, Document FLC1311, Document FLC1251, Document FLC1218, Document FLC1261, Document FLC1349, Document FLC1401, Document FLC1338, (response to questions 17 and 18 of CMA's section 26 notice dated 6 March 2018); hospitals: [NHS Health Board 1], [NHS Trust 1], [NHS Trust 2], [NHS Trust 3], [NHS Trust 4], [NHS Trust 5], [NHS Trust 6], [NHS Trust 7], [NHS Trust 8] and [NHS Trust 9]. Document FLC3590, Document FLC4126.1, Document FLC3834, Document FLC3670, Document FLC4731, Document FLC3891, Document FLC3498.1, Document FLC4650, Document FLC4796, Document FLC4839 (response to question 3 of CMA's section 26 notice dated 20 August 2018)). Aspen stated that its understanding is that fludrocortisone suspension can be used interchangeably with Fludrocortisone Acetate Tablets (Aspen: Document FLC2010, response to question 13, Annex 1A, Aspen's response to CMA's section 26 notice dated 19 April 2018). The assessment of the constraint posed by non-tablet forms of fludrocortisone is in paragraphs 3.28 to 3.29.

no licensed product available that would meet the patient's special needs.[412] NHS volumes demonstrate that this is very rare: Fludrocortisone Acetate Tablets accounted for 99% of the volumes of all fludrocortisone acetate dispensed by the NHS in 2017, even despite the recent significant price increase for that product (see Figure 2).[413] As a result, other forms of fludrocortisone acetate do not act as a sufficient constraint on the Focal Product to be included in the relevant product market.

6.26. The fact that volumes of Fludrocortisone Acetate Tablets dispensed for NHS-reimbursed use have stayed relatively stable over the years (see Section 4.F.III), despite an increase (on 1 March 2016) of the ASP for that product[414] by approximately 1,800%[415] (significantly higher than the level normally used in a hypothetical monopoly test) supports the finding that there are no other substitute medicines, whether individually or taken together, capable of acting as a constraint on suppliers of Fludrocortisone Acetate Tablets. Consistent with the above, at no point during the Relevant Period did Aspen undertake any promotional or marketing activity with respect to the Focal Product.[416]

6.27. Fludrocortisone Acetate Tablets may also be prescribed for treating NPH.[417] However, as noted in paragraph 3.24 above, other products used for treating this condition do not act as a constraint on suppliers of Fludrocortisone Acetate Tablets and are therefore not in the same market, given the use of the Focal Product in treating NPH is also likely to be relatively limited, and may be used as a complement to other treatments rather than a substitute.

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[412] Document PD0048, MHRA guidance – *Off-label or unlicensed use of medicines: prescribers' responsibilities*, 1 April 2009 (https://www.gov.uk/drug-safety-update/off-label-or-unlicensed-use-of-medicines-prescribers-responsibilities). See also Document PD0049, *General Medical Council's guidance on Good practice in prescribing and managing medicines and devices*, March 2013 (http://www.gmc-uk.org/Prescribing_guidance.pdf_59055247.pdf).

[413] For instance, fludrocortisone suspension – which was identified by specialists as an alternative to Fludrocortisone Acetate Tablets – is far more expensive than the tablet form, even after the much higher price set for tablets from March 2016. Document FLC1571, response to questions 8-10, Annex 1, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018; Document PD0050, NHSBSA - Amendments to the Drug Tariff June 2018 https://www.nhsbsa.nhs.uk/sites/default/files/2018-05/Drug%20Tariff%20June%202018.pdf; Document PD0051, NHSBSA - Amendments to the Drug Tariff May 2016 https://www.nhsbsa.nhs.uk/sites/default/files/2017-04/May_2016.pdf; and Document FLC2010, response to question 13, Annex 1A, Aspen's response to CMA's section 26 notice dated 19 April 2018.

[414] There is also no reason to think that the need for treatment of patients with Addison's Disease changed in a material way such that the need for Fludrocortisone Acetate Tablets by these patients decreased.

[415] The ASP increase from Aspen to wholesalers has likely been passed on to pharmacies and, ultimately the NHS. The NHS England Reimbursement Price also increased by over 1,800% in March 2016.

[416] Document FLC1844, document 3 provided in response to question 10, Annex 1A, Aspen's response to the CMA's section 26 notice dated 19 April 2018.

[417] Aspen also stated that Fludrocortisone Acetate Tablets is licensed for treating adrenal cortical insufficiency in septic shock. However, it also stated that the Focal Product is not routinely used in treating adrenal insufficiency in septic shock. Document FLC2010, response to question 13, Annex 1A, Aspen's response to CMA's section 26 notice dated 19 April 2018.

c. Fludrocortisone Acetate Tablets requiring different storage conditions are in the same relevant product market

6.28. Fludrocortisone Acetate Tablets are available in the UK in two different storage conditions ie Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone. For the reasons set out below, the CMA finds that they are part of the same relevant product market.

i. No medical or regulatory difference

6.29. Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone are bioequivalent and identical in their therapeutic use. Both can be used to fulfil a prescription for Fludrocortisone Acetate Tablets.

6.30. The MHRA granted the generic MA for Ambient Storage Fludrocortisone on the basis that it is '*essentially similar*' to Cold Storage Fludrocortisone.[418]

6.31. There are no clinical barriers to switching between the two products. Prescriptions for Fludrocortisone Acetate Tablets are mostly open, without reference to supplier or brand.[419] The NHS does not record whether prescriptions specify storage conditions.[420] Therefore, it is at the discretion of the pharmacist to select whether to stock and dispense Cold Storage Fludrocortisone or Ambient Storage Fludrocortisone.[421]

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[418] Document FLE0816, Fludrocortisone Acetate 0.1mg Tablets CTD MODULE 2.5: Clinical Overview, page 5: '*This* [MA application] *is made on the basis that this is essentially similar to Florinef 0.1 mg Tablets of E.R. Squibb & Sons Limited, UK. The active ingredient and the route of administration are the same for both products. The indications sought for fludrocortisone are the same as those for Florinef 0.1 mg Tablets. Additionally, the proposed SPC for the applicant's Fludrocortisone Acetate 0.1mg Tablets has been based on the SPC for Florinef 0.1 mg Tablets.*'

[419] Document FLC1571, response to question 5, Annex 1A, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018: *'In our experience, prescriptions for fludrocortisone acetate are usually open and anyway there is only a single preparation available in the UK*.' See also [Consultant to Aspen]'s statement that, prior to the debranding of Florinef, '*well over 90%*' of prescriptions used the generic name (Document FLC1991, page 45, lines 10 to 12, Transcript of interview with [Consultant to Aspen] on 25 October 2017). See also Document FLE0981, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 8 January 2016, headed '*for release term sheet – AGI/Tiopharma* [sic]': '*Brand shows virtual total is written as generic'*.

[420] NHSBSA records whether prescriptions are open or closed but does not record whether prescriptions specify anything regarding the storage conditions for the relevant medicine. Document FLC4724, response to question 6, Annex 1, NHSBSA's response to the CMA's section 26 notice dated 10 October 2018.

[421] By contrast, where the prescriber specifies, for example, the brand name or a particular supplier of a drug that should be dispensed, the pharmacy is required to dispense that particular medicine. SI 2013/349 The National Health Service (Pharmaceutical and Local Pharmaceutical Services) Regulations 2013, Schedule 4, paragraph 5(2), provides that where a person presents to a pharmacist '*an order for drugs*', the pharmacist must '*provide the drugs so ordered*'.

6.32. The Society for Endocrinology identified only a '*minor benefit'* to clinicians and patients[422] in the ambient storage nature of the product, which needs to be contrasted with '*the major disadvantage of a much higher price for the medication'*.[423] It regretted that '*clinicians and patients are currently not able to make any choice as with Florinef no longer available,* [clinicians] *now are forced to prescribe the monopolized new preparation'.*[424] It explained that not having to refrigerate the product *'adds convenience to its use but as the tablets can still be used for 30 days when stored at room temperature this convenience is not transformative*' and that '*patients with primary adrenal insufficiency tend to have excellent compliance*.'[425]

6.33. DHSC treats these two products as identical within the context of the Drug Tariff.

ii. The demand side

6.34. Quantitative and qualitative evidence relating to the demand for Fludrocortisone Acetate Tablets is consistent with the CMA's conclusion that Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone form part of the same relevant product market.

6.35. Since March 2016, when Aspen began selling only Ambient Storage Fludrocortisone in the UK, pharmacies[426] and wholesalers[427] have met pharmacy demand for Fludrocortisone Acetate Tablets to a greater extent by purchasing cheaper parallel imports of Cold Storage Fludrocortisone: parallel imports of Cold Storage Fludrocortisone increased from around 6% of total volumes of Fludrocortisone Acetate Tablets in 2014 and 2015 to around 20% of total volumes of Fludrocortisone Acetate Tablets in 2016 and 2017.[428]

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[422] Document FLC1571, response to questions 7b and 7c, Annex 1A, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018.
[423] Document FLC1571, response to questions 7c and 7d, Annex 1A, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018.
[424] Document FLC1571, response to questions 7c and 7d, Annex 1A, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018.
[425] Document FLC1571, response to question 7a, Annex 1A, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018.
[426] Six of the eight pharmacies responding to the CMA's information request (dated 6 March 2018) have taken Cold Storage Fludrocortisone as a parallel import since March 2016 (although volumes are generally limited given the nature of Parallel Import availability): [Pharmacy 1], [Pharmacy 2], [Pharmacy 7], [Pharmacy 6], [Pharmacy 9] and [Pharmacy 11] (See Document FLC1253, FLC1311, Document FLC1312, Document FLC1250, Document FLC1251, Document FLC1401, Document FLC1337 and Document FLC1338).
[427] Five of the eight wholesalers responding the CMA's section 26 notice dated April 2018 took at least some parallel imports since March 2016 ([Wholesaler 3], [Wholesaler 8], [Wholesaler 2], [Wholesaler 6], [Wholesaler 7], [Wholesaler 4]). Document FLC0608, Document FLC0615 and Document FLC0616 (question 1), Document FLC1881 and Document FLC1882 (question 1 and Appendix 1), Document FLC2412 (Tab appendix 3, question 10), Document FLC1999 (question 10), Document FLC1344 (question 7 and 10) and Document FLC1590 (question 10).
[428] See paragraphs 4.175 and 4.175.

There is a limit to the weight which can be attached to the quantitative evidence in this case, given the near simultaneous withdrawal of Cold Storage Fludrocortisone and introduction of Ambient Storage Fludrocortisone by Aspen in the UK. However, customers' willingness to take Cold Storage Fludrocortisone as a parallel import does demonstrate some competitive interaction between Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone.

6.36. Pharmacists either source Fludrocortisone Acetate Tablets directly from a supplier or via a wholesaler. In the latter case, the wholesaler will be responsible for selecting the supplier. Qualitative evidence from pharmacists and wholesalers indicates that price was a greater determinant than factors relating to storage conditions (alone or together, including patient preferences and the cost or practicality of handling the product eg refrigeration) in their decision to purchase Ambient Storage Fludrocortisone or Cold Storage Fludrocortisone. Specifically, in relation to wholesalers:[429]

(a) Two of the eight wholesalers told the CMA that they would have continued to purchase (cheaper) Cold Storage Fludrocortisone if both products were supplied directly in the UK.[430] Others actually did so, by purchasing parallel imports of Cold Storage Fludrocortisone (see paragraph 6.35 above).

(b) All wholesalers contacted by the CMA noted price as a factor taken into account when choosing where to source supplies, favouring the cheapest supplier able to meet their volume requirements.[431]

[429] In its section 26 notice dated April 2018, the CMA requested information from wholesalers who purchased between 84% and 94% of Aspen and parallel importers sales each year between 2015 and 2017 (ie [Wholesaler 1], [Wholesaler 2], [Wholesaler 8], [Wholesaler 3], [Wholesaler 4], [Wholesaler 5], [Wholesaler 6] and [Wholesaler 7]. Document FLC2460 and Document FLC2461 (questions 1 to 3 and Appendix 1), Document FLC2412 (Appendices), Document FLC2735, Document FLC2724 (questions 1 to 3), Document FLC2725 (Appendix 1), Document FLC1756 (Appendix 1), Document FLC1322 (Appendix 2) and Document FLC2482 (question 2), Document FLC1759 (Appendix 1), Document FLC1797 (questions 11 and 12 and appendices Document FLC1787, Document FLC1788, Document FLC1789, Document FLC1790, Document FLC1791, Document FLC1792, Document FLC1793, Document FLC1794, Document FLC1795, Document FLC2438, Document FLC2439 and Document FLC2443). For the calculation of total Aspen and parallel import volumes, see Figure 8.
[430] See [Wholesaler 2] (Document FLC0675, question 9) and [Wholesaler 6] (Document FLC1999, questions 13 b and 28 in response to the CMA's section 26 notice dated April 2018).
[431] [Wholesaler 1], [Wholesaler 2], [Wholesaler 3], [Wholesaler 4], [Wholesaler 5], [Wholesaler 6] and [Wholesaler 8] told the CMA that factors they take into account when choosing a supplier of a drug include: price, quantity available, consistency and security of supply. (Document FLC0717 (question 8), Document FLC0675 (question 8), Document FLC2411 (question 13), Document FLC1589 (question 13), Document FLC1755 (question 13), Document FLC1999 (question 13), Document FLC1881 (question 4). All responses mentioned in this footnote are to the CMA's section 26 notice dated 6 March 2018.

(c) While wholesalers noted benefits to ambient storage[432] mostly because cold storage products require more complicated and/or higher cost transportation and storage due to needing to maintain cold chain conditions, these cost differences – on a per pack basis – are very small.[433] In addition, a number of the costs identified by respondents are fixed costs associated with the handling of cold storage products, so the incremental effect of handling one additional cold storage product line is likely to be low. Most of the wholesalers contacted noted that they handle cold storage products,[434] which implies that they would face these fixed costs in any event.

6.37. Further, in relation to pharmacies:

[432] Four wholesalers ([Wholesaler 4], [Wholesaler 7], [Wholesaler 3] and [Wholesaler 2]) noted that there are additional difficulties in supplying cold chain products, mostly because cold storage products require more complicated and/or higher cost transportation due to needing to maintain cold chain conditions. (Document FLC1589 (question 27 a and d) Document FLC1344 (question 14 b), Document FLC2411 (questions 27 a and 27 d) and Document FLC1797 (question 17 a)). All responses mentioned in this footnote are to the CMA's section 26 notice dated April 2018.

[433] For example, in relation to [Wholesaler 7], the marginal increased cost related to storage has not deterred it from supplying Cold Storage Fludrocortisone through parallel imports. See [Wholesaler 7] (Document FLC1344 (question 14b) and Document FLC2482 (question 5). [Wholesaler 3] states ambient products were "marginally cheaper" to handle. (Document FLC2411 (question 27 a and 27 d) and Document FLC2445 (question 3). In addition to this, [Logistics Provider] stated its typical charge for ambient temperature-controlled storage is around £[✂] per ISO pallet per week, while cold storage would be £[✂] per week (Document FLC4653C, response to question 2b). [Wholesaler 4] estimated the costs of storage, picking and distribution of cold storage product is around £[✂] per line compared to £[✂] per ambient product line (Document FLC1589, question 27 d) and Document FLC2058 (question 4). Aspen's own estimates of indirect costs do not seem to differ materially on a per tablet basis between Cold and Ambient Storage Fludrocortisone (see paragraphs 4.165 to 4.167 and Figure 6). All responses mentioned in this footnote are to the CMA's section 26 notice dated April 2018.

[434] See responses from [Wholesaler 2], [Wholesaler 1], [Wholesaler 5], [Wholesaler 4], [Wholesaler 6] and [Wholesaler 8] (Document FLC1797 (question 17a), Document FLC1758 (question 18 a), Document FLC1755 (question 27a), Document FLC1589 (question 27a), Document FLC1999 (question 27a), Document FLC1881 (question 29 a)). All responses mentioned in this footnote are to the CMA's section 26 notice dated April 2018.

(a) Some pharmacy chains[435] indicated they do not have central visibility of patient preferences.[436,437] This indicates it is not a strong driver of their purchasing strategy.

(b) While there is some evidence from distributors to indicate that some pharmacy customers have expressed a preference for Ambient Storage Fludrocortisone,[438] others are not aware of customers expressing such preference.[439] In addition, whilst pharmacies identified there are additional costs to handling Cold Storage Fludrocortisone there are mixed views as to the significance of these.[440]

6.38. On the basis of the evidence set out above, the CMA finds that, were both Ambient Storage Fludrocortisone and Cold Storage Fludrocortisone readily available in the market, a sufficient number of customers would switch in

[435] The CMA requested information from [Pharmacy 8], [Pharmacy 10], [Pharmacy 1], [Pharmacy 6], [Pharmacy 5], [Pharmacy 2], [Pharmacy 7], [Pharmacy 9] and [Pharmacy 11]. These pharmacies account for between 20% and 45% of the total Fludrocortisone Acetate Tablets sold by Aspen and parallel importers each year between 2015 and 2017. This does not include data for [Pharmacy 8] ([Pharmacy 8] retains no information since the sale of its pharmacy business to [Pharmacy 5]. [Pharmacy 5] does not hold information on [Pharmacy 8] sales prior to taking ownership of its stores). [Wholesaler 8] is also a pharmacy, but its response has been included with those of wholesalers as it undertakes both functions. (See Document FLC1994 (Appendix 1), Document FLC1312 (Appendix 1), Document FLC2041, Document FLC2042 (Appendix 1), Document FLC1260 (Appendix 1), Document FLC2875, Document FLC1250 (Appendix 1), Document FLC1402 (Appendix 1), Document FLC2056, Document FLC1217 (Appendix 1), Document FLC1218 (question 3), Document FLC1337 (Appendix 1), Document FLC2455 (question 1) and Document FLC1162. For the calculation of total Aspen and parallel import volumes, see Figure 8. All responses mentioned in this footnote are to the CMA's section 26 notice dated 6 March 2018.

[436] [Pharmacy 1], [Pharmacy 2], [Pharmacy 10], [Pharmacy 6], [Pharmacy 5] and [Pharmacy 11] (see Document FLC1253, Document FLC1311, Document FLC1218, Document FLC1261, Document FLC1349, Document FLC1338, questions 6 and 20 a). Only [Pharmacy 5] provided a further explanation and noted by way of context that it would be unusual for patients to express a preference or otherwise question what has been prescribed. All responses mentioned in this footnote are to the CMA's section 26 notice dated 6 March 2018.

[437] [External Consultant 2] told the CMA that pharmacists have a duty of care and would therefore prefer dispensing Ambient Storage Fludrocortisone over Cold Storage Fludrocortisone given the higher level of compliance. Document FLC1774, page 34, lines 6 to 27, Transcript of interview with [External Consultant 2] on 6 March 2018. However, this statement is not supported by any evidence from the pharmacy chains consulted by the CMA.

[438] Two distributors (one parallel importer ([Parallel Importer 13]) and [Wholesaler 7]) selling parallel imported Cold Storage Fludrocortisone noted that some pharmacies will not take that product due to its storage conditions ([Parallel Importer 13] also noted the difference in pack size). Document FLC2420 and Document FLC1344 (questions 7 and 14(c) in response to the CMA's section 26 notice dated 8 March 2018).

[439] Two wholesalers ([Wholesaler 8] and [Wholesaler 3]) were not aware of any pharmacy preference (although one accepted it would be logical for pharmacies to prefer Ambient Storage Fludrocortisone) and one ([Wholesaler 6]) stated the independent pharmacies made their decision based on price and had generally preferred Cold Storage Fludrocortisone when available as it was cheaper. (Document FLC1881 (question 29b), Document FLC2411 (question 27), and Document FLC1999 (question 27b). All responses mentioned in this footnote are to the CMA's section 26 notice dated April 2018.

[440] Responses noting lower cost (due to storage or wastage) but without commenting on the size of the difference: [Pharmacy 2], [Pharmacy 5], [Pharmacy 11], [Pharmacy 7] (Document FLC1311, Document FLC1349, Document FLC1251, Document FLC1338, question 14). Responses stating these benefits were small: [Pharmacy 10], [Pharmacy 6] and [Pharmacy 9] (Document FLC1218, Document FLC1261, Document FLC1401, question 14). All responses mentioned in this footnote are to the CMA's section 26 notice dated 6 March 2018.

response to relative price changes, such that the price of Ambient Storage Fludrocortisone would be constrained by Cold Storage Fludrocortisone.

iii. The supply side

6.39. Contemporaneous evidence as to how undertakings supplying Fludrocortisone Acetate Tablets view their competitors is also relevant for the purposes of market definition.[441] Aspen's internal forecasts indicate an expectation that Ambient Storage Fludrocortisone would constrain its incumbent Cold Storage Fludrocortisone product.[442] Similarly, Aspen's internal documents, including a draft version of the SDA,[443] show that Aspen viewed Cold Storage Fludrocortisone as a constraint on Ambient Storage Fludrocortisone.[444]

III. The relevant geographic market

6.40. In line with previous cases in the pharmaceutical sector,[445] the CMA considers it is appropriate to define the geographic market as national in this case. In particular, in order to sell the Focal Product in the UK, it is necessary to obtain an MA from the MHRA, and an MA covers the whole of the UK.[446] In addition, the Pricing Framework (see paragraphs 3.62 to 3.66), which determines how pharmacies are reimbursed for the dispensing of Fludrocortisone Acetate Tablets is specific to the UK.

6.41. The CMA finds that, in light of the above, the relevant geographic market in this case is national (UK-wide) in scope.

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[441] *Aberdeen Journals v Director General of Fair Trading* [2002] CAT 4, paragraph 103.
[442] One document FLE0105, excel spreadsheet titled '*Fludrocortisone generic ambient*' dated 05 October 2015 set out an estimate of '[✂] *or more'* of the market being lost to the '*Ambient product*' with no change in price; Document FLE0137, excel spreadsheet dated 8 January 2016 forecasts that the share of the market that would be captured by Ambient Storage Fludrocortisone would be '*circa* [✂]*% or more* […] *over time*'.
[443] Document FLE1812, draft SDA annotated '*Amilco mark up 8 February 2016'*.
[444] Aspen's internal documents indicate a degree of concern as to the effect of parallel imported Cold Storage Fludrocortisone on volumes and prices of Ambient Storage Fludrocortisone in the UK, if the two were sold simultaneously in that market (see paragraphs 4.184 to 4.188). As noted above, there is a limit to the weight which can be attached to this evidence given it does not reflect domestic supply of Cold Storage Fludrocortisone. However, customers' willingness to take Cold Storage Fludrocortisone as a parallel import does demonstrate some competitive interaction between Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone.
[445] Commission Decision of 15 June 2005 in Case 37507 *AstraZeneca*, paragraph 503; Case CA98/02/2011 *Reckitt Benckiser*, OFT decision of 12 April 2011, paragraphs 4.170 and 4.171; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 380; and *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, footnote 28 referring to the reasoning in Case CE/9742-13 *Pfizer and Flynn Pharma,* CMA Decision of 7 December 2016, paragraphs 4.184 and 4.185.
[446] The existence of parallel imports is not inconsistent with the market being national in scope since parallel importers need to obtain a parallel import product licence from the MHRA to sell in the UK.

B. Aspen held significant market power in the Relevant Market since November 2014

6.42. For the reasons set out below, the CMA finds that Aspen, as sole UK supplier active in the Relevant Market since November 2014, has held significant market power throughout the period of the SDA (which is relevant to the assessment of the object and effects of the SDA),[447] on the basis of:

(a) Aspen's very large market share (of at least 80%) since it entered the Relevant Market in November 2014 and the fact that it faced no material constraints from parallel importers;

(b) Aspen's pricing behaviour and financial performance, as reflected in its ability to profitably increase and sustain prices materially higher than its costs at least since March 2016; and

(c) other relevant factors in assessing Aspen's market power (including the lack of constraint arising from the risk of potential competition (either from existing competitors or from new entrants) and the absence of countervailing buyer power held by DHSC or intermediate customers).

6.43. As part of its admission of liability with respect to the Infringement, Aspen has accepted that it held significant market power throughout the period of the SDA on the basis of the CMA's assessment set out in this section.

I. Aspen held a very large market share and faced no material constraints from parallel importers

6.44. Market shares provide a useful first indication of the market structure and of the relative importance of the various undertakings active in the market. In *Albion Water Limited v Water Services Regulation Authority*, the CAT noted that '*market share is, generally speaking, an important indicator of market power'*.[448] In light of the case law of the Court of Justice, market shares in

[447] See also Commission Notice: *Guidelines on the application of Article 81(3) of the Treaty* (now Article 101(3) of the TFEU, OJ C 101/97, 27.4.2004, paragraph 25; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*). The relevance of market power in assessing an agreement under Chapter I/Article 101 TFEU is set out in paragraph 169 for restrictions by '*object'*, and paragraph 330 for restrictions by '*effect'* (referring to Commission's *Guidelines on horizontal cooperation agreements*, (2011) OJ C11/1, paragraphs 28 and 29).

[448] On that basis, it found that Dŵr Cymru's possession of a market share of 100% over many years gave rise to '*a very strong presumption that Dŵr Cymru is in a dominant position'*. See *Albion Water Limited v Water Services Regulation Authority* [2006] CAT 36, paragraphs 118 to 123.

excess of 50% are in themselves proof of the existence of significant market power.[449]

6.45. In addition, the market shares of other undertakings operating in the same market and how those have changed over time can be relevant.[450] An undertaking is more likely to hold market power if its competitors hold relatively weak positions and the undertaking in question has enjoyed a stable market share that is much higher than the market shares of competitors.[451]

6.46. As set out in Figure 8 below, Aspen has held a very large market share (by sales volumes and revenues) of at least 80% since November 2014 in the Relevant Market, while facing no material constraints from competitors.[452] This reflects the fact that, since its acquisition of the Florinef business in November 2014, and until the implementation of the Commitments, it has been the sole UK supplier in the Relevant Market. That level of market share is in itself proof of the existence of significant market power.

6.47. In order to calculate market shares, the CMA has obtained data from Aspen and parallel importers to estimate the total value and volume of Fludrocortisone Acetate Tablet sales in the UK. This methodology does not

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[449] See C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60. See also T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 245: '*the possession, over a long period, of a very large market share constitutes in itself, save in exceptional circumstances, proof of the existence of a dominant position … market shares of more than 50% constitute very large market shares*'.

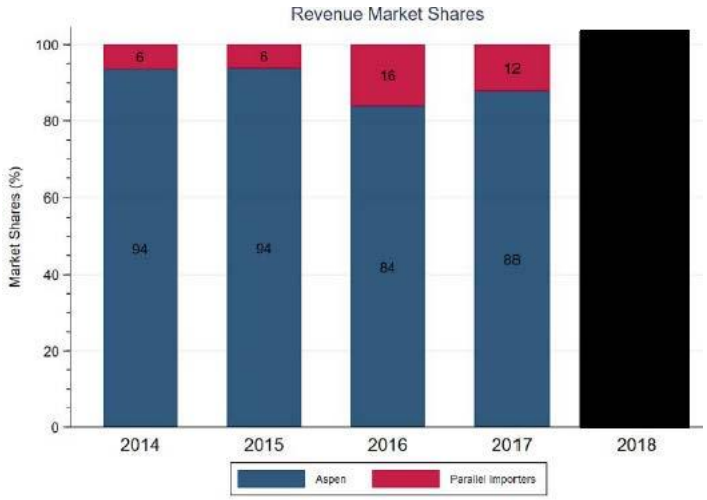
[450] OFT415 *Assessment of market power* (December 2005), paragraph 3.3; the European Commission's *Guidelines on its enforcement priorities in applying Article 102 to abusive exclusionary conduct*, paragraph 13; see also *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, paragraph 310.

[451] Assessment of market power guidelines, OFT415, paragraph 4.2; T-219/99 *British Airways v Commission*, EU:T:2003:343, paragraphs 210 and 211; T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 253; and T-336/07 *Telefonica v Commission*, EU:T:2012:172, paragraph 163.

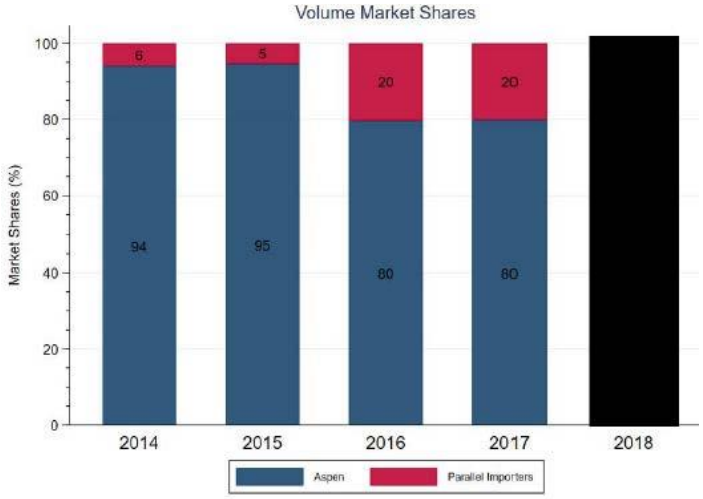
[452] C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 176. See also T-340/03 *France Telecom v Commission*, EU:T:2007:22, paragraph 103: '*During the period at issue, WIN … had a very high market share* [between 50% and 72%] *which, save in exceptional circumstances,* ***proves*** *that it had a dominant position*' (emphasis added). Compare the European Commission's decision in COMP/38.233 *Wanadoo Interactive*, paragraph 212 (upheld in T-340/03): '*Very large market shares, in excess of 50%,* ***must*** *be regarded as serious,* ***and indeed sufficient****, evidence of the existence of a dominant position, save in exceptional circumstances*' (emphasis added). See also C-62/86 *Akzo v Commission* EU:C:1991:286, paragraph 60; *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11: '*market shares of this order* [78% by value / 67% by volume; or 73% by value / 63% by volume] *suffice to establish that Aberdeen Journals was dominant unless exceptional circumstances are shown*' (paragraph 310); and T-66/01 *Imperial Chemical Industries v Commission*, EU:T:2010:255, paragraph 256. Compare also Case 85/76 *Hoffmann-La Roche v Commission*, EU:C:1979:36, paragraph 41: '*very large market shares are in themselves evidence of the existence of a dominant position*'; C-62/86 *Akzo v Commission*, EU:C:1991:286, paragraph 60: '*With regard to market shares the Court has held that very large shares are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position … That is the situation where there is a market share of 50%*'; and Commission Decision in Case AT.39612 *Perindopril (Servier)*, recital 2561: '*In the case-law, it has been held that market shares of more than 50% constitute very large market shares and are in themselves, and save in exceptional circumstances, evidence of the existence of a dominant position*'.

allow the CMA to exclude sales outside the Relevant Market, but this does not impact the CMA's assessment based on this analysis.[453]

Figure 8: Annual market shares of the supply of Fludrocortisone Acetate Tablets for Aspen and parallel importers 2014–2018 (based on sales revenues and volumes)



[453] This presents certain limitations; in particular, Aspen's sales include sales which are outside of the Relevant Market (to veterinary users and exports). If these were to account for a large proportion of Aspen's sales, this could overestimate Aspen's market share with regard to human use in the UK (the Relevant Market). However, these limitations do not significantly impact the calculation of market shares. Given the scale of Aspen's sales relative to parallel imports, even if all sales in excess of NHS use are attributed to Aspen, it would not materially affect the CMA's conclusion that Aspen had a very high market share. For example, in 2015 Aspen would still have a market share of 90%. In 2015, total tablet volumes from Aspen and PI were 32,160,600, of which Aspen accounts for 30,428,700. Total NHS volumes were 16,811,644. Even if the entire difference (15,348,956) were attributed to Aspen and discounted from its sales, this would still leave 15,133,744 tablets sold by Aspen, or 90% of the NHS volume. Source: Aspen, [Parallel Importer 1], [Pharmacy 4], [Parallel Importer 3], [Parallel Importer 5], [Parallel Importer 6], [Parallel Importer 7], [Parallel Importer 9], [Parallel Importer 10], [Parallel Importer 12], [Parallel Importer 15]. Document FLC1836 (question 1), Document FLC1361 and Document FLC1366 (questions 7 and 9), Document FLC2703 (questions 7 and 9), Document FLC1308 and Document FLC1309 (response to questions 7 and 9), Document FLC1444 and Document FLC1452 (response to questions 7 and 9), Document FLC2403 (response to questions 7 and 9), Document FLC1455 (response to questions 7 and 9), Document FLC1242 (response to questions 7 and 9), Document FLC2418 (response to question 7), Document FLC1421 (response to questions 7 and 9), Document FLC4854 and Document FLC4856 (response to questions 2 and 3, labelled questions 7 and 9) (all responses are to the CMA's section 26 notice dated April 2018); Document PD0012, PCA data for England; Document PD0028, PCA data for Wales; Document PD0029, PCA data for Northern Ireland for months January 2014 to March 2018; Document PD0030, PCA data for Scotland for financial years 2014/15 to 2017/18. Further, sales outside of the Relevant Market are likely to be very low following the introduction of a higher price in March 2016. As a result, this issue should not affect market shares in later years to a material extent.



Source: Aspen, [Parallel Importer 1], [Pharmacy 4], [Parallel Importer 3], [Parallel Importer 5], [Parallel Importer 6], [Parallel Importer 7], [Parallel Importer 9], [Parallel Importer 10], [Parallel Importer 12], [Parallel Importer 15]. Document FLC1836 (question 1), Document FLC1361 and Document FLC1366 (questions 7 and 9), Document FLC2703, (questions 7 and 9), Document FLC1308 and Document FLC1309 (response to questions 7 and 9), Document FLC1444 and Document FLC1452 (response to questions 7 and 9), Document FLC2403. (response to questions 7 and 9), Document FLC1455 (response to questions 7 and 9), Document FLC1242 (response to questions 7 and 9), Document FLC2418 (response to question 7), Document FLC1421 (response to questions 7 and 9), Document FLC4854 and Document FLC4856 (response to questions 2 and 3, labelled questions 7 and 9). All responses are to the CMA's section 26 notice dated April 2018.
Notes:
[1] For revenue market shares, CMA analysis based on Aspen and parallel importer's sales revenue from sales of Fludrocortisone Acetate Tablets.
[2] Volume market shares, CMA analysis based on the total number of tablets sold by Aspen and parallel importers.
[3] 2014 data: For Aspen – the data relate to the months November and December only.
[4] 2018 data: For Aspen – the data relate to months January to March only. For parallel importers – the data relate to months January to February/March.

6.48. The only actual competition faced by Aspen since November 2014 came from parallel imports of Cold Storage Fludrocortisone initially sold in the EU by Aspen.[454] Since 2014, parallel importers have not been able to increase their market share beyond 5% individually[455] and 20% collectively, despite the

[454] A pharmaceutical product which has been authorised in another EU Member State can only be marketed in the UK under the parallel import licensing scheme provided that the imported product is not therapeutically different from the version of the product for which a UK MA has been granted. See Document PD0052, MHRA - Medicines: apply for a parallel import licence https://www.gov.uk/guidance/medicines-apply-for-a-parallel-import-licence. All the PLPIs issued by the MHRA in relation to Fludrocortisone Acetate Tablets relate to Florinef, ie a product originating from Aspen. Therefore, 100% of the Fludrocortisone Acetate Tablets supplied in the UK have originated from Aspen, where Aspen is acting as the MA-holder in the UK or as the MA-holder in those European countries from which parallel imports are made. Document FLC0075, FL2 to MHRA response to the CMA's section 26 notice dated 13 July 2017.
[455] The largest (volume) share was achieved by [Parallel Importer 1] in 2016 at [✂]%; it subsequently fell to [✂]% in 2017. Other parallel importers which achieved similar shares (over 4%) include [Parallel Importer 10], [Parallel Importer 7] and [Parallel Importer 6], although shares across parallel importers have tended to fluctuate. Source: Aspen, [Parallel Importer 1], [Pharmacy 4], [Parallel Importer 3], [Parallel Importer 5], [Parallel Importer 6], [Parallel Importer 7], [Parallel Importer 9], [Parallel Importer 10], [Parallel Importer 12], [Parallel Importer 15]. Document FLC1836 (question 1), Document FLC1361 and Document FLC1366 (questions 7 and 9), Document FLC2703, (questions 7 and 9), Document FLC1308 and Document FLC1309 (response to questions 7 and 9), Document FLC1444 and Document FLC1452 (response to questions 7 and 9), Document FLC2403 (response to questions 7 and 9), Document FLC1455 (response to questions 7 and 9), Document FLC1242 (response to questions 7 and 9), Document FLC2418 (response to question 7), Document FLC1421 (response to questions 7

significant arbitrage opportunities for parallel importers created by the price differential between the UK and some other jurisdictions.[456] The constraints faced by parallel importers in terms of volume and reliability of supply of excess product volumes in other EU Member States, has prevented them from increasing volumes of imports.[457] The volume and reliability of supply issues were likely exacerbated by Aspen's ownership of Cold Storage Fludrocortisone and its efforts to restrict parallel imports of Cold Storage Fludrocortisone into the UK from other EU countries (see paragraphs 4.184 to 4.187).[458]

6.49. The existence of such constraints explains the inability of parallel importers to substantially increase their individual and collective market share in the UK, and therefore to materially constrain Aspen's power to behave to an appreciable extent independently of its competitors.

II. Pricing behaviour and financial performance

6.50. The European Courts have confirmed that an undertaking's conduct can also be an indicator of whether it holds market power.[459] This approach has been followed by the CAT, which has held that an undertaking's pricing ability can indicate significant market power. The CAT observed in *Albion Water* that an undertaking that is in a position to price without reference to the costs of

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and 9), Document FLC4854 and Document FLC4856 (response to questions 2 and 3, labelled questions 7 and 9). All responses are to the CMA's section 26 notice dated April 2018.

[456] Aspen data indicates that the price of Fludrocortisone Acetate Tablets has remained below £[✂] per pack of 100 tablets in [✂], and below £[✂] per pack of 100 tablets in some other countries, such as [✂]. Document FLC1836 and Document FLC1839, response to question 36, Aspen's response to the CMA's section 26 notice dated 19 April 2018.

[457] See responses from [Parallel Importer 11], [Parallel Importer 7], [Parallel Importer 1], [Parallel Importer 4], [Parallel Importer 6], [Parallel Importer 9], [Parallel Importer 8], [Parallel Importer 13], [Parallel Importer 12], [Parallel Importer 3], [Parallel Importer 10], [Pharmacy 4] to questions from the CMA. Document FLC1436, Document FLC1456, Document FLC1360, Document FLC1431, Document FLC1432, Document FLC2405, Document FLC1249, Document FLC1389, Document FLC2420 (response to question 16), Document FLC1419, Document FLC1369, Document FLC1340.2 (response to question 6), Document FLC2415 (response to question 13). All responses are to the CMA's section 26 notice dated April 2018.

[458] See [Parallel Importer 9] and [Parallel Importer 12] Document FLC1249 (response to question 16) and Document FLC1419 (response to question 6). See also paragraphs 4.184 and seq., Aspen stated that, in order to secure continuity of supply for patients in the Netherlands, Aspen monitored sales in the Netherlands to ensure enough stock remained in-country to service patients' needs: Document FLC1834 and Document FLC1496 (response to question 29)(All responses are to the CMA's section 26 notice dated April 2018). The evidence on the CMA's file indicates that Aspen's concern was motivated more by the potential impact of parallel imports on sales volumes and prices of Ambient Storage Fludrocortisone in the UK than by ensuring supply to patients in other countries. In particular, it sought to reduce supplies of Florinef in other EU countries in order to limit the amount of parallel imports available.

[459] Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 67 to 68; T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraphs 261 to 269; upheld in C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, paragraph 181.

supplying its customers is '*plainly under no competitive constraint as to the prices it charges'*.[460]

6.51. The CMA's Assessment of market power guidelines note further that:

'An undertaking's conduct in a market or its financial performance may provide evidence that it possesses market power. Depending on other available evidence, it might, for example, be reasonable to infer that an undertaking possesses market power from evidence that it has set prices consistently above an appropriate measure of its costs, or persistently earned an excessive rate of profit'.

6.52. In line with the above, persistent significantly high returns, relative to those which would prevail in a competitive market of similar risk and rate of innovation, are therefore strongly indicative of significant market power.[461] The ability to sustain overall profit margin is also consistent with market power.[462]

6.53. Aspen's pricing behaviour and financial performance shows that it has been able to exercise significant market power in the Relevant Market:

(a) prior to the SDA, Aspen was taking steps to implement a strategy to increase its prices significantly; and

(b) during the period of the SDA (and thereafter), Aspen has profitably implemented that strategy, while maintaining very high market shares over a prolonged period of time.

6.54. Prior to the SDA, Aspen was already implementing a strategy for Fludrocortisone Acetate Tablets which shows that it considered itself able to act independently of its competitors and customers. In particular, Aspen had taken action to de-brand Florinef[463] as part of an intended strategy to increase

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[460] *Albion Water and Another v Water Services Regulation Authority and Others* [2006] CAT 36, paragraph 180.
[461] *Assessment of market power guidelines* (OFT415), paragraphs 6.5 and 6.6. See also Case IV.30.787 *Eurofix-Bauco v Hilti*, paragraph 71; T-30/89 *Hilti AG v Commission*, EU:T:1991:70, paragraph 93. See also Commission Decision in Case IV/30.178 *Napier Brown – British Sugar*, paragraph 55: British Sugar's ability to maintain price rises indicated its ability to behave to an appreciable extent independently of its competitors and customers. Case CE-9742/13 *Phenytoin sodium* (CMA Decision dated 7 December 2016), paragraph 4.222 et. seq. upheld on appeal in *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 241 ('*We agree with the CMA that, provided only objective facts are relied on, then* [high prices] *may be relevant to establishing the existence of dominance as well as having to be examined to see if they contribute to a finding of abuse*.').
[462] *Assessment of market power guidelines* (OFT415), paragraph 3.1. Case 27/76 *United Brands v Commission*, EU:C:1978:22, paragraphs 126 to 128.
[463] Aspen had discussed internally a strategy of debranding and increasing the price of Fludrocortisone Acetate Tablets a few months after that product was acquired from BMS (see paragraphs 4.6 to 4.7). Aspen implemented

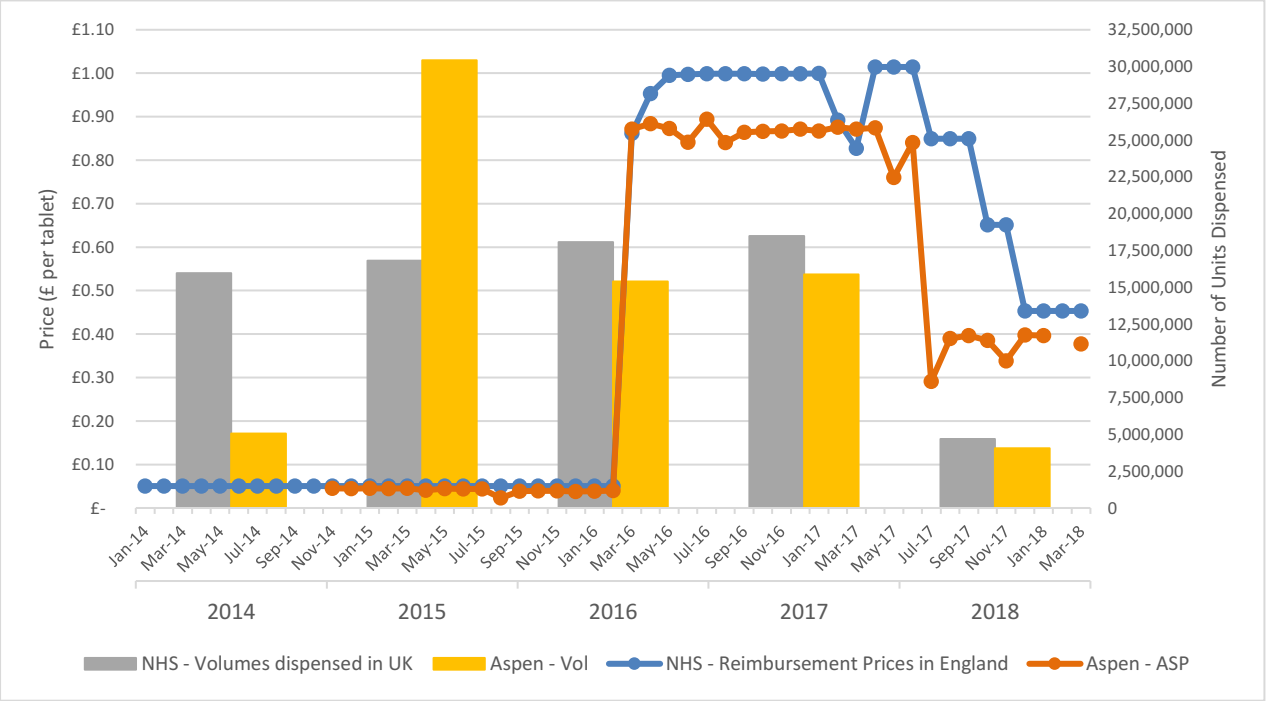
its prices significantly by around [✂]% in the short term.[464] Internal contemporaneous documents (see paragraph 8.153) show that Aspen's expectation was that it could profitably implement and sustain such a strategy. This strategy was abandoned in favour of the SDA (see paragraphs 4.5 to 4.8).

6.55. At the time the SDA entered into force on 1 March 2016, Aspen introduced Ambient Storage Fludrocortisone at a significantly higher List Price than the previous List Price of Cold Storage Fludrocortisone, from c. £0.05 to £1 per tablet. Between March 2016 and July 2017, Aspen therefore charged a List Price that were more than 1,800% higher than its pre-March 2016 List Price.

the process of debranding throughout the negotiations of the SDA (until the debranding was approved) (see paragraph 4.8).

[464] As set out in paragraphs 4.5 to 4.8, Aspen's [✂] team planned to launch debranded Cold Storage Fludrocortisone at a price of £[✂] per pack of 100 tablets, eventually rising to around £[✂] per pack of 100 tablets. Document FLE0124, email from [Aspen Employee 18] (Aspen Global Incorporated) to [Aspen Employee 7] and another Aspen employee dated 30 November 2015. This email referred to a *'potential 1st generic price point £*[✂]; See also Document FLE0138, instant messaging discussion between [Aspen Employee 1] and [Aspen Employee 2] of Aspen Europe dated 8 January 2016: '*we were going to go in steps to circa £*[✂]*/pack*'. See also Document FLE0133, email from [Aspen Employee 11] to [Consultant to Aspen] on 6 January 2016 and Document FLE0599, electronic messaging between [Aspen Employee 3] and [Aspen Employee 1] dated 21 April 2017 where [Aspen Employee 1] stated that he had planned £[✂] per pack of 100 tablets for the debranded Cold Storage Fludrocortisone.

Figure 9: Average monthly selling price and annual volumes of Aspen's and NHS Fludrocortisone Acetate Tablets (on a yearly basis, 2014-2018)



Source: Document FLC1836 Aspen's response to question 1 of the CMA's section 26 notice dated 19 April 2018; Document PD0012, PCA data for England; Document PD0028, PCA data for Wales; Document PD0029, PCA data for Northern Ireland for months January 2014 to March 2018; Document PD0030, PCA data for Scotland for financial years 2014/15 to 2017/18.
Notes:
[1] NHS England Reimbursement Prices are based on NHS England's PCA data for the period January 2014 to March 2018.
[2] 2018 data:
(a) For Aspen, the data relate to the months January to March only.
(b) For the NHS, the data relate to months January to March from England, Wales, Scotland and Northern Ireland. Data from Scotland is not yet available for the financial year 2018/19.
[3] Aspen's volume data for 2014 start from November 2014 when it purchased the Florinef MA from BMS.
[4] Aspen monthly ASP for February 2018 is excluded from graph as Aspen made no sales. Aspen noted: [✂]. Document FLC1836 response to question 1, Aspen's response to the CMA's section 26 notice dated 19 April 2018.

6.56. Aspen's prices since the conclusion of the SDA have been substantially higher than before:

(a) In the period from March 2016 to June 2017, the monthly ASP remained stable around £0.87 per tablet.[465] While the List Price and ASP were reduced to c. £0.45 and £0.40 per tablet respectively in July 2017, this is still c. 800% higher than the price until the end of February 2016.

[465] From March 2016 to April 2017, the monthly ASP continued to fluctuate between £0.85 and £0.90 per tablet (an increase of 1833% from £0.05 per tablet in November 2014). It reached a peak of £0.89 in July 2016. This is a price increase of 1883% from £0.05 per tablet in November 2014. Its ASP fell to £0.76 per tablet in May 2017, before increasing to £0.84 again in June 2017.

(b) This increase more than offsets any loss in volumes that followed the price increase of March 2016 (around 50% of Aspen's sales), making Aspen's strategy highly profitable, including after the price decrease of July 2017.[466] The loss of volumes related to loss of sales to veterinary users (which, as discussed at paragraph 6.21, would have likely happened regardless of the price increase, albeit at a slower pace) and to parallel exporters, as well as to the growth of parallel imports.

6.57. Internal Aspen evidence contemporaneous to the decision to reduce its ASP in July 2017 only shows concerns linked to possible adverse publicity or regulatory intervention following the previous price increases (see paragraphs 4.162 and 4.163). That evidence does not contain any clear reference to:

(a) a change in Aspen's cost basis;[467]

(b) concerns within Aspen relating to competitive constraints or changes in market conditions; or

(c) a strategy to re-gain volumes sold to veterinary users[468] or for export.[469]

III. Other relevant factors in assessing Aspen's market power

6.58. In assessing the existence and degree of market power, the CMA considers relevant evidence from all indicators in the round.[470] In addition to market shares, pricing behaviour and financial performance, the CMA considers factors that contribute to, and provide further indicators of, an undertaking's significant market power such as barriers to entry and expansion and the absence of countervailing buyer power.

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[466] Aspen sold more than 30 million tablets in 2015. The total number of tablets sold by Aspen in 2016 fell by roughly 50 per cent to just under 15.4 million tablets vis-à-vis 2015, then remained stable in 2017 at roughly 15.9 million tablets. The actual Supply Price paid by Aspen to Tiofarma in this period decreased to €[✂] under the SAA, resulting in a lower cost of sales and higher gross profit. (Document FLC1874, Aspen's response to question 4 of the CMA's section 26 notice, dated 25 May 2018).

[467] While Aspen no longer paid, following the SAA, a supply price to Amilco including a 30% share of the ASP, it had paid a purchase price reflecting that expected share of profit. (see Document FLC1530, [External Consultant 1]'s response to question 3a of the CMA's section 26 notice dated 19 April 2018 and Document FLC1533 (*Fludrocortisone* [Healthcare Business Consultants] *workings*)).

[468] Document FLC1834 and Document FLC1496, response to question 16, Annex 1A, Aspen's response to the CMA's section 26 notice dated 28 February 2018.

[469] Aspen was aware in devising its strategy to increase prices that it would lose export volumes. There is no indication that Aspen sought to regain these volumes subsequently. See Document FLE0134, email from [Aspen Employee 11] to [Aspen Employee 1] and [Consultant to Aspen] dated 6 January 2016 headed '*Fludrocortisone generic ambient 06012016.xslx*'; and Document FLE0135, spreadsheet attached to the same email named '*Fludrocortisone generic ambient 06012016*'; Document FLC1834 and Document FLC1496, response to question 26, Annex 1A, Aspen's response to the CMA's section 26 notice dated 19 April 2018.

[470] *Assessment of market power guidelines*, OFT415, paragraph 3.6.

a. Assessment of barriers to entry

6.59. An undertaking with a large market share in a market protected by significant barriers to entry and/or expansion is likely to have market power.[471] The notion of barriers to entry does not require that barriers are absolute in order to include them in the assessment of the existence of market power. The analysis of barriers to entry includes factors affecting timely and sufficient entry, and factors increasing or decreasing the likelihood of entry.

6.60. In order for potential competition to effectively constrain an undertaking, entry would need to have the potential to occur on a timely basis.[472]

6.61. Any company seeking to supply the Relevant Market directly would need to develop[473] and obtain regulatory approval for a new bio-equivalent Fludrocortisone Acetate Tablets product. This is because there is no Fludrocortisone Acetate Tablet product licensed outside the UK which could be licensed in the UK through the simplified procedure.[474,475]

6.62. The evidence on the CMA's file concerning the development of a new Fludrocortisone Acetate Tablets product (and obtaining an MA) shows that this would require material investment and resources which may act as a (not insurmountable) barrier to entry:[476]

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[471] *Assessment of market power guidelines*, OFT415, paragraphs 5.3 to 5.7.
[472] *Assessment of market power guidelines*, OFT415, paragraph 5.31.
[473] The steps to develop, manufacture a generic drug and obtain any necessary regulatory approval are described in paragraphs 3.43 to 3.48. As noted in that section, it is also possible for potential entrants to gain access to an existing product in the UK.
[474] Tiofarma confirmed at interview that none of the products sold in other EU jurisdictions could easily be used as a basis to obtain an MA in the UK. With regard to the ability to use MAs in other jurisdictions as the basis for applying for a UK MA, [Tiofarma Employee 1] stated '*…the reference products in all these different countries -- none of them are up to today's standards. So, you can't refer to a product that is not up to today's standards unless it's national, unless it's in your own country.*' Document FLC4907, page 145, line 6 to line 9, Transcript of interview with [Tiofarma Employee 1] on 24 July 2018.
[475] The simplified procedure for obtaining an MA in relation to Fludrocortisone Acetate Tablets may only be followed by a company that already holds a bioequivalent product. Not having access to the simplified procedure imposes material delays and costs. See Document FLC1834 and Document FLC1496, response to question 31, Annex 1A, Aspen's response to the CMA's section 26 notice dated 19 April 2018; Document FLC2074.2, response to question 29, Annex 1A, Tiofarma's response to the ACM's request for information dated 10 October 2017.
[476] It is worth noting that the development of any product is time consuming. [Company 2] told the CMA that, in general, developing a new generic product is a lengthy process, noting that developing a dossier in relation to the relevant product would usually take around two years, with the necessary regulatory approvals to supply that product in the UK market usually taking a further two years to obtain. [Company 2] did not point to any factor relating to Fludrocortisone Acetate Tablets, which would make its development or approval easier or quicker. Document FLC2045, response to question 8, Annex 1A, [Company 2]'s response to the CMA's section 26 notice dated 7 June 2018. See also paragraphs 3.43 to 3.48.

(a) it took Tiofarma three years to finalise the development of Ambient Storage Fludrocortisone and obtain an MA following the revival of its efforts, together with [Pharmaceutical Company 2], in 2012 (see paragraph 4.9 to 4.10); and

(b) Tiofarma submitted that the development of a generic formulation of fludrocortisone could cost at least €[✂] and possibly more than €[✂][477] (approximately £[✂] to £[✂]);[478] Aspen estimated that such a development process would cost in the region of $[✂][479] (approximately £[✂]).[480]

6.63. The fact that no new MA has been granted by the MHRA to supply the relevant product in the UK, despite ASPs substantially exceeding manufacturing costs, is consistent with a finding that the investment (and related risk) required to enter the market may act as a (not insurmountable) barrier to entry.[481]

6.64. Until the implementation of the Commitments, the only meaningful risk of entry Aspen has faced since November 2014 was presented by the MA for Ambient Storage Fludrocortisone. As discussed in paragraphs 8.53 to 8.89, the CMA concludes that, prior to the SDA, Amilco and Tiofarma, working together, had real concrete possibilities to enter the Relevant Market independently and within a relatively short timescale. However, Aspen neutralised this threat by entering into the SDA. The emergence of a potential competitor therefore did not in practice undermine Aspen's significant market power.

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[477] Document FLC2074.2, response to question 30, Annex 1A, Tiofarma's response to the ACM's request for information dated 10 October 2017.
[478] Using exchange rate for November 2017 of 1.1183. See Document PD0035, HMRC – Guidance – November 2017: monthly exchange rates.
[479] Aspen suggests that purchasing the intellectual property and know-how (eg from a company with an MA in another EU country) would cost in the region of [✂], and that it would take six months to convert to a UK registration. Document FLC1837, response to question 33, Document FLC1834 and Document FLC1496, response to question 31, Annex 1A, Aspen's response to the CMA's section 26 notice dated 19 April 2018. Aspen did not explain why the cost of purchasing the IP would be significantly higher than that for developing it. As set out in paragraph 4.146, the cost paid by Aspen to Tiofarma for its MAs was inflated as it was based on an upfront payment equivalent to the profit share element of the SDA that would have been paid over the remaining SDA period.
[480] Using exchange rate for May 2018 of 1.4234. See Document PD0036, HMRC – Guidance – November 2017: monthly exchange rates.
[481] Document FLC0028.1 and its attachment Document FLC0036.2 (FLUDROCORTISIONE2), MHRA's response to question 1 of the CMA's section 26 notice dated 3 May 2017. No MA was granted during the period of May 2017 to March 2018. See Document FLC1126, MHRA's response to question 4 of the CMA's section 26 notice dated 28 February 2018. See also www.mhra.gov.uk/spc-pil/.

6.65. Aspen's internal documents show that, having secured worldwide rights over Ambient Storage Fludrocortisone, entry was not expected to be likely for at least two years, or to have a material effect for three years (despite the far higher price of Fludrocortisone Acetate Tablets).[482] These forecasts reveal that Aspen perceived it would be able to behave independently of competitors for at least that period.

6.66. As discussed in paragraph 8.154, in agreeing the SAA the Parties discussed the risk of entry before the end of the initial period of the SDA, which would have undermined Aspen's ability to maintain the forecast volumes and price. Aspen recognised that this risk was low, as shown by the board paper prepared for the meeting at which Aspen decided to enter into the SAA.[483]

b. Countervailing buyer power

6.67. An undertaking which would otherwise have significant market power may find its market power is effectively constrained, in practice, by countervailing buyer power.[484] For this to be the case, it is not enough for a buyer to have some countervailing power, the relevant question is '*not just the presence or absence of* [such power], […] *but the* ***degree*** *of such* [countervailing buyer power] *and the extent to which it operated as a constraint on* [the undertaking]'*s ability to exert market power*'.[485]

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[482] For example, an internal Aspen email states that '*due to the price increase we have obtained, we are expecting generic competition (in reality 18-19 and 19-20) may look even worse as always it depends upon timing and how many which at the moment is a bit of a guess*.' Document FLE0486, email chain between [Aspen Employee 2] and [Aspen Employee 15] dated 17 November 2016. That generic entry was expected but uncertain is further supported by other contemporaneous evidence. For example, an email following the price increase notes '*38,000 units is roughly what we are seeing in April / May – however we are also starting to see some PI in the UK and it is a question as to how soon a competitor enters, as at the new price the product is very attractive*'. Document FLE0339, Email from [Aspen Employee 2] to [Aspen Employee 28] and [Aspen Employee 10] dated 16 May 2016, headed '*RE: Budget volume alignment*'. Document FLE0456 Aspen Board paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016.

[483] Document FLE0456 Aspen Board paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016.

[484] *Assessment of market power guidelines*, OFT415, paragraphs 6.1 to 6.4. See also *Genzyme Limited v Office of Fair Trading* [2005] CAT 32, paragraph 243. Compare C-457/10 P *AstraZeneca v Commission*, EU:C:2012:770, in which the intervener's arguments that the State's monopsonist power and framework of price regulation constrained AstraZeneca's market power were dismissed in light of the strong presumption of dominance that its market shares and pricing established, paragraphs 177 and 181.

[485] *National Grid v Gas and Electricity Markets Authority* [2009] CAT 14 at paragraph 60: '[…] *"*[T]*he right question is not the binary one of whether CBP* [countervailing buyer power] *exists or not. In other words, it is not enough to ask whether there is CBP, and if so to hold that there cannot be* [dominance]*. CBP is the power of counterparties to offset the powers of the party whose allegedly superior powers are under consideration, and the important question is what degree of CBP is there, and (bearing in mind all the circumstances) does it operate to a sufficient extent so as to mean that there is no* [dominance]*? CBP is not an absolute concept in terms of its strength. It is a concept which embodies a possible range of strengths. In any case where it is relevant, the relevant question is likely to be not whether there is CBP or not, but whether there is any CBP, and if so how much and to what effect does it have* […]"*'*. See also *Flynn Pharma and Pfizer v Competition and Markets*

6.68. The assessment of countervailing buyer power is '*an assessment of how the market actually operates (or is likely to operate) on the true facts, not on artificial "facts" or partial facts*'. Any potential constraint '*must be viewed realistically and for what it is'; it turns on 'the actual relationship between buyer and supplier in practice*'.[486]

6.69. In the context of pharmaceutical markets, the ultimate buyer of drugs is the NHS. The DHSC, which is responsible for the NHS, holds certain powers to intervene in drug pricing. However, the potential for economic regulation is not a competitive constraint in itself.[487] The CAT, Court of Appeal, European Commission and European Courts have consistently held, in the pharmaceutical sector and in other sectors, that the prospect of '*regulatory'* intervention does not negate the possibility of significant market power.[488]

6.70. In the specific context of DHSC powers to intervene in drug pricing under the NHS Act, the CAT confirmed that it is not necessary when assessing market power to decide the precise extent of the DHSC's powers as a question of

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Authority [2018] CAT 11, paragraph 203: '*to be an effective constraint on behaviour the buyer in question must not only have the theoretical capability of exercising countervailing pressure on suppliers but there has to be a real possibility that this pressure will be exercised in practice and to a sufficient extent.'*

[486] *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, paragraphs 105(i), 110(c) and 126.

[487] *Assessment of market power guidelines*, OFT415, paragraph 3.4.

[488] In *Hutchison 3G (UK) v Office of Communications* [2005] CAT 39, the CAT agreed with Ofcom that '*a potentially regulated person cannot claim that it does not have* [significant market power] *because regulation has procured a situation in which it no longer has it*' and went on to hold that '*the possibility of regulation being brought to bear on H3G is a factor that cannot be prayed in aid by H3G as militating against its having* [significant market power]*'*. As *'a form of regulation'*, potential intervention by Ofcom was *'to be disregarded as a matter of principle*' in the assessment of Hutchison's market power (paragraphs 98 to 99 and 138(b)). In *Hutchison 3G v Ofcom* [2009] EWCA Civ 683, the Court of Appeal held consistently that: '*A question as to how an undertaking would operate on a market cannot be answered, in this context, by saying that it would behave in a way that would comply with the regulatory controls that might be imposed on it if it did not. That would result in a regulatory system being self-defeating. Its existence would mean that the mischief which it exists to deal with would be found not to be present because of the very existence of the system*' (paragraph 61). See also *National Grid v Ofgem* [2009] CAT 14, paragraph 80; *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* (Case No. 1001/1/1/01), paragraphs 153 to 155 and 168. In Case AT.39612 *Perindopril (Servier)*, the European Commission rejected Servier's argument that '*both the prices of patent protected products and of generics are regulated and consequently cannot be relied upon to establish a dominant position*', noting that '*Dominance is an objective notion. A source of market power may be important in explaining how that market power came into being but is immaterial as to the question of its presence or absence*' (footnote 3356). Similarly, in C-280/08 P *Deutsche Telekom AG v Commission*, EU:C:2010:603, Deutsche Telekom argued that because of the framework of price regulation in which it operated, it could not have abused its dominant position (it did not dispute dominance). The General Court and Court of Justice rejected its argument that this meant it could not abuse its position, the Court of Justice finding that '*regulation did not in any way deny* [Deutsche Telekom] *the possibility of adjusting its retail prices* […] *or, therefore, of engaging in autonomous conduct that is subject to Article* [102]*'* (paragraph 84). It further stated that '*the mere fact that the appellant was encouraged by the intervention of a national regulatory authority such as RegTP* [the regulator] *to maintain the pricing practices which led to the margin squeeze of competitors who are at least as efficient as the appellant cannot, as such, in any way absolve the appellant from responsibility under Article 82 EC*' (paragraph 84). The Court of Appeal has also confirmed that '*the failure of the Department to exercise any powers it may have had could not have absolved the appellants from their "special responsibility not to allow their conduct to impair genuine undistorted competition"*'. *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey, dated 17 December 2018.

statutory interpretation or otherwise.[489] The question is instead whether the DHSC was, as a matter of fact (in the particular case) able to exercise buyer power in the form of regulatory power materially to influence pricing.[490] In its order refusing permission for Pfizer to appeal the judgment in *Phenytoin*, the Court of Appeal confirmed that:

'the CAT was clearly entitled to conclude that it did not need to decide the precise extent of the Department of Health's powers and to find that the Department had no effective means to limiting the appellants' prices. Both the case law and common sense show that the focus should be on whether there is an effective constraint rather than the theoretical position'[491]

6.71. As explained in paragraphs 6.54 to 6.57, Aspen was able to increase its ASPs for Fludrocortisone Acetate Tablets by over 1,800% in March 2016 (and even after reducing prices following the SAA, still charge prices c. 800% higher than the price until the end of February 2016), despite low and stable costs.

6.72. The CMA finds that neither the NHS (including CCGs) nor the DHSC has been able sufficiently to constrain Aspen's conduct since November 2014 so as to prevent Aspen from holding and/or exercising market power in the Relevant Market. This is based on the following factors:

(a) the inability of the NHS (including CCGs) to exercise choice, in particular due to there being no substitutes to Fludrocortisone Acetate Tablets that could have been routinely prescribed by physicians (see paragraphs 6.24 to 6.25).[492] As a result, since November 2014, when Aspen became the sole UK supplier of Fludrocortisone Acetate Tablets, the NHS has had no choice but to pay the price charged by Aspen for Fludrocortisone Acetate Tablets;[493]

(b) the fragmented structure of the NHS: a series of judgments and decisions at both EU and UK level have held that national health authorities do not

[489] *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 307.
[490] *Flynn Pharma and Pfizer v Competition and Markets Authority* [2018] CAT 11, paragraph 307.
[491] Document PD0058, *Flynn Pharma Limited & Ors v Competition and Markets Authority*, Order made by the Rt. Hon. Lord Justice Newey, dated 17 December 2018.
[492] It is also relevant to note in this context that once a prescriber has written a prescription for a particular drug, the NHS has no choice but to fund the medicine dispensed against that prescription (see paragraph 3.36). See *Genzyme Limited v Office of Fair Trading* [2004] CAT 4, paragraphs 248 and 249.
[493] The CMA discussed at paragraph 6.48 the potential difficulties in continuity of supply that may arise with parallel imports, which may limit the extent to which this could be relied on exclusively as a source of supply. Moreover, as set out in paragraph 3.42 and paragraphs 3.62 and 3.63, parallel imports are not taken into consideration for the calculation of the NHS England Reimbursement Price.

have sufficient buyer power to constrain the high degree of market power that can exist in pharmaceutical markets;[494] and

(c) the limitations on the statutory and regulatory powers of the DHSC,[495] the limitations on DHSC's ability to exercise those powers in practice, and the fact that DHSC has not used those powers to set the prices of individual generic non-branded medicines since 2014 (paragraphs 3.73 to 3.75).

6.73. The CMA finds that Aspen was not constrained by countervailing buyer power at the level of its intermediate customers (wholesalers, pharmacies, CCGs) as those customers did not constitute an effective constraint so as to prevent Aspen from holding significant market power in the Relevant Market. This is because:

(a) as the sole UK supplier of Fludrocortisone Acetate Tablets, Aspen was the only choice for all of its customers other than parallel imports; and

(b) for the reasons set out above, parallel importers did not present an alternative for those customers to such a degree that they exerted a sufficient constraint to offset Aspen's market power.

[494] For instance, in *Genzyme* the CAT pointed out that '*the NHS is not a single trading entity; it is a collection of different parts which exercise different functions, and which cannot be relied upon to act as an effective counterweight to anticompetitive behaviour by drug companies*'. *Genzyme Limited v Office of Fair Trading* [2005] CAT 32, paragraph 456. For a detailed discussion of the NHS's alleged buyer power, see paragraphs 241 to 289 of that judgment. See also Commission decision of 15 June 2005 Case 37507 *AstraZeneca*, paragraph 554. This specific point was upheld on appeal by the General Court (T-321/05 *AstraZeneca v Commission*, EU:T:2010:266, paragraph 262). The same point has been made in the merger control context: for example, in *Bournemouth/Poole* the Competition Commission observed that in light of the '*split between those exercising choice and the commissioners that pay*', no party exercised a sufficient constraint to offset market power. Competition Commission (CC) *Report on anticipated merger of Royal Bournemouth and Christchurch Hospitals NHS Foundation Trust/Poole Hospital NHS Foundation Trust* (a case which postdates the NHS Act 2006). The CC noted that those who exercise choice (GPs and patients) could not be expected to act as a single entity and so were too diffuse to offset market power (see paragraph 7.2 and 7.5 of the CC's report).

[495] Until July 2018, the DHSC did not have the statutory power to require the provision of financial and cost information for generic medicines. This made it difficult for the DHSC to investigate or meaningfully assess anomalies or abuses in pharmaceutical pricing. DHSC's powers do not have retrospective effect and so could not be used to address pricing anomalies that occurred prior to these powers coming into effect (see paragraphs 3.73 to 3.75).

7. THE SDA IS AN AGREEMENT FOR THE PURPOSE OF THE CHAPTER I PROHIBITION AND ARTICLE 101 TFEU

7.1. The CMA concludes that in concluding the SDA, the Parties entered into an agreement for the purposes of the Chapter I prohibition and Article 101 TFEU, the contents of which are described in more detail below.

A. Legal framework

7.2. The Chapter I prohibition and Article 101(1) TFEU prohibit agreements between undertakings which have as their object or effect the prevention, restriction or distortion of competition and which may affect trade within the UK/between EU Member States.

7.3. An agreement is 'a *concurrence of wills between at least two parties, the form in which it is manifested being unimportant, so long as it constitutes the faithful expression of the parties' intention*'.[496]

7.4. The General Court has held that in order to establish a concurrence of wills '*it is sufficient that the undertakings in question should have expressed their joint intention to conduct themselves on the market in a specific way*'.[497]

7.5. Additionally, the Courts have defined the concept of an agreement as a '*common understanding'* between the parties - which has the same meaning as '*concurrence of wills'*. For example, in its judgment in *Hitachi*, the General Court held that: '*the Commission was right to find that the common understanding constituted an agreement between undertakings within the meaning of Article* [101(1) TFEU]'.[498]

7.6. That a party may have played only a limited part in setting up an agreement, may not be fully committed to its implementation, or may have participated only under pressure from another party, does not mean that it is not party to the agreement.[499]

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[496] T-41/96 *Bayer AG v Commission*, EU:T:2000:242, paragraph 69 (upheld on appeal in joined cases C-2/01 P and C-3/01 P *Bundesverband der Arzneimittel-Importeure eV* and *Commission v Bayer AG*, EU:C:2004:2, paragraphs 96 to 97).
[497] T-7/89 *SA Hercules Chemicals NV v Commission*, EU:T:1991:75, paragraph 256.
[498] T-112/07 *Hitachi v Commission*, EU:T:2011:342, paragraph 272.
[499] *Agreements and Concerted Practices* (OFT401), December 2004 (adopted by the CMA Board), paragraph 2.8. See also T-25/95 *Cimenteries CBR and Others v Commission*, EU:T:2000:77, paragraphs 1389 and 2557 (this judgment was upheld on liability by the Court of Justice in joined cases C-204/00 P etc. *Aalborg Portland A/S and Others v Commission*, EU:C:2004:6, although the fine was reduced); and C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, paragraphs 79 to 80.

7.7. The form of an agreement is unimportant, and in particular it is not necessary that an agreement is formal or legally binding: agreements may include written contracts, oral agreements and '*morally'* binding '*gentlemen's agreements'*.[500]

7.8. An agreement need not be entered into by the parties explicitly. An agreement may be entered into tacitly, ie the conduct of the parties may amount to an expression of their joint intention to conduct themselves on the market in a specific way. The Court of Justice held in the *Bayer* case that:

'the existence of an agreement within the meaning of that provision [Article 101(1) TFEU] *can be deduced from the conduct of the parties concerned'.*[501]

B. Application to this case

7.9. For the reasons set out below, the CMA concludes that in concluding the SDA, the Parties entered into an agreement for the purposes of the Chapter I prohibition and Article 101 TFEU.

7.10. The SDA contains the concurrence of wills between the Parties with respect to their future behaviour in the Relevant Market. Specifically, the Parties had a common understanding that:

(a) Amilco and Tiofarma would not enter that market independently by supplying Ambient Storage Fludrocortisone (or allow any third party to do so) (see Clause 6.1 of the SDA as analysed by the CMA in paragraphs 7.13 to 7.15 below); and

(b) in exchange for not entering the market, Aspen would make significant value transfers to Amilco and Tiofarma (of a pecuniary or non-pecuniary nature) (see Clauses 3.3, 10.1 and 15 of the SDA).

7.11. Aspen effected those value transfers under the SDA as follows:

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[500] C-41/69 *ACF Chemiefarma NV v Commission*, EU:C:1970:71, paragraphs 106 to 114. See also *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2004] CAT 24, paragraph 658. See also Commission Decision of 30 October 2002 2003/675/EC *Video Games, Nintendo Distribution and Omega-Nintendo*, paragraph 247.
[501] C-2&3/01 P *BAI and Commission v Bayer* [2004] ECR I-23, paragraph 100. See also T-168/1 *GlaxoSmithKline Services Unlimited v* Commission, EU:T:2006:265, paragraphs 82-83: the existence of an agreement may be established by '*indirect evidence, for example in the form of conduct*'. In T-450/05 *Peugeot v Commission*, EU:T:2009:262, paragraph 174, the General Court held that an agreement requires '*an acquiescence* […] *express or implied*'. An agreement may consist of either an isolated act, or a series of acts, or a course of conduct: in C-49/92 P *Commission v Anic Partecipazioni SpA*, EU:C:1999:356, the Court of Justice held that collusion by an undertaking may be established if '*evidence of its conduct corroborates a convergence of durations*' (paragraph 94). See also C-107/82 *AEG-Telefunken v Commission* [1983] ECR 3151, paragraph 38.

(a) By withdrawing its own Cold Storage Fludrocortisone product, Aspen made Tiofarma the sole manufacturer of Fludrocortisone Acetate Tablets for supply in the UK (see paragraphs 7.19 to 7.38 below); and

(b) Aspen agreed to share with Amilco a fixed 30% profit margin calculated on the basis of Aspen charging a List Price more than 1,800% higher than its price prior to the SDA (see paragraphs 7.39 to 7.61 below).

7.12. In accordance with their settlement letter and the terms of settlement annexed to it, Aspen, Amilco and Tiofarma have admitted the Infringement and therefore do not contest the CMA's interpretation of the agreement between the Parties, including its interpretation of the SDA.

I. Amilco and Tiofarma agreed not to enter the Relevant Market independently

7.13. Clause 6.1 of the SDA granted Aspen 'an exclusive license to use Tiofarma Data, the Trademarks and the MA to the extent required for the purposes of Commercialising the Product in the UK either itself or through its nominated Affiliate.'[502] The Product is defined pursuant to Clause 2.2.2.27 and Annexure B of the SDA as 'Fludrocortisone (for human use)' sold under 'PL 17299/0001' (ie the MA for Ambient Storage Fludrocortisone obtained by Tiofarma on 9 November 2015).

7.14. That grant of exclusivity was tantamount to a commitment by Tiofarma and Amilco not to enter the Relevant Market independently from Aspen during that period: Amilco and Tiofarma were prevented, for the term of the SDA, from using the MA for Ambient Storage Fludrocortisone to supply that product independently of Aspen in the UK, and/or from facilitating market entry by another company seeking to supply Ambient Storage Fludrocortisone) in that market.[503] Indeed, aside from reliance on that MA, Amilco and Tiofarma had

[502] Document FLE0225, clause 6, page 8, Supply and Distribution Agreement between Tiofarma B.V., Aspen Global Incorporated and Amilco Limited dated 1 March 2016.
[503] The concept of exclusive licence is defined in various legislations as preventing the licensor not only to deal with third parties but also to exploit the object of the licence independently from the licensee. For instance, under the European Commission Regulation 316/2014 of 21 March 2014 on the application of Article 101(3) of the TFEU to categories of technology transfer agreements, an '*exclusive licence*' means a licence under which the licensor itself is not permitted to produce on the basis of the licensed technology rights and is not permitted to license the licensed technology rights to third parties, in general or for a particular use or in a particular territory. Similarly, pursuant to section 130 of the Patent Act 1977, an exclusive licence from the proprietor of or applicant for a patent conferring on the licensee, or on him and persons authorised by him, to the exclusion of all other persons (including the proprietor or applicant), any right in respect of the invention to which the patent or application relates, and "exclusive licensee" and "non-exclusive licence" shall be construed accordingly. See also See Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, section 12.2.5.3.

no alternative means to enter the market independently within a reasonable timeframe (as noted above, the only other MA for Fludrocortisone Acetate Tablets was held by Aspen). Therefore, while the grant of exclusivity was not described in the SDA as a non-entry or non-compete provision, it was designed to achieve this and had the desired outcome. That commitment was binding on Amilco and Tiofarma so long as Aspen fulfilled its obligations under the SDA, namely to supply exclusively Ambient Storage Fludrocortisone manufactured by Tiofarma in the UK.[504]

7.15. In line with this contractual restriction, during the period of the SDA, Amilco and Tiofarma made no attempt to commercialise Ambient Storage Fludrocortisone in the Relevant Market. Tiofarma rejected expressions of interest from several third parties concerning potential deals to distribute Tiofarma's Ambient Storage Fludrocortisone product in the UK.

7.16. The CMA therefore finds that, under the SDA, Amilco and Tiofarma agreed not to enter the Relevant Market for the duration of the agreement.

II. In exchange, Aspen made significant value transfers to Amilco and Tiofarma (of a pecuniary or non-pecuniary nature) premised on the postponement of competition

7.17. As a result of the exclusivity over Ambient Storage Fludrocortisone granted to Aspen under the SDA, competition between the Parties was prevented for the duration of that agreement: Aspen would retain its market position as the sole UK supplier of Fludrocortisone Acetate Tablets because Amilco and Tiofarma had agreed not to enter the market independently or to facilitate entry by a third party (as explained in paragraphs 7.13 to 7.16).

7.18. The CMA finds that, in exchange, Aspen agreed to make value transfers of a pecuniary or non-pecuniary nature which were premised on the postponement of competition and constituted significant benefits to Amilco and Tiofarma. In particular, as set out below:

(a) By withdrawing its Cold Storage Fludrocortisone manufactured by Haupt and replacing it with Ambient Storage Fludrocortisone for the duration of the SDA, Aspen made Tiofarma the sole manufacturer of Fludrocortisone

[504] Clause 4 of the SDA. Pursuant to Clause 4.2 of the SDA, any party had the right to terminate the agreement at the end of the initial three-year period provided that it gave at least six months' notice to the other party. According to Clause 27.1 of the SDA, Amilco and Tiofarma could not have unilaterally terminated the SDA prior to the end of the initial 3-year period of the contract (except in case of a material breach of contract by Aspen).

Acetate Tablets in the UK, as Aspen ceased to supply Cold Storage Fludrocortisone in the UK (see below paragraphs 7.19 to 7.38); and

(b) Aspen agreed to share with Amilco a fixed 30% profit margin calculated on the basis of a List Price (ie £1 per tablet) more than 1,800% higher than its price prior to the SDA (ie around £0.05 per tablet). More specifically:

1. All Parties had a common understanding that Aspen would significantly increase its prices for Fludrocortisone Acetate Tablets at launch (ie more than 1,800% higher than the price prior to the SDA) (see below paragraphs 7.42 to 7.44); and
2. Aspen and Amilco further understood that the payments Aspen would make to Amilco would be a fixed amount calculated on the basis of that increased price for the term of the SDA, ie that Aspen would pay £[✂] per pack to Amilco (see paragraphs 7.39 to 7.61).

a. Tiofarma was made the sole manufacturer of Fludrocortisone Acetate Tablets for supply in the UK

7.19. For the reasons set out below, the CMA finds that the Parties had a common understanding that, for the duration of the SDA, Aspen would purchase all of its requirements for Fludrocortisone Acetate Tablets from Tiofarma, ie that it would withdraw Cold Storage Fludrocortisone from the UK market. As a result, Aspen would supply exclusively Ambient Storage Fludrocortisone supplied by Tiofarma in the UK for the duration of that agreement. This commitment is reflected in Clauses 15.2 and 15.3 of the SDA, as negotiated, understood and implemented by the Parties.

7.20. Given that Aspen was the sole UK supplier of the product and that Tiofarma would therefore at once become the manufacturer for the total UK market, Aspen's commitment in this regard constituted a significant benefit to Tiofarma.

i. Aspen's contractual obligations

7.21. Clause 15 of the SDA ('*Commercialisation obligations of Aspen*') required Aspen to buy minimum supply volumes of Fludrocortisone Acetate Tablets from Tiofarma (the 'minimum supply obligation').

7.22. Specifically, the following key sub-clauses establish Aspen's minimum supply obligation for Ambient Storage Fludrocortisone:

(a) Clause 15.3 of the SDA committed Aspen to 'purchase a minimum sales quantity of 90% (ninety percent) of the minimum sales quantity recorded in Annexure C (as amended from time to time pursuant to clause 15.2) for any six month period (the first such period being 1 September 2016 to 28 February 2017).'[505] Clause 15.3 further provided that if the Parties were unable to agree on the minimum sales quantity for a given period, this would then be calculated, absent third-party entry, as 100% of the sales of Ambient Storage Fludrocortisone in the previous period (and 70% in the event of third-party entry).

(b) Clause 15.2 stated that 'the Parties shall, at least 60 (sixty) days prior to 1 September 2016, start discussions to agree the minimum sales quantity for the period 1 September 2016 to 28 February 2017. Thereafter the cumulative sales quantity for the following 6 month period shall be mutually agreed by Amilco and Aspen acting reasonably and in good faith. After the meetings contemplated above, Annexure C shall be updated accordingly from time to time.'

(c) Clause 15.2 also specified that the minimum sales quantity would be based on 'the latest PCA (Prescription Cost Analysis) data for England, Scotland and Wales and Northern Ireland, IMS data and Aspen's actual sales of the Product (being defined as Ambient Storage Fludrocortisone) for the previous six month period, and shall take into account the impact of any Competing Products including products imported into the [UK] for sale in the [UK]. Aspen shall provide Amilco with a suggested sales quantity 60 (sixty) days prior to the commencement of all following 6 month periods and the parties shall settle and agree same by no later than the day immediately preceding the commencement of the relevant 6 month period.'

7.23. Annexure C to the SDA (replicating Schedule 2 of the Term Sheet), which formed the basis of the minimum sales quantity obligation contained in Clause 15.3, provided as follows:

		Volume Packs
2016	*Mar-16*	*0*

[505] Under an initial draft version of the Term Sheet, this obligation was intended to apply from the commencement date. However, that obligation was delayed by six months due to uncertainties about the relevance of Aspen historical sales data (paragraph 4.68). To mitigate that uncertainty, the Parties put in place monitoring mechanisms that would enable them to adapt Aspen's obligations to purchase Ambient Storage Fludrocortisone in line with the realities of the market following the price increases (see paragraphs 4.130 to 4.133).

2016	*Apr-16*	*38 000*
2016	*May-16*	*62 202*
2016	*Jun-16*	*62 202*
2016	*Jul-16*	*52 000*
2016	*Aug-16*	*52 000*
2016	*Sep-16*	*45 000*
2016	*Oct-16*	*45 000*
2016	*Nov-16*	*45 000*
2016	*Dec-16*	*45 000*
2016	***10 mths***	***446 404***

7.24. The average of the 10 months for which volumes were provided in Annexure C was around 44,640 packs/month. By comparison, the average number of Fludrocortisone Acetate Tablets dispensed monthly by the NHS (ie for human use) in the UK was approximately 44,334 packs of 30 tablets in 2014 and 46,699 packs of 30 tablets in 2015 (see Section 4.F.III and Figure 7). It follows that this number broadly represented the historic average of Aspen's total sales of Cold Storage Fludrocortisone for human use in the UK.

ii. Aspen's commitment to supply exclusively Ambient Storage Fludrocortisone in the UK

7.25. As set out in this section, the CMA finds that:

(a) under Clause 15.3 of the SDA, Aspen had agreed to a minimum supply obligation requiring it to purchase at least 90% of its total requirements for Fludrocortisone Acetate Tablets in the UK from Tiofarma as from September 2016.

(b) In reality, the Parties' common understanding was that Aspen's minimum obligation went further, as they entered into the SDA on the basis that Aspen would withdraw its Cold Storage Fludrocortisone from the UK market and replace it entirely with Ambient Storage Fludrocortisone for the duration of the SDA.

7.26. As a result, the SDA ensured that Tiofarma would be made the sole manufacturer of Fludrocortisone Acetate Tablets for the UK market and not just the manufacturer of 90% of Aspen's requirements for the product. It also meant that Amilco's profit share margin would be calculated on all volumes of that product sold in the UK by Aspen (see below).

7.27. This common understanding was reflected in the clauses of the SDA as negotiated, understood and implemented by the Parties.

Aspen was contractually bound by the 90% minimum supply obligation

7.28. The following evidence shows that the Parties at the very least understood that Aspen was bound by the commitment set out on the face of the SDA (in Clause 15.3) to purchase as a minimum 90% of its total requirement for Fludrocortisone Acetate Tablets from Tiofarma:

(a) On 23 February 2016, [Tiofarma Employee 1] stated in an email to [Person 1 acting for Amilco] commenting on the draft SDA: '*15.3 – the 90% defines where Aspen is allowed to commercialize a competing product*'.[506] The CMA infers that '*competing product*' includes Cold Storage Fludrocortisone, the only alternative version of Fludrocortisone Acetate Tablets that existed at the time; and

(b) In interview with the CMA, [Person 1 acting for Amilco] made clear that Aspen's commitment to purchase 90% of its total requirements for Fludrocortisone Acetate Tablets from Tiofarma was in recognition of the exclusivity the SDA offered Aspen.[507] [Person 1 acting for Amilco] therefore acknowledged that Amilco and Tiofarma were willing to grant Aspen exclusivity over Ambient Storage Fludrocortisone, but only if that meant that Aspen would acquire as a minimum 90% of its requirements from Tiofarma.

7.29. For the reasons set out in paragraphs 4.127 to 4.133 above, the Parties were not able to reach an agreement upfront on the '*minimum sales quantity*', that is the exact volumes that should be included within Annexure C (and which would thus form the basis of the 90% minimum supply obligation in Clause 15.3). Nonetheless, the terms of the SDA still required Aspen to procure as a minimum 90% of its requirements for the product from Tiofarma, subject to the following provisions specifying when that requirement would apply:

(a) Aspen's minimum supply obligation set out in Clause 15.3 was delayed to 1 September (ie six months into the initial three-year period of the SDA)

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[506] Document FLC3307, email from [Tiofarma Employee 1] to [Person 1 acting for Amilco] dated 23 February 2016, headed *'aspen agreement'*.

[507] '*I think the reason why that* [minimum sales quantity clause] *was there is because they insisted on an exclusivity from us'.* Document FLC1666.2, page 94 lines 6 to 7, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017. He further confirmed: '*We were tied in to supply only* [Aspen]. *So we need some sort of assurance of some sort of commercial value to this contract. So the minimum requirements were there*'. Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 101, lines 8 to 11.

(however, in practice Aspen had already started purchasing all its monthly requirements of Fludrocortisone Acetate Tablets in February 2016, even prior to the entry into force of the SDA in March 2016 (see paragraph 4.92 to 4.95), thus easily meeting the 90% minimum supply obligation); and

(b) under Clause 15.2, the Parties were due to further negotiate and revise the minimum supply obligations that would apply in each relevant period in light of the latest available market data[508] (the volumes provided in Annexure C did not cover the entirety of the first mandatory six-month period – ie 1 September 2016 to 28 February 2017 – for the purposes of Clause 15.3).

In reality, Aspen had committed to supply exclusively Ambient Storage Fludrocortisone in the UK from the beginning of the SDA

7.30. However, the Parties' common understanding was that Aspen's minimum supply obligation went further than a requirement to buy only 90% of its total requirement for Fludrocortisone Acetate Tablets in the UK. Indeed, the Parties entered into the SDA on the basis that for the duration of the SDA, Aspen would withdraw its Cold Storage Fludrocortisone from the UK market and replace it entirely with Ambient Storage Fludrocortisone supplied by Tiofarma.

7.31. This is clear from:

(a) the steps taken by Aspen prior to entering into the SDA (see paragraphs 4.91 to 4.104 and paragraphs 7.32 to 7.33 below);

(b) documentary and witness evidence relating to the negotiations of the SDA (see paragraphs 4.51 to 4.90 and 7.34 to 7.38 below); and

(c) the intentions of the Parties (see paragraphs 8.145 to 8.158 below).

7.32. The following actions taken prior to the signature of the SDA (and set out in more detail at paragraphs 4.91 to 4.104) show that the Parties understood at the time of entering the SDA that Aspen had no plans to continue selling Cold Storage Fludrocortisone in the UK (subject to Tiofarma satisfying its volume requirements):

(a) First, Aspen withdrew Cold Storage Fludrocortisone from the Relevant Market in February 2016. Aspen's justification for withdrawing that product

[508] Pursuant to Clause 15.2 of the SDA, Aspen and Amilco monitored Aspen's actual sales of Fludrocortisone Acetate Tablets during the first months of the SDA in order to set the appropriate volumes. See paragraphs 4.127 to 4.133.

could only have been that it planned to purchase all of its requirements for Fludrocortisone Acetate Tablets from Tiofarma, as this was the only alternative source of Fludrocortisone Acetate Tablets for direct sale in the UK. As set out in paragraphs 4.99 to 4.104, Amilco had been actively involved in certain commercial steps leading to that withdrawal and actively monitored the progress made by Aspen as regards the regulatory steps taken for that same purpose. In practice the Parties signed the SDA on the basis of Aspen having already withdrawn Cold Storage Fludrocortisone.

(b) Secondly, Aspen placed purchase orders of Ambient Storage Fludrocortisone with Tiofarma of 400,000 packs (12 million tablets) one month after signing the Term Sheet (see paragraph 4.94), which was broadly equivalent to Aspen's forecasted total requirements (ie NHS demand for the product) of Fludrocortisone Acetate Tablets for the first nine months of the SDA (as set out in the Term Sheet and Annexure B of the SDA). It was clear from these two steps taken by Aspen that it would no longer sell Cold Storage Fludrocortisone from March 2016.

7.33. This in turn meant that Aspen's minimum supply obligation under Clauses 15.2 and 15.3 after the initial six-month period (and therefore in subsequent periods) would be calculated on the basis of all sales of Fludrocortisone Acetate Tablets by Aspen in the Relevant Market, thereby contractually binding Aspen, and protecting Amilco's and Tiofarma's position.[509]

7.34. This is consistent with documentary and witness evidence relating to the negotiations of the SDA:

(a) When asked by the CMA about Clause 15.3 in interview, [Aspen Senior Executive 1] explained that [Person 1 acting for Amilco] made a demand for '*100 per cent of the volumes*'. [Aspen Senior Executive 1] explained that he did not see any reason not to accept this request and that agreeing to exclusivity would give [Person 1 acting for Amilco] comfort that Aspen was committed to making the transaction work.[510]

(b) contemporaneous documents relating to the negotiations of Clauses 3.3 (see paragraphs 4.78 to 4.90, and above) reveal that the Amilco had

[509] Pursuant to Clause 15.2 of the SDA, the minimum supply obligation was to be calculated on the basis of sales of Ambient Storage Fludrocortisone as recorded by Aspen, IMS and PCA data, excluding parallel imports. Following the withdrawal of Cold Storage Fludrocortisone, such sales would necessarily have to be equivalent to Aspen's total supply in the UK.
[510] Document FLC4905, page 21, lines 3 to 9, and page 22, lines 21 to 22, Transcript of interview with [Aspen Senior Executive 1] on 14 May 2018.

sought to restrict contractually Aspen's ability to procure products other than Ambient Storage Fludrocortisone, provided that Tiofarma could satisfy Aspen's volumes requirements (this restriction was not included in the final version of the SDA due to legal and regulatory concerns, as set out at paragraph 7.37 below):

1. In a comment on the draft SDA, an external lawyer acting for Amilco set out that Amilco's commercial position was for Aspen not to be entitled to market Cold Storage Fludrocortisone for the duration of the SDA unless Tiofarma materially failed to supply the product to Aspen.[511]
2. An email from [Aspen Employee 12] of Aspen to [Person 1 acting for Amilco] of 12 February 2016 (see paragraph 4.85) also shows that Aspen did not have any objections to an agreement in principle that the right for Aspen to sell Cold Storage Fludrocortisone would only apply in the event that Tiofarma failed to supply Aspen with sufficient volumes of Ambient Storage Fludrocortisone to meet the demand in the Relevant Market.[512]
3. [Person 1 acting for Amilco]'s reply to that email from [Aspen Employee 12] of Aspen shows that Amilco was content to maintain Aspen's right to commercialise Cold Storage Fludrocortisone (or in fact any alternate fludrocortisone product) in those limited circumstances only.[513]

7.35. The CMA's findings that Aspen had agreed to an obligation to purchase all of its requirements for Fludrocortisone Acetate Tablets from Tiofarma as a result of Clause 15 is not undermined by the fact that Aspen and Amilco were unable to reach an agreement upfront on the exact volumes that should be included within Annexure C (and which thus form the basis of the 90% minimum supply obligation in clause 15.3 - see paragraph 4.67 to 4.68

[511] Document FLE1811, email from [Assistant to Person 1 acting for Amilco] to [Aspen Senior Executive 2] and [Aspen Employee 12] dated 8 February 2016 and Document FLE1812, draft SDA annotated 'Amilco mark up 8 February 2016': *'For discussion, Amilco's position is that Aspen should not be entitled to market their competing product while acting as exclusive distributor for the Tiofarma product unless Tiofarma materially fails to supply the Product to Aspen.'*

[512] This was reflected in Aspen's proposed wording for Clause 3.3, following a conversation with [Person 1 acting for Amilco]: *'For the avoidance of doubt Aspen, its Affiliates and/or any Third Party nominated by Aspen shall be entitled to Commercialise its own branded pack of the Product in the Territory or any part or parts thereof in the event that Amilco and/or Tiofarma is unable to fulfil its supply obligations in terms hereof.'* Document FLC1143.170, email chain between [Person 1 acting for Amilco] and [Aspen Employee 12] dated 12 February 2016.

[513] FLE0903, email from [Person 1 acting for Amilco] to [Aspen Employee 12] dated 12 February 2016. '*So if Tio are unable to fulfil its supply obligations Aspen can seek alternative supplies for Fludrocortisone 100mcg tablets until Tio resume supplies. How does this sound?*'

above). Indeed, this disagreement merely reflected the uncertainty of future volumes. Specifically:

(a) At the time of entering into the SDA, there was genuine uncertainty as to the size of the loss of volumes that would follow the planned price increase of Fludrocortisone Acetate Tablets. (That expected loss of volumes (which materialised) was down to demand from veterinary users and parallel exporters diminishing.)

(b) During the negotiations phase, Amilco and Aspen made some estimates about the size of NHS demand, and had conflicting incentives in that regard: Amilco wanted to secure the highest possible volumes (at least all NHS demand) for its own product, whereas Aspen needed to ensure that such volumes did not exceed its actual needs for the first six months (as, if that had been the case, it would have effectively committed to purchase more product than it could sell in that period and over the periods that follow).[514]

7.36. The revision to Clause 15 (specifically its delayed implementation) neutralised Aspen's risk of contractually committing to a fixed volume exceeding actual demand in initial period (which would have been the case had it overestimated NHS demand). However, it was clear from the steps taken by Aspen prior to entering into the SDA (as set out above at paragraph 7.32) that:

(a) for the first six months of the SDA Aspen would sell exclusively Ambient Storage Fludrocortisone (regardless of the exact volumes);

(b) as a result, after the first six months, Clause 15 of the SDA would contractually bind Aspen to a minimum supply obligation calculated on the basis of its sales of Ambient Storage Fludrocortisone (Cold Storage Fludrocortisone having been withdrawn) in the initial six-month period (see paragraph 7.33).

7.37. Similarly, the CMA's finding that Aspen had agreed to an obligation to purchase all of its requirements for Fludrocortisone Acetate Tablets from Tiofarma is not undermined by the fact that Aspen had maintained a

[514] In practice, the figures that were included in Annexure C of the SDA as an example for the initial period were very much in line with the historic average of Aspen's total sales of Fludrocortisone Acetate Tablets for human use in the UK, ie around 16 million tablets per year. They were also just above Aspen's actual sales of Fludrocortisone Acetate Tablets in 2016 (which were 15.4 million tablets in 2016), consistent with the finding that the Parties' were intending to reflect total NHS demand (excluding parallel imports).

contractual right to supply Cold Storage Fludrocortisone under Clause 3.3 of the SDA. This is because this right was effectively constrained by the minimum supply obligation, as discussed above. Moreover, contemporaneous documents relating to the negotiations of this clause reveal that the Parties had first sought to restrict contractually Aspen's ability to procure products other than Ambient Storage Fludrocortisone (as set out above at paragraph 7.34(b)). The inclusion of Clause 3.3 in its final form, without apparent restrictions on Aspen's ability to source alternatives, was the result of, on the one hand, concerns raised by Amilco in relation to competition law[515] and, on the other hand, concerns raised by Aspen relating to its duty to comply with security of supply obligations.[516] It is clear however that the inclusion of Clause 3.3 did not undermine the common understanding that Aspen would withdraw its Cold Storage Fludrocortisone in the UK and replace it entirely with Ambient Storage Fludrocortisone (provided that Tiofarma supplied sufficient quantities), in line with the minimum supply obligation set out at Clause 15.

7.38. Finally, it is also clear that Aspen's commitment to withdraw Cold Storage Fludrocortisone from the UK market and replace it entirely with Ambient Storage Fludrocortisone manufactured by Tiofarma is linked to the SDA (which is specific to the UK) rather than flowing from a global strategy. As at the date of responding to the CMA's section 26 notice in April 2018, Aspen was selling Cold Storage Fludrocortisone exclusively in all other European jurisdictions in which it sold Fludrocortisone Acetate Tablets even though it

[515] Amilco's lawyers raised concerns about the inclusion of restrictions in Clause 3.3 in relation to compliance with competition law (Document FLE1811, email from [Assistant to Person 1 acting for Amilco] to [Aspen Senior Executive 2] and [Aspen Employee 12] dated 8 February 2016 and Document FLE1812, draft SDA annotated 'Amilco mark up 8 February 2016': *'Our legal team are advising on the potential competition law implication of such an approach* [ie preventing Aspen from commercialising their own product]*'*) and eventually proposed to delete the clause entirely (in an email, [Aspen Employee 12] informed [Person 1 acting for Amilco] that [Amilco's External Legal Adviser] told her that [Amilco's External Legal Adviser]'s *'preference was to delete clause 3.3. in its entirety'.* Document FLE1852, email from [Aspen Employee 12] to [Person 1 acting for Amilco] dated 15 February 2016.

[516] [Aspen Employee 12] explained to [Person 1 acting for Amilco] that '*from a commercial perspective, Aspen does need to ensure continuity of supply to patients and so requires the right to source alternate supply in the event of non-supply by Amilco/Tiofarma*'. Document FLE1852, email from [Aspen Employee 12] to [Person 1 acting for Amilco] dated 15 February 2016.
As Clause 3.3 was nonetheless deleted in the next iteration of the draft sent by Amilco on 19 February (Document FLE1871, 'Amilco draft – 19 February 2016'), Aspen repeated on 22 February that Clause 3.3 needed to be maintained: '*This provision* [entitling Aspen to commercialise alternate product in the event that Amilco / Tiofarma is unable to fulfil its supply obligation] *stands to be retained as Aspen has an obligation to ensure continuity of supply'.* Document FLE1906, draft SDA annotated 'Aspen draft – 22 February 2016'.

acquired world-wide rights to Ambient Storage Fludrocortisone in October 2016 under the SAA.[517]

b. Amilco was paid a fixed 30% profit margin calculated on the basis of Aspen charging a List Price more than 1,800% higher than its price prior to the SDA

7.39. Pursuant to the SDA, Amilco was entitled to a 30% share of the profit from all sales of Ambient Storage Fludrocortisone by Aspen. As explained above, Aspen committed to (and did) withdraw Cold Storage Fludrocortisone from the UK and replace it entirely with Ambient Storage Fludrocortisone supplied by Tiofarma for the duration of the SDA. As a result, Amilco would effectively benefit from a 30% profit share of all of Aspen's sales of Fludrocortisone Acetate Tablets in the UK during that period.

7.40. However, that was not the full extent of the value transfers under the SDA to Amilco. As set out below, there was a common understanding between the Parties that, under the SDA Aspen would significantly increase its prices for Fludrocortisone Acetate Tablets (ie more than 1,800% higher than the price prior to the SDA) (see paragraphs 7.42 to 7.44).

7.41. Aspen and Amilco further understood that under the SDA

(a) the Supply Price, which included Amilco's 30% 'profit share', was calculated on the basis of this significantly increased price;

(b) Amilco's 'profit share' would be a fixed amount of £[✂] per pack of 30 tablets[518] for the duration of the SDA, provided no third parties entered the Relevant Market during the lifetime of the SDA.

i. Relevant terms of the SDA

7.42. Clause 10.1 of the SDA states that Ambient Storage Fludrocortisone shall be sold and supplied by Amilco to Aspen at the Supply Price as recorded in Annexure B. The Supply Price was defined in Clause 2.2.2.33 of the SDA as '*the price recorded in column 5 of Annexure B* […] *which is/are payable by Aspen for each* [pack] *of the relevant Product as supplied by Tiofarma in*

[517] In April 2018, Aspen was supplying Cold Storage Fludrocortisone in 9 other countries in the EU: Czech Republic, Denmark, Finland, Iceland, Ireland, Italy, Netherlands, Norway and Sweden. Document FLC1834, Aspen's response to question 35 of the CMA's section 26 notice dated 19 April 2018.
[518] Except in the event that Aspen increased the price discount it offered to wholesalers beyond [✂]%, in which case Amilco's share of Aspen's revenues would be increased in line with Clause 10 of the SDA.

accordance with the provisions of the Agreement, as may be adjusted by Tiofarma or Amilco pursuant to the terms in Clause 10'.

7.43. The default Supply Price set out in column 5 of Annexure B was £[✂] per pack of 30 tablets, which Aspen committed to pay to Amilco as per Clause 10.6. The default £[✂] figure was calculated as the sum of:

(a) a '*profit share element*' of £[✂], or 30% of the '*proposed'* List Price (equivalent to £30 per pack of 30 tablets, described in Annexure B as '*the Proposed retail selling price*', less a wholesaler discount of [✂]%, ie £[✂] per pack); and

(b) a '*cost of goods*' of £[✂][519] per pack of 30 tablets.

7.44. As such, the default Supply Price set out in the SDA was premised on a significant increase in the List Price for Fludrocortisone Acetate Tablets, by more than 1,800% (from around 5 pence per tablet, or £5.05 per pack of 100 tablets prior to the SDA to £1 per tablet, or £30 per pack of 30 tablets).

7.45. While the '*profit share element'* (ie the element of the Supply Price retained by Amilco, which was described in the SDA as a fixed percentage of 30%[520] of the List Price) was subject to adjustment mechanisms and therefore could have varied (see paragraphs 4.120 to 4.122), evidence set out in this section shows that in entering into the SDA, Amilco and Aspen shared a common understanding that, in return for exclusivity over Ambient Storage Fludrocortisone (ie for the postponement of competition), the 'profit share element' paid to Amilco would in fact be a fixed amount provided no third parties entered the Relevant Market during the lifetime of the SDA.[521]

7.46. This is reflected in the default Supply Price (including a profit share element of £[✂] per pack of 30 tablets for the duration of the SDA) and in the payment mechanism of the SDA, as negotiated, understood and implemented by the Parties.

7.47. The CMA relies on a body of contemporaneous evidence that shows a consistent common understanding that the List Price of Ambient Storage Fludrocortisone would be broadly equivalent to £1 per tablet during the

[519] On the assumption of a GBP/EUR exchange rate of £1=€1.35, with the figure to be converted to pound sterling at the average exchange rate prevailing in each calendar quarter.
[520] Under the SDA, the 30% profit share element of the Supply Price increases to [✂]% if Aspen grants wholesalers a discount of over [✂]% from the List Price.
[521] Specifically, Amilco and Aspen had a shared understanding that the underlying '*proposed*' List Price for Ambient Storage Fludrocortisone would be set by Aspen at around £30 per pack of 30 tablets (or £1 per tablet) and the wholesaler discount at [✂]%.

lifetime of the SDA (absent the entry of a new competitor), and therefore that the Supply Price would remain fixed. Such documents include:

(a) the initial approach document sent on behalf of Amilco to Aspen in August 2015;

(b) correspondence between Amilco and Aspen relating to the negotiations of the pricing terms of the SDA; and

(c) evidence relating to the implementation of, and compliance with, the SDA.

ii. The initial approach document

7.48. The initial approach document[522] sent by [External Consultant 1] on behalf of Amilco to Aspen in August 2015 notes that Fludrocortisone Acetate Tablets '*may be considered to be underpriced compared to similar types of* […] *products'*. It referred to [✂] and [✂][523] (which, at the time, had a List Price of around £1 and £0.80 per tablet respectively) as relevant benchmarks for Aspen to set the price Fludrocortisone Acetate Tablets in the UK.

7.49. In subsequent internal documents[524] Aspen's [✂] management referred to the benchmarks highlighted by the initial approach document, noting in particular that Cold Storage Fludrocortisone was '*underpriced*' relative to those products (see also paragraphs 4.5 to 4.8).

7.50. The initial approach document sent on behalf of Amilco, and Aspen's reference to the benchmarks referred to in that document in an internal presentation a day after receiving it, provide context to the subsequent discussions between Aspen and Amilco about the List Price. Specifically, both Parties would have been aware of the document's assertion that Aspen's Fludrocortisone Acetate Tablets were 'underpriced' relative to other higher priced medicines (that could be used as a benchmark for a price increase), and that cooperation between Amilco and Aspen could be one way of effecting that increase benefitting both Amilco and Aspen. The cover email accompanying the document was clear that if Aspen chose not to participate, Amilco would bring the product to market anyway: '*should* [Aspen] *choose not*

[522] Document FLC1531, page 5, Paper prepared by [External Consultant 2] on 21 August 2015, [Healthcare Business Consultants]' response to the CMA's section 26 response notice dated 19 April 2018.
[523] [✂].
[524] The day after Aspen was approached by Amilco, an internal Aspen presentation outlining Aspen's strategy in the UK identified Fludrocortisone Acetate Tablets as a potential priority de-branding project, and proposed to adopt [✂] Tablets as a benchmark for increasing its price: '*Florinef? Underpriced relative to value £5.05 versus* [✂]. Document FLE0087 and Document FLE0088, email from [Aspen Employee 1] to [Aspen Senior Executive 1] dated 25 August 2015. The price identified is incorrect and appears to relate to the price of [✂] tablets 10mg, correctly identified in the paper prepared by [External Consultant 2] referred to above.

to participate, it will happen anyway' (the '*it*' referring to the launch of Ambient Storage Fludrocortisone in the UK) (see paragraph 4.33).

iii. Correspondence between Amilco and Aspen relating to the negotiations of the pricing terms of the SDA

7.51. Prior to entering into the SDA, correspondence between [Person 1 acting for Amilco], [Aspen Senior Executive 1] and [Aspen Senior Executive 2] about the negotiation of Amilco's profit share shows that they consistently assumed an increase to a default starting List Price of £1 per tablet/£30 per pack, and sought to negotiate Amilco's profit share on the understanding that it would represent a fixed amount flowing from that default List Price.

7.52. First, exchanges between [Aspen Senior Executive 1] and [Aspen Senior Executive 2] in December 2015 leading to the Term Sheet show the intention – in relation to the possibility of acquiring an exclusive licence from Tiofarma – to '*lock in a gross margin*' for Aspen,[525] based on a List Price of £1 per tablet (see paragraph 8.151), thus confirming the intention to charge a List Price at that amount. Furthermore, a plain meaning of the term '*lock in a gross margin*' would be that Aspen would pay a fixed amount flowing from that List Price.

7.53. Second, the written correspondence between [Aspen Senior Executive 2], [Person 1 acting for Amilco] and [Aspen Senior Executive 1] shortly after the first conversation between [Person 1 acting for Amilco] and [Aspen Senior Executive 1] took place in December 2015 consistently referred to a *'Proposed retail selling price agreed 30 pounds per pack of 30 tablets'*.[526]

7.54. Third, when negotiating the future terms of the SDA with [Person 1 acting for Amilco] in December 2015, the value of the 'profit share element' (which became the basis for the Supply Price to be paid by Aspen to Amilco and Tiofarma) was referred to not only as a percentage, but also as a fixed amount of around [✂] per tablet (which corresponds – together with the cost of goods paid to Tiofarma – to the Supply Price of £[✂] per pack that was ultimately included in the SDA).[527]

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[525] Document FLE0968, email from [Aspen Senior Executive 1] to [Aspen Senior Executive 2] dated 14 December 2015.
[526] Document FLE0970, email from [Aspen Senior Executive 2] to [Aspen Senior Executive 1] dated 17 December 2015; Document FLC1143.13, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] dated 18 and 22 December 2016. See paragraphs 4.53 to 4.61.
[527] As set out in more detail in paragraph 4.58 above, after some initial discussions, [Person 1 acting for Amilco] requested a profit share of [✂] pence per tablet plus costs of goods (calculated as [✂]% of a pre-wholesale discount price, assumed to be [✂] pence – ie a [✂]% discount - plus the fixed price paid to Tiofarma). Aspen offered [✂] pence (that is [✂]% of [✂]p). Document FLC1143.94, email chain between [Aspen Senior Executive

(a) While in principle the terms of the SDA did not restrict Aspen from amending its discounting policy after reaching this common understanding, contemporaneous documentary evidence and witness evidence shows that Amilco's 'profit share' was protected by a contractual mechanism reflecting the shared understanding that Amilco would receive a fixed margin per pack sold by Aspen (see paragraphs 4.74 to 4.77):

(b) [Person 1 acting for Amilco] and [Aspen Senior Executive 2] agreed on a mechanism that effectively ensured that the 'profit share' paid to Amilco would remain fixed *regardless* of whether Aspen increased the discounting rate to wholesalers from the standard [✂]%.[528] [Person 1 acting for Amilco] told the CMA that the rationale behind that mechanism was to protect Amilco from changes in Aspen's discount strategy.[529]

(c) In further discussions between [Aspen Employee 1] and [Person 1 acting for Amilco] in February 2016 relating to the commercialisation of Ambient Storage Fludrocortisone, [Aspen Employee 1] noted that the trigger for a review of Aspen's discounting strategy would be the entry of a new competitor (which would lead to a discussion between parties to '*agree a discounting strategy'*).[530]

(d) Another Aspen employee, [Aspen Employee 4], reported a conversation with [Person 1 acting for Amilco] to various Aspen staff, copying [Person 1 acting for Amilco], that if an additional discount was '*necessary'*, Amilco's margin would be calculated on '*sales net of this discount'*.[531] This reveals Aspen's commitment to Amilco that, absent an event such as the entry of a new competitor, any increase in Aspen's discount would not be passed

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2] and [Person 1 acting for Amilco], dated 21 December 2015. As it was confirmed, likely following consultation with Aspen's [✂] team, that Aspen's discount policy in the UK was [✂]% (rather than [✂]% as assumed previously in the negotiations of Amilco's profit share element), Amilco and Aspen settled at [✂] pence (see Document FLC1143.13, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco] dated 18 and 22 December 2016) (see paragraphs 4.53 to 4.61). This figure is reproduced in Annexure B of the Term Sheet, which provides that the Supply Price per pack of 30 tablets is [✂].

[528] Indeed, pursuant to this mechanism, agreed by email on 22 December 2015 and included in Annexure B of the SDA, the 'profit share element' paid to Amilco was to be increased to [✂]% if the wholesaler discount applied by Aspen was increased above [✂]%. See Document FLC1143.13, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 22 December 2015. This mechanism protected Amilco's margin against increases in the wholesaler discount of up to [✂]%, and provided it with partial protection against wholesaler discounts beyond this level.

[529] Document FLC1666.2, page 89, lines 21 and 22, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017: *'They can do whatever they want to do* [with the discount] *but we have to protect our, our, our, our actual margins too'.*

[530] Document FLE0394, email from [Aspen Employee 1] to [Aspen Senior Executive 2], [Aspen Employee 4] and [Person 1 acting for Amilco] on 10 February 2016.

[531] Document FLE0394, email from [Aspen Employee 4] to [Aspen Senior Executive 2], [Aspen Employee 1], and [Person 1 acting for Amilco] on 12 February 2016.

on to Amilco, whose margin would not be adversely impacted (and whose profit share would therefore be fixed).

7.55. Furthermore, at the time the key terms of the SDA were being agreed in December 2015, [Person 1 acting for Amilco] stated to Aspen that he only considered there to be two variables in the agreement: '*the actual amount of discount to wholesalers and the exchange rate from Euro to Pounds*'.[532] Only in the final stages of the drafting of the Term Sheet, when operational details were being considered, were changes in retail selling price identified as a third variable that could affect the Supply Price to be paid to Amilco.[533]

7.56. When this third variable was included in the course of the negotiations, Amilco did not seek to obtain a mechanism to protect its margin from unilateral variations in price by Aspen.[534] This is in contrast with the protection mechanism that Amilco sought in relation to a variation of the discount (as set out above).

7.57. However, such contractual protection was not necessary given that the Parties had a common understanding that the List Price of Ambient Storage Fludrocortisone would not vary during the SDA. The absence of explicit contractual restriction on Aspen's ability to amend the List Price reflects the need to maintain Aspen's ability to react to market developments, for example in the (unlikely) event that a cheaper competitor were to enter the market, so as to pursue a pricing strategy that was in the interest of both Aspen and Amilco (due to the profit share mechanism).[535]

7.58. This evidence is therefore consistent with the CMA's finding that Aspen agreed to share with Amilco a fixed 30% profit margin calculated on the basis of a List Price (ie £1 per tablet) more than 1,800% higher than its price prior to the SDA (ie around £0.05 per tablet) and, specifically, that the payments Aspen would make to Amilco would be a fixed amount calculated on the basis of that increased price for the term of the SDA, ie that Aspen would pay £[✂] per pack to Amilco.

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[532] Document FLC1143.13, email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] dated 22 December 2015.
[533] Document FLE0156, email from [Aspen Senior Executive 2] to [Person 1 acting for Amilco] dated 13 January 2016; and Document FLC1143.13 email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] dated 22 December 2015.
[534] Document FLC1666.2, page 91, lines 1 to 4, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017: *'CMA:* [you had] *no equivalent protection on the price*. [Person 1 acting for Amilco]*: No we can't*'.
[535] See on this point Document FLC4905, [Aspen Senior Executive 1] interview with the CMA of 14 May 2018, pages 25 and 26.

iv. Evidence relating to the implementation of, and compliance with, the SDA

7.59. Contemporaneous evidence from the period after the SDA entered into force confirms that Aspen had committed to purchase all of its UK requirements from Tiofarma and Amilco for which it expected to pay a default Supply Price of £[✂] per pack (including the 'profit share element' of £[✂]):

(a) In an email to [Aspen Employee 2] dated 29 April 2016, [Aspen Employee 1] highlighted how errors in volume or ASP forecasts underpinning the SDA would affect Aspen rather than Amilco (this concern therefore reflects the fixed nature of the payments to Amilco):

'[…] *We must be clever on this – the deal gives* [Amilco/Tiofarma] *their margin up front £*[✂]*/pack. If we get this massively wrong, we will have a significant issue.'*[536]

(b) In an email of 7 November 2016 and a text message of 9 November 2016 (ie after the termination of the SDA) [Aspen Employee 1] acknowledged to [Aspen Employee 3] that Aspen's ability materially to amend its pricing strategy had been restricted during the period of the SDA. In these messages [Aspen Employee 1] sought confirmation that he did not need any longer to agree '*everything*' with Amilco and Tiofarma in relation to its pricing strategy, and '*presumed*' that this restriction had come to an end as a result of the termination of the SDA:

'[…] *The Tiopharm* [sic] *contracts* [ie the SDA] *dictates that any price change i.e. Discounts or promotional activity is "agreed between the parties" Presumably now. We have a free reign to grow further the volumes?'*

But I need confirmation I don't need to agree everything with Tiopharm [sic] *and their broker. (They didn't want to touch price when I had mentioned previously).'*[537]

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[536] Document FLE0304, email from [Aspen Employee 1] to [Aspen Employee 2] dated 29 April 2016.

[537] See further correspondence in paragraphs 4.134 to 4.140. At interview with the CMA, [Aspen Employee 1] told the CMA that in the text message, '*they didn't want to touch price'* referred to Aspen [✂] management while '*I don't need to agree everything with Tiopharm* [sic] *and their broker* [Amilco]*'* merely meant that he would no longer need to have monthly meetings with Amilco and Tiofarma. However, this correspondence implies a direct link between the SDA and a restriction imposed on [Aspen Employee 1] not to depart from the pricing strategy set out in the SDA ('*the Tiopharm* [sic] *contracts dictates* […]'), rather than a mere concern linked to the burden of a reporting obligation. Furthermore, this correspondence implies that the termination of the SDA should remove a previous restriction and give *'free reign* [sic] *to grow volumes'*. Even accepting the explanation that '*they didn't want to touch price when I had mentioned previously'* referred to Aspen's [✂] management, there is no logic supporting that such a refusal to amend the price would be linked merely to a monthly reporting obligation

7.60. Finally, evidence of how Amilco and Aspen implemented the pricing provisions of the SDA also confirms that they had in fact agreed that Aspen would pay a fixed 'profit share' (£[✂] per pack) to Amilco for the duration of the SDA:

(a) Aspen notified the NHSBSA on 23 February 2016 that Cold Storage Fludrocortisone was to be substituted by Ambient Storage Fludrocortisone at the price of £30 per pack of 30 tablets. Aspen maintained a List Price of £30 and a discount policy of around [✂]% (subject to minor variations[538] which were not picked up by any reconciliation mechanism) throughout the period of the SDA (ie from 1 March 2016 to 19 October 2016) [✂].

(b) In accordance with Clause 10.1, from 1 March 2016 until 19 October 2016 (ie the period during which the SDA was in force) Aspen paid to Amilco upon each delivery an amount equal to the agreed forecast volumes and supply price (ie £[✂] , comprising Amilco's 'profit share' of £[✂] and the 'cost of goods' of £[✂]).

(c) Amilco actively enforced Clause 7.1 of the SDA, under which Aspen had an obligation to provide Amilco with a monthly report including not only sales volume, pre-wholesale discount price and current stock availability (which was the necessary information for the calculation of volume requirements and the Supply Price), but also the gross value of Aspen's sales and level of all discounts and rebates (see paragraphs 4.127 to 4.133).

(d) Clauses 10.2 and 10.3, which set out an ex-post reconciliation mechanism to capture variations arising from a change in the pricing and volumes set out in Annexure B and reflect these variations in the Supply Price (see paragraphs 4.134), was never invoked by any of the Parties.[539]

7.61. After seven months, the SDA was superseded by the SAA (see paragraphs 4.141 to 4.149). The SAA effectively maintained Amilco's position under the

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incumbent on [Aspen Employee 1], and that the removal of that monthly reporting obligation alone would change the instructions from Aspen [✂] management. The CMA therefore considers that Aspen interpreted the SDA as imposing a restriction on its ability to pursue a pricing strategy aimed at growing volumes. Document FLC4896, Transcript of Interview with [Aspen Employee 1] on 6 December 2018, page 75, lines 4 to 13.

[538] While the discount policy varied slightly each month over the period of the SDA (within a range from [✂]% to [✂]%, with an impact on Aspen's total revenue of c. 1%) (see paragraph 4.160), such variations were ignored for the purpose of determining the value of the profit sharing element (effectively as if the [✂]% discount set out in Annexure B had been applied consistently). As a result, the reconciliation mechanism was not triggered except for exchange rate variations on the '*cost of goods*' element of the Supply Price.

[539] Clause 10.5 of the SDA, which provided a mechanism for an annual review of the Supply Price and was similarly never invoked by the Parties, was only due to be triggered for the first time in May 2017.

SDA to the extent that the purchase price paid by Aspen (which Tiofarma passed almost in its entirety to Amilco, see paragraph 4.147) was based on the expected payments that Amilco would have received for the remaining period of 29 months of the SDA (see paragraphs 4.143 and 4.146). The purchase price paid by Aspen under the SAA further supports the finding that the Parties had previously agreed that Aspen would pay a 'profit share' of £[✂] per pack to Amilco for the duration of the SDA.

8. ASSESSMENT OF THE OBJECT AND EFFECT OF THE SDA

8.1. In this section, the CMA concludes that the SDA had the object and the effect of preventing, restricting or distorting competition in breach of the Chapter I prohibition and Article 101 TFEU.[540] Aspen, Amilco and Tiofarma have admitted liability for the Infringement on the basis of a Summary Statement of Facts (for Aspen) and of the Statement of Objections (for Amilco and Tiofarma) which materially covers the CMA's assessment set out in this section.

A. The legal and economic context relevant to the SDA

8.2. This case involves the supply of Fludrocortisone Acetate Tablets, an unbranded, generic drug which has been off patent since 1971. They are therefore a homogenous, fungible commodity, such that any generic supplier that entered the market could expect to win market share if it priced competitively.

8.3. In the UK, suppliers of unbranded generic drugs, such as Fludrocortisone Acetate Tablets, are in principle free to set their prices as they choose. This approach is based on the expectation that competition will bring down prices of a drug once competitors enter, or have real concrete possibilities to enter the market within a short period of time, and compete on price.[541]

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

'Generic medicines make the drugs bill affordable and promote innovation. When an original branded drug loses its patent protection, generic equivalents are launched, typically by many manufacturers. The competition between these manufacturers drives down prices'.[542]

8.5. When multiple suppliers are active in the market, the process of competition can be expected to lead to lower prices and reduced market shares for the incumbent supplier. Usually, the only significant way for a new generic entrant to compete with the incumbent's product is on price, which in turn may elicit a response from the incumbent supplier, especially because demand for

[540] Any reference to the 'SDA' in the remainder of this document refers to the concurrence of wills contained in the SDA and described in paragraphs 7.9 to 7.10, and further detailed in the remainder of Section 7.
[541] See Document PD0053, Department of Health & Social Care - Health service medical supplies (costs) bill factsheet.
[542] See Document PD0054, British Generic Manufacturers Association - About generics.

different generic suppliers is substitutable and demand is dependent on therapeutic need, and therefore largely fixed.

8.6. Subsequent generic entrants would have an incentive to engage in stronger price competition in order to encourage pharmacies to dispense their products. The more generic companies enter, the stronger the price competition will normally tend to become, and the faster prices will normally tend to fall.[543]

8.7. This model of relying on competition to keep prices for generic drugs down can only work where competitors enter the market and compete on price. Effective entry in such markets does not always occur, however, which could be due to specific market features (such as barriers to entry/expansion or because the market is too small to attract entry) or because of anti-competitive behaviour. This may result in entry being delayed or not occurring at all, shielding a drug from effective competition.

8.8. Accordingly, incumbent suppliers of such generic drugs could find themselves in the position of holding significant market power in relation to old medicines which, although still important, have not been subject to any recent innovation or investment.

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

> '[…] *a handful of companies appear to be exploiting our freedom of pricing for unbranded generic medicines where there is no competition in the market, leaving the NHS with no choice but to purchase the medicine at grossly inflated prices* […]'[544]

8.10. Aspen's Fludrocortisone Acetate Tablets were such a generic product during the Relevant Period. As explained at paragraph 3.18 above, a drug containing the API fludrocortisone acetate was first authorised in the EU in 1954 and Fludrocortisone Acetate Tablets (as commercialised in its current form) were

[543] Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraphs 212 to 215; see also CMA decision of 12 February 2016 in Case CE-9531/11 *Paroxetine,* paragraph 6.34.
[544] See Document PD0055, UK Parliament - Health Service Medical Supplies (Costs) Bill https://hansard.parliament.uk/commons/2016-10-24/debates/16102429000001/HealthServiceMedicalSupplies(Costs)Bill.

introduced in the UK in November 1988,[545] as Florinef 0.1 mg Tablets.[546] Florinef (including the associated MA and proprietary data for the UK) was acquired by Aspen in November 2014.

8.11. Throughout these 26 years, no competing Fludrocortisone Acetate Tablets product was supplied in the UK.

8.12. As a branded product, however, Florinef remained under the PPRS and its regulated price remained low. From at least January 2014, the NHS England Reimbursement Price of Florinef was £0.05 per tablet.[547]

8.13. Around 18 months after acquiring Florinef, in March 2016, Aspen discontinued the brand and introduced a generic version of Fludrocortisone Acetate Tablets. Under the UK regulatory regime, debranding the drug meant that it was no longer regulated under the PPRS or the statutory scheme for branded drugs. From March 2016 onwards, Fludrocortisone Acetate Tablets sold by Aspen became a generic drug, outside price regulation. Aspen's decision to discontinue the Florinef brand therefore allowed it to price the generic version without constraints and to increase prices for Fludrocortisone Acetate Tablets. Contemporaneous evidence clearly shows that Aspen's decision to discontinue the Florinef brand was taken as part of a wider strategy to raise the List Price of generic Fludrocortisone Acetate Tablets in the course of 2016 (see paragraphs 4.5 to 4.8).

8.14. As explained in paragraphs 8.2 to 8.10, there was no effective price control for generic drugs during the period in which the SDA was in force (ie 1 March to 19 October 2016). Aspen increased its List Price for Fludrocortisone Acetate Tablets to around £1 per tablet upon entry into the SDA in March 2016 (compared with a List Price equivalent to £0.05 per tablet prior to that date).

8.15. Until implementation of the Commitments, Aspen has remained the sole UK supplier of Fludrocortisone Acetate Tablets.[548]

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[545] Amilco submitted that Florinef has been off patent since 1971 and the last regulatory data protection period in the UK expired in 1998. Document FLC4883, page 5, paragraph 3.3, submission made by Amilco to the CMA on 5 February 2019.
[546] Document FLE0816, Tiofarma's MA application for Fludrocortisone Acetate 0.1mg Tablets (PL 17507/0058) CTD MODULE 2.5: Clinical Overview.
[547] See Figure 5 above.
[548] Document FLC0028.1 and its attachment Document FLC0036.2 (FLUDROCORTISIONE2), MHRA's response to question 1 of the CMA's section 26 notice dated 3 May 2017. No MA for Fludrocortisone Acetate Tablets was granted during the period of May 2017 to March 2018. See Document FLC1126, MHRA's response to question 4 of the CMA's section 26 notice dated 28 February 2018. See also www.mhra.gov.uk/spc-pil/.

I. The market conditions prior to the Parties entering into the SDA

8.16. '*Pay for delay'* cases concerning patent litigation between originators and generic entrants can raise complex questions of judgement as to the right balance between two conflicting public interests: in rewarding innovation via a temporary monopoly right, and in price competition,[549] and therefore cannot be equated with '*a simple agreement for exclusion of a potential competitor from the market or for market sharing'*.[550]

8.17. By contrast, where there is no patent that could potentially prevent generic entry, the analysis is more straightforward. Moreover, Aspen, unlike the incumbent in the European Commission's only '*pay for delay'* case that did not involve patent litigation (*Fentanyl*), was not an originator: it acquired the MA for Fludrocortisone Acetate Tablets long after the innovation that led to their creation had been rewarded.

8.18. At the time the Parties entered into the SDA, Aspen was the sole UK supplier of Fludrocortisone Acetate Tablets - an unbranded generic medicine and, for the reasons discussed above in Section 6, held significant market power.

8.19. If competitors entered the Relevant Market, the main parameter of competition would therefore be price. In order to win a share of the finite total market, entrants would expect to undercut the price of the incumbent, Aspen. Independent entry to the Relevant Market would therefore be expected to result in erosion of Aspen's sales volumes and/or prices.[551]

8.20. If independent entry could be avoided, however, Aspen could expect to maintain its position as sole UK supplier – to maintain its market share – and its ability to charge high prices.[552] Aspen therefore had an incentive to prevent or delay Amilco and Tiofarma's entry into the market. It could do so by creating a decisive incentive for Amilco and Tiofarma not to enter, by sharing with it the supra-competitive profits resulting from the absence of generic competition.[553] Amilco and Tiofarma would receive value transfers from Aspen

[549] See, for example, *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 7.
[550] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 244.
[551] Compare Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 132: the incumbent J&J expected Novartis '*to launch the generic patch in the Netherlands in August 2005, which would result in a significant decrease in price of J&J's product, a significant loss of market share for J&J and the need to offer higher discounts to pharmacies.*'
[552] Compare Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 118: J&J aimed by cooperating with Novartis '*not to have a depot generic on the market and in that way to keep the high current price level…*'.
[553] See by analogy Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 214.

which constituted a significant benefit while avoiding the costs and uncertainties of entry.

8.21. Any arrangements that could achieve this – that would frustrate the process of merits-based competition and the benefits for patients and the NHS that flow from it – merit particular scrutiny. It is fundamental to fair and merits-based competition that undertakings must determine their commercial conduct independently. It is for this reason that competition law prohibits any form of coordination which deliberately substitutes practical cooperation for the risks of competition.[554]

8.22. In principle, therefore, undertakings should not engage in regular or detailed discussions with potential competitors – especially where a potential competitor is at, or near, the point of launching its own product. Such a context means that undertakings should be especially cautious about engaging in this type of contact.

8.23. However, as explained in paragraphs 4.30 to 4.43 and 4.52, Amilco approached Aspen in 2015 making clear that it was close to obtaining an MA and intimating that a deal could be done pursuant to which Aspen would obtain an exclusive licence over that MA, such that Aspen would not face competition from it.

8.24. As the General Court explained in *Lundbeck* (cited with approval by the CAT in *Paroxetine*):

> *'If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that progress, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes.'*[555]

8.25. At the time of entering into the SDA, Amilco and Tiofarma had taken or were taking the necessary steps to prepare for the launch of generic Fludrocortisone Acetate Tablets, including obtaining an MA, and had made significant investments to that end. Amilco and Tiofarma were potential competitors of Aspen (see further in the next section). Any value transfer by

[554] C-209/07 *Competition Authority v Beef Industry Development Society*, EU:C:2008:643, paragraphs 32 to 34.
[555] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 171; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 158.

Aspen to Amilco and Tiofarma to cease or slow their progress would delay effective competition at the expense of patients and the NHS.

II. Amilco and Tiofarma, working together, constituted potential competitors in the Relevant Market at the time of the SDA

8.26. For the reasons set out below, the CMA concludes that Amilco and Tiofarma, working together, were potential competitors to Aspen in the Relevant Market at the time of the SDA.

a. Legal framework applicable to the concept of potential competition

8.27. The examination of the conditions of competition on a given market must be based not only on existing competition between undertakings already present on the relevant market, but also on potential competition in order to ascertain whether, in the light of the structure of the market and the economic and legal context within which it functions, there are real concrete possibilities for the undertakings concerned to compete among themselves or for a new competitor to enter the relevant market and compete with established undertakings.[556]

8.28. The Court of Justice has stated that where an undertaking has a *'firm intention and an inherent ability to enter the market*' and faces no insurmountable barriers to entry, it will be a potential competitor in that market.[557]

8.29. In examining potential competition, the critical assessment is therefore whether in the absence of the agreement under investigation, there would have existed '*real and concrete possibilities*' for the undertaking(s) in question to enter the market and compete with the undertakings established in that market. This is established when:

(a) The undertaking(s) in question had a '*firm intention and an inherent ability*' to enter the market at the time the agreement was concluded. A '*firm intention and an inherent ability to enter the market*' is established where the potential entrant has taken '*sufficient preparatory steps to enable it to enter the market concerned within such a period of time as to impose*

[556] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 99; T-374/94 etc. *European Night Services and Others v Commission*, EU:T:1998:198, paragraph 137; T-461/07 *Visa Europe and Visa International v Commission* EU:T:2011:181, paragraph 68; and T-360/09 *E.ON Ruhrgas and E.ON v Commission*, EU:T:2012:332, paragraph 85.
[557] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraphs 46 and 58.

competitive pressure' on the incumbent. Such preparatory steps '*permit the conclusion that* [an undertaking] *has a firm intention and an inherent ability to enter the market*';[558] and

(b) The potential entrant would 'not meet barriers to entry that are insurmountable'.[559]

8.30. Further, the incumbent's perception is a relevant factor in the assessment of the existence of a competitive relationship with an undertaking outside the market. This is because, if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the incumbent (as set out further in paragraphs 8.49 to 8.52 below).[560]

8.31. When examining whether an undertaking was a potential competitor, the analysis should be conducted principally on contemporaneous evidence.[561] However, although subsequent evidence '*cannot be decisive*', it can be taken into account to the extent that it is '*capable of clarifying those parties' positions at the time, confirming or challenging their arguments in that respect as well as allowing a better understanding of the market concerned.*'[562]

i. '*Real concrete possibilities*' of entering the market: a firm intention and inherent ability to enter

8.32. In order to determine whether an undertaking is a potential competitor in the market, it must be determined whether there are '*real and concrete possibilities* [of that undertaking] *joining that market and competing with* [the incumbent]'.[563]

8.33. To do so, it is necessary to determine whether, at the time the agreement was concluded, the undertaking had taken '*sufficient preparatory steps to enable it to enter the market concerned within such a period of time as would impose competitive pressure* [on the incumbent].'[564] Such assessment of whether a potential entrant had '*real concrete possibilities'* of entering the market to compete with the incumbent and a '*firm intention and an inherent ability*' to do

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[558] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraphs 43 and 44.
[559] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 45.
[560] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraphs 42, 55 and 56, citing C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraphs 33 and 34.
[561] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 138, citing by analogy T-540/08 *Esso and Others v Commission* EU:T:2014:630, paragraph 75.
[562] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 141.
[563] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 36.
[564] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 43.

so includes therefore (as set out further in paragraphs 8.35 to 8.48 below) an examination of:

(a) the preparatory steps taken to enable market entry;

(b) the timeframe for potential entry, ie whether entry was possible within 'a sufficiently short period to exert effective competitive pressure'[565] on the incumbent 'on the basis of costs which would have been economically viable';[566] and

(c) whether there were any insurmountable barriers to entry.

8.34. In addition, the potential entrant's '*firm intention and inherent ability*' to enter the market can be confirmed by additional factors. For example agreements or value transfers between an incumbent and another generic drug company may be evidence that a competitive relationship existed between them (as set out further in paragraphs 8.49 to 8.52 below).[567]

ii. Preparatory steps for the purpose of entry

8.35. In the context of the pharmaceutical industry, what constitutes '*sufficient preparatory steps*' must take into account the normal regulatory barriers to entry (including applicable intellectual property rights). In *Paroxetine*, the Court of Justice stated that such steps may include the measures taken by the relevant undertaking to obtain the required regulatory authorisations for the marketing of the relevant drug. The steps taken by the undertaking to put itself in a position to have adequate stocks of that medicine either through its own production or through supply contracts with third parties (eg CMOs) are also relevant. Of equal relevance are the range of marketing initiatives adopted by the potential entrant to market its medicine.[568] Such steps permit the conclusion that an undertaking has a '*firm intention and an inherent ability*' to enter the market.[569]

8.36. In *Lundbeck* the General Court stated that a potential entrant requires only '*real concrete possibilities and the capacity to enter the market*' which '*is*

[565] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 203.
[566] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 104.
[567] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraphs 55 and 56.
[568] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 44. In markets involving an originator that holds a patent that is close to expiry, the legal steps actually undertaken by that manufacturer with a view to challenging, either as a principal issue or as an incidental question, the process patents held by a manufacturer of originator medicines are also relevant.
[569] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraphs 43 and 44.

certainly the case when those undertakings had made significant investments in order to enter the market and when they had already obtained MAs or had taken the necessary steps to obtain them within a reasonable period.'[570]

8.37. The General Court (cited with approval by the CAT in *Paroxetine*) acknowledged that, given the various possible routes to market in the pharmaceutical sector, the concept of potential competition covers a broad range of necessary regulatory and commercial activities, including the process of obtaining an MA, while also noting the potential negative implications for patients and national health systems of unduly narrowing that concept:

'Potential competition includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market. That potential competition is protected by Art.101. If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes.'[571]

8.38. Consistent with that framework, in *Lundbeck*, Merck and Ranbaxy were considered potential competitors even though Merck did not hold an MA in every relevant market, and Ranbaxy did not hold an MA at all. Further, the General Court accepted that the European Commission could base its finding of potential competition on an entrant's real concrete possibilities of following multiple different routes to market, without it being necessary for the European Commission to be able to show which route was most feasible or likely at the time of the relevant agreement.[572] Specifically, the General Court confirmed the European Commission's finding that Ranbaxy had real concrete possibilities to enter the relevant market on the basis that it could have brought its product to market in more than one way (ie supplying the manufactured product directly, or selling its API to a third party which would

[570] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 131. See also paragraph 157, which shows that the European Commission also took into account the strength of the incumbent's process patents, the fact that one generic undertaking had actually entered, and the significant amounts the incumbent paid to the generic undertakings to keep them out of the market.
[571] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 171.
[572] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 204.

have entered the market itself), without it having taken a view on which was more likely.[573]

8.39. In its *Perindopril* decision, the European Commission found that Niche and Matrix were each a potential competitor to Servier on the basis of a combined analysis which considered the steps taken by those companies under a cooperation agreement in order to develop a product which could be launched as a generic alternative to Servier's perindopril. Specifically, Matrix was responsible for development of the necessary API and for the production of the drug in final dosage form while Niche was responsible for obtaining an MA for the product and for reaching agreements with potential customers (and had reached agreement with fourteen commercial partners at the time of the relevant agreement).[574] The creation of a distribution network through such contracts was considered necessary since Niche would not have the in-house distribution capability to market the product.[575] In relation to Matrix, the European Commission noted that '[o]*n the assumption that Niche/*[…] *settled with* [the incumbent], *and Matrix did not, the Commission considers that Matrix would likely have found an alternative partner for the API it was developing and would have been a serious threat to* [the incumbent's] *perindopril position*.'[576]

8.40. In *Perindopril (Mylan)*, the General Court upheld the European Commission's decision in relation to Matrix, finding that '*the classification of an undertaking as a potential competitor cannot be rejected merely because it is not able to enter a given market by itself, where it has the possibility of finding business partners through which it can access that market, or has already concluded an agreement with those business partners.*'[577] The General Court also confirmed that it was appropriate for the Commission to have conducted a combined assessment of potential competition for Niche and Matrix in circumstances where those companies took joint steps to enter the market on the basis of some form of partnership and where such partnerships were

[573] The General Court noted that '*before concluding the agreement with Lundbeck, Ranbaxy had taken several steps to sell its API, and not to sell finished products made from that API. The fact that the sale of finished products may have been more profitable does not prevent the sale of its API being considered as a real concrete possibility for Ranbaxy to compete with Lundbeck, as was mentioned in the minutes of the meeting of 17 April 2002*.' T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraphs 320 to 322.
[574] Commission Decision in Case AT.39612 *Perindopril (Servier)*, paragraph 1284 and T-691/14 *Servier and Others v Commission*, EU:T:2018:922, paragraph 501.
[575] Commission Decision in Case AT.39612 *Perindopril (Servier)*, paragraph 448.
[576] Commission Decision in Case AT.39612 *Perindopril (Servier)*, paragraph 1493.
[577] The General Court further clarified that the Commission's combined assessment was sufficient, taken together with evidence of the incumbent's perception, to find that Matrix (in the light of its relationship with a separate undertaking, Niche) was individually a potential competitor to Servier. T-682/14, *Mylan Laboratories and Mylan v Commission* EU:T:2018:907, paragraphs 87 and 88.

common practice.[578] [579] Indeed, it confirmed that in the assessment of real concrete possibilities, the Commission may take into account '*in particular, the fact that several operators have an ability to enter that market jointly, but not alone*'.[580] It further held that the Commission's approach was '*not called into question by the fact that Niche and Matrix are two autonomous companies*'.[581]

8.41. The position of a potential competitor also '*cannot depend on whether it can be demonstrated that an undertaking intends to enter the market in the near future*. This is because a potential competitor may exert competitive pressure on the incumbent by its existence alone, '*a pressure represented by the likelihood that a new competitor will enter the market if the market becomes more attractive*.'[582] It also cannot depend on whether the potential entry would certainly have taken place or proved to be successful, only whether the potential entrant '*had real concrete possibilities in that respect. To assert the contrary would amount to denying any distinction between actual and potential competition.*'[583] There is '*no requirement*' to demonstrate '*with certainty*' that the undertaking will enter or will be capable of retaining its place in the market.[584]

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[578] '*It should be borne in mind that a potential competitor is an undertaking that has real concrete possibilities of entering the market in question and that the essential factor on which that classification must be based is the ability of that undertaking to enter the market (see paragraph 46 above). That ability must be examined in the light of the facts of the case and the structures of the relevant market* […], *in particular the practice of using partnerships in order to access the market. The Court of Justice and the General Court have thus examined whether there are real concrete possibilities of entering a market* ***by concluding agreements with partners*** *(see, to that effect, C-234/89 Delimitis v Henninger Bräu,* EU:C:1991:91*, paragraph 21, and Visa Europe and Visa International Service v Commission, T-461/07,* EU:T:2011:181*, paragraphs 83 and 90 to 94*) […] *Contrary to the applicants' arguments at the hearing in response to a question put to them by the Court in relation to that case-law, taking into consideration business partnerships in the assessment of potential competition does not amount to attributing an ability to enter the market to an operator which does not actually have such an ability, in order to subsequently penalise it despite its inability to enter the market. It is intended merely to take into account, as required by the case-law relating to the assessment of real concrete possibilities, the reality and the structure of the relevant market and, in particular, the fact that several operators have an ability to enter that market jointly, but not alone.*' (emphasis added) T-682/14, *Mylan Laboratories and Mylan v Commission* EU:T:2018:907, paragraphs 87 and 88.

[579] In the pharmaceutical sector, it is very common for companies to cooperate to bring products to market and to sub-contract various stages of the manufacturing process, see the Commission's Pharmaceutical Sector Inquiry Final Report, 8 July 2009, paragraphs 49 and 53, available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

[580] T-682/14, *Mylan Laboratories and Mylan v Commission* EU:T:2018:907, paragraph 88. See also T-461/07, *Visa Europe and Visa International Service v Commission*, EU:T:2011:181, paragraphs 82 and 83 and the case-law cited; T-472/13, *Lundbeck v Commission* EU:T:2016:449, paragraphs 197 and 204.

[581] T-682/14, *Mylan Laboratories and Mylan v Commission* EU:T:2018:907, paragraph 91.

[582] T-461/07 *Visa Europe and Visa International Service* v *Commission* EU:T:2011:181, paragraph 169; and T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 144. See also C-307/18 Generics (UK) Ltd and Others v CMA, EU:C:2020:28, paragraph 100.

[583] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 159; T-679/14 *Teva v Commission* EU:T:2018:919, paragraph 91.

[584] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraph 38.

8.42. Further, potential entry by a product which is less commercially attractive than the incumbent's product again does not mean that a potential entrant does not have real concrete possibilities to enter the market and compete with the incumbent.[585]

iii. The timeframe for potential entry

8.43. The CMA must demonstrate, by factual evidence and/or an analysis of the structures of the relevant market, '*that the market entry could have taken place sufficiently quickly for the threat of a potential entry to influence the conduct of the participants in the market, on the basis of costs which would have been economically viable*'.[586] The entry must be able to take place '*within such a period of time as would impose competitive pressure*' on the incumbent.[587]

8.44. With respect to the timeframe within which potential entry should take place, it is only required to take place '*with sufficient speed to form a constraint on market participants*',[588] in '*a sufficiently short period to exert effective competitive pressure*',[589] '*without fixing a specific limit in that respect*.'[590] A potential competitor does not have to have '*a readily marketable product as long as the company is able to enter within a "short period of time"*'.[591]

8.45. With respect to a set period of time that would be sufficient for potential entry, in *Paroxetine* the CAT cited the General Court's assessment of timing by reference to the Commission's Guidelines on horizontal cooperation agreements for illustrative purposes. Specifically, '*the Commission refers to a period of one year while stating that 'in individual cases longer time periods can be taken into account' and the '*[t]*he time period needed by companies already active in the market to adjust their capacities can be used as a yardstick to determine this period."*[592] Indeed, the General Court has also recognised that the timeframe over which competitive pressure may be exercised by a potential entrant may be longer, but this will depend on the company's objective ability to enter the market, even if it encounters delays in

[585] T-679/14 *Teva v Commission* EU:T:2018:919, paragraphs 155 to 157.
[586] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 104 ; See also T-360/09 *E.ON Ruhrgas and E.ON v Commission* EU:T:2012:332, paragraph 114.
[587] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraph 43.
[588] T 461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraph 189.
[589] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 203.
[590] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraph 155, citing T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 131.
[591] Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 226.
[592] *GSK v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 92 to 93, citing Case T-461/07 *Visa Europe and Visa International v Commission* EU:T:2011:181, paragraph 171.

entering the market. Specifically, '[t]*he mere fact it takes longer than planned to enter the market does not mean that such entry will not take place, particularly since…the cost and time necessary for entering a new product market may be considerable*'.[593]

8.46. Finally, it is not necessary to prove that the generic entrant would have entered the market before the expiry of the agreements in order to establish the existence of potential competition.[594]

iv. The relevance of entry barriers

8.47. Where specific market characteristics exist that may have an impact on potential entry, it is necessary to test whether those characteristics form an '*insurmountable barrier*' to the potential entrant which '*rule out*' any potential competition.[595]

8.48. It is relevant to assess whether there are any '*significant regulatory hurdles*' preventing a potential competitor from launching its product.[596]

v. The perception of the incumbent

8.49. The CMA may '*rely inter alia on the perception of the undertaking present on the market in order to assess whether other undertakings are potential competitors*.'[597]

8.50. Indeed, a potential competitor may exert competitive pressure on the incumbent by its existence alone (see paragraph 8.41). Therefore, '*if the latter is perceived as a potential entrant to the market, it may, by reason merely that it exists, give rise to competitive pressure on the operator that is established in that market*.'[598]

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[593] T-114/02 *BaByliss SA v Commission* EU:T:2003:100, paragraph 102. The Court also stated that '[t]*he fact … that the applicant's actual entry … was deferred several times, by comparison with its announcements, is not a sufficient reason for concluding that BaByliss cannot be regarded as a potential competitor*'.
[594] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 163.
[595] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 124, citing T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 230. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 31: '*…since Article 101 TFEU also concerns potential competition, the Gentlemen's Agreement was capable of restricting competition, unless insurmountable barriers to entry to the European market existed that ruled out any potential competition from Japanese producers'*. See also T-112/07 *Hitachi and Others v Commission* EU:T:2011:342, paragraph 230.
[596] Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 232.
[597] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 104. See also T-360/09 *E.ON Ruhrgas and E.ON v Commission* EU:T:2012:332, paragraph 106, which adds, consistent with the case law quoted above, that '*the purely theoretical possibility of market entry is not sufficient to establish the existence of potential competition*'.
[598] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 42.

8.51. It follows that the incumbent's perception of the commercial threat that a potential entrant poses, and its reaction to this threat, are relevant to an assessment of potential competition.[599] Specifically, the potential entrant's '*firm intention and an inherent ability to enter the market*' can be confirmed by additional factors:[600]

(a) First, the conclusion of an agreement between undertakings operating at the same level of the production chain even where some are not active on the market is a '*strong indication*' that a '*competitive relationship existed*' between them.[601] This additionally provides a strong indication that the market in question is '*not impenetrable*'[602] and that the incumbent '*perceived those undertakings as a potential threat at the time the agreements at issue were concluded*'.[603]

(b) Secondly, transfers of value from the incumbent to a potential entrant '*in exchange for the postponement of the latter's market entry*' provide an indication of the incumbent's perception of the commercial threat that a potential entrant poses and therefore of a competitive relationship between them (even in a situation where there is a claim to a patent infringement). '[T]*he greater the transfer of value, the stronger the indication.*'[604]

8.52. For instance, in *Lundbeck,* the fact that an incumbent transferred value under an agreement demonstrated that Lundbeck perceived the recipient as a potential competitor.[605] This was particularly so given that the incumbent occupied a more informed position in the market and '*it would be surprising if an undertaking as experienced as Lundbeck would have decided to pay several million euros to the generic undertakings in exchange for their commitment not to enter the market during a certain period if the possibility that those generic undertakings could enter the market was purely theoretical.*'[606]

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[599] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 57.
[600] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 54.
[601] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 55; See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraphs 33 and 34.
[602] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 103, citing T-112/07 *Hitachi and Others v Commission* EU:T:2011:342, paragraph 226; and T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 231, confirmed by the Court of Justice in C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraphs 30 to 35.
[603] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 181, citing T-519/09 *Toshiba v Commission* EU:T:2014:263, paragraph 231.
[604] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 56.
[605] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 228.
[606] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 161.

b. Assessment

8.53. In line with the case law set out above, the CMA concludes that Amilco and Tiofarma, working together, were potential competitors and could have entered the market in the short term to be an actual competitor of Aspen at the time they entered the SDA in March 2016.

8.54. This is because:

(a) Amilco and Tiofarma, working together, had real concrete possibilities of entering that market:

1. they had taken '*sufficient preparatory steps*' (including obtaining the relevant MA, and manufacturing a stock equivalent to 9 months of forecast supply volumes) by the time of entering into the SDA, which demonstrate their '*firm intention and an inherent ability*' to enter the market in the short term (ie in the course of 2016);
2. there were no insurmountable barriers to entry;

(b) Aspen perceived Amilco and Tiofarma to be a competitive threat at the relevant time.

8.55. Before discussing each of these factors, the CMA will set out why Amilco and Tiofarma ought to be considered together for the purpose of determining whether a competitive relationship existed between them and Aspen at the time of completing the SDA.

i. Amilco and Tiofarma should be considered together

8.56. The jurisprudence is clear that, depending on the circumstances of the case, it may be appropriate to consider an undertaking's position as a potential competitor in the light of the possibility for it to work together with another undertaking for the purpose of market entry (see paragraph 8.40 above). In such circumstances, both undertakings can be considered to be potential competitors of the incumbent undertaking.[607]

8.57. In the present case, assessing whether Amilco and Tiofarma, working together, were potential competitors to Aspen in the light of their cooperation

[607] See also T-682/14, *Mylan Laboratories and Mylan v Commission* EU:T:2018:907, paragraphs 87 and 88.

in this context is not only appropriate,[608] but also most reflective of the circumstances of the case at hand.

(a) Amilco [✂] and Tiofarma had a long-standing business partnership for the purpose of commercialising medicines in the UK. Tiofarma undertook development and CMO work for [Pharmaceutical Company 2] since the early 2000s until the divestment of [Pharmaceutical Company 2] [✂] in 2015.[609] In that period, Tiofarma had manufactured a portfolio of over [✂] products for [Pharmaceutical Company 2].[610] Following the divestment of [Pharmaceutical Company 2] [✂], and up to at least July 2018, Tiofarma has continued to work on the development of a number of drugs for [✂] Amilco, including Ambient Storage Fludrocortisone.[611] This ongoing commercial partnership was based on mutual trust rather than any formal contract.[612]

(b) Amilco and Tiofarma worked together to develop Ambient Storage Fludrocortisone throughout all stages of the process, until entering into the SDA which brought the product to market. As explained in paragraphs 4.9 to 4.22, the dossier for Ambient Storage Fludrocortisone was initially developed by [Pharmaceutical Company 2] in partnership with Tiofarma and was ready to be filed in late 2014,[613] when [✂] was negotiating the sale of [Pharmaceutical Company 2] to [Pharmaceutical Company 3] (which was agreed in January 2015). However, Ambient Storage Fludrocortisone was not part of this transaction. Instead, [✂] placed the development dossier for this product (while retaining ultimate ownership over the product) under the nominal control of Tiofarma, which applied for an MA in December 2014. Tiofarma subsequently obtained an MA for Ambient Storage Fludrocortisone in November 2015. The further steps

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[608] C-234/89 *Delimitis v Henninger Bräu* EU:C:1991:91, paragraph 21; and T-461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraphs 83 and 90 to 94.
[609] Document FLC1981, page 10 lines 4 to 5, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[610] Document FLC1981, page 11 lines 6 to 8, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017.
[611] Document FLC4907, page 16, lines 3 to 18, Transcript of interview with [Tiofarma Employee 1] on 24 July 2018.
[612] Document FLC1981, page 10, line 25 to page 11, line 2, and page 31, lines 8 to 17, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017. Document FLC4925, page 82, lines 1 to 5, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018: '*it's just not the way we worked. We worked for ten years* […] *It was purely on trust. For many years, they made product* [sic] *for me without even a contract.'*
[613] Tiofarma ultimately filed the MA application to the MHRA in December 2014. [Tiofarma Employee 1] told the CMA that when the dossier was handed over by [Pharmaceutical Company 2] to Tiofarma, it was ready to be filed. See Document FLC1981, page 29, lines 22 to 25, Transcript of interview with [Tiofarma Employee 1] on 22 November 2017: '*The dossier was ready when it was handed to us* […] *And it was good enough to go straight through the MHRA*.' See paragraph 4.22.

taken jointly to commercialise the product into market (including updating project plans together and agreeing a supply price from Tiofarma to Amilco at a level that would assist Amilco's entry into the market) are explained in the section that follows.

(c) Under their informal arrangement regarding Ambient Storage Fludrocortisone, Amilco remained the owner and ultimate beneficiary of Ambient Storage Fludrocortisone,[614] while Tiofarma's interest in the product was limited to its role as the registered manufacturer (even after it obtained an MA, which it held on behalf of Amilco). The rationale for that ongoing partnership were their complementary skills, assets and expertise.

1. Amilco, [✂], had extensive expertise in commercialising drugs in the UK, but had neither the regulatory capabilities to hold an MA nor any manufacturing capacity. It relied for those purposes on Tiofarma.
2. Tiofarma had a regulatory function and sufficient manufacturing capacity and had already manufactured sufficient stock of Ambient Storage Fludrocortisone to supply the entire UK market prior to the SDA (see paragraph 8.62 below). However, it did not have expertise in commercialising drugs in the UK (such as commercial relationships with wholesalers and pharmacists and detailed knowledge of the UK reimbursement schemes). Tiofarma stated that it incurred product development, regulatory and production costs on the expectation that it would be able to gain a return on that investment by manufacturing the product as CMO for one of [Person 1 acting for Amilco]'s companies.[615]
3. While Amilco owned the rights to Ambient Storage Fludrocortisone, it intended to rely on Tiofarma's regulatory infrastructure and manufacturing capacity. Tiofarma intended to rely on [Person 1 acting for Amilco] and his companies to find a route to market for Ambient Storage Fludrocortisone once the MA had been obtained, trusting he had the relevant experience to do so as someone who had

[614] Including the associated MAs and proprietary data, and the cash flows generated through these assets under the SDA, see paragraph 4.114, until these were sold to Aspen in October 2016.
[615] Document FLC2074.2, Annex 1A, Tiofarma's response to the ACM's request for information dated 10 October 2017.

successfully run a pharmaceutical business and brought several products to market. [616]

8.58. The above shows that Amilco [✂] and Tiofarma developed Ambient Storage Fludrocortisone jointly, exploiting in that context their combined assets and expertise for the purpose of commercialising medicines in the UK.[617] In that context, Amilco and Tiofarma were able to rely on each other's skills, assets, expertise and connections (in particular, Amilco was the owner of the rights to Ambient Storage Fludrocortisone while Tiofarma was the formal holder of the MA and manufacturer). What matters therefore is that (as set out in more detail below) at the time of entering into the SDA, they had the capacity to bring Ambient Storage Fludrocortisone to the market in competition with Aspen's Cold Storage Fludrocortisone.

ii. Amilco and Tiofarma together had real concrete possibilities of entering the Relevant Market at the time of the SDA and a firm intention and an inherent ability to do so

8.59. The CMA finds that, at the time they entered into the SDA in March 2016, Amilco and Tiofarma had real concrete possibilities of entering the market, on the basis that they had taken '*sufficient preparatory steps*' to demonstrate their '*firm intention and an inherent ability*' to enter the market within such a period as would impose competitive pressure on Aspen. In this section, the CMA sets out that:

(a) The preparatory steps that they had taken were sufficient to enable market entry, showing a firm intention and inherent ability to do so;

(b) the various alternative routes available to Amilco and Tiofarma to enter the market absent the SDA; and

(c) the timeframe for such potential entry.

[616] While Tiofarma expected [Person 1 acting for Amilco] to be involved in future sales of that product, it was not dependent on that involvement to be able to make sales in the UK: Tiofarma was also approached by a number of pharmaceutical companies to purchase Ambient Storage Fludrocortisone from it, without any involvement of [Person 1 acting for Amilco]. Most of those companies would also have had the necessary expertise to commercialise the product in the UK.
[617] See in particular paragraphs 4.9 to 4.28.

Amilco and Tiofarma took sufficient preparatory steps to enable market entry

8.60. Before entering into the SDA (and even before the Term Sheet had been signed), Amilco and Tiofarma had made substantial investments in time and resources, over a period of at least four years to develop and prepare to commercialise a new market-ready product, using their substantial skills, assets and expertise.[618] These steps demonstrate that Amilco and Tiofarma, working together, took sufficient preparatory steps to bring the product to market within such a period of time as would impose competitive pressure on Aspen. Such steps included:

(a) the development work to successfully create a generic version of Cold Storage Fludrocortisone;

(b) the completion of regulatory processes in order to obtain the required regulatory authorisations for the marketing of this product in the UK; and

(c) various commercial steps to prepare for market entry, including in particular to enable the manufacture of the product at scale.

8.61. Prior to approaching Aspen in August 2015 [Person 1 acting for Amilco] had, in partnership with Tiofarma[619], successfully created a generic version of Fludrocortisone Acetate Tablets and prepared a complete dossier (ie all of the required documentation) to support an MA application for Ambient Storage Fludrocortisone. The regulatory process completed in November 2015, when the MA for Ambient Storage Fludrocortisone was granted.

8.62. From September 2015 (ie two months before [Person 1 acting for Amilco] approached Aspen's [✂] management, and more than three months before the conclusion of the Term Sheet for the SDA with Aspen), Amilco and Tiofarma took concrete steps towards preparing for market entry in the short-to-medium term:

(a) In September 2015, Amilco and Tiofarma prepared and updated detailed project plans pursuant to which they were planning to undertake each of the key required tasks leading up to market entry, including the procurement of API and excipients, batch manufacturing, packaging and

[618] See paragraphs 4.9 to 4.28.
[619] The rights to the dossier were initially held within [Pharmaceutical Company 2], until they were formally transferred to Tiofarma at the end of 2014, although [Person 1 acting for Amilco] retained beneficial rights over the product, see paragraphs 4.9 to 4.11 and paragraphs 4.14 to 4.19.

testing, process validation and the finalisation of artworks (see paragraphs 4.23 to 4.27 above).[620] The planned completion date for all preparatory regulatory steps was March 2016 (see paragraph 4.25).

(b) Acting upon these plans, on 17 September 2015, [Tiofarma Employee 2] gave instructions to colleagues to order API (and auditing the API supplier), carry out checks and testing (micro-validation and stability checks), and set up the packaging with the following message: '*a new client is placing his product with us. This client is of major importance considering its potential. Various operations need to be implemented for this.* […] I *would like everyone to carry out/ set out his/her operations'*. In a subsequent message, he said that everything needs to start '*as soon as possible'*.[621]

(c) In October 2015, [Person 2 acting for Amilco] and [Tiofarma Employee 1] and [Tiofarma Employee 2] discussed the supply price to be paid by Amilco to Tiofarma (see further below paragraph 8.70).

(d) In line with the September 2015 project plans (see subparagraph (a) above), by 18 November 2015, Tiofarma had procured '[✂] *of API*',[622] corresponding to an amount sufficient to produce one year's worth of supply in the UK market.[623]

(e) On 9 November 2015, Tiofarma obtained the MA for Ambient Storage Fludrocortisone. This meant that, as of that date, Ambient Storage Fludrocortisone met the requisite standards for safety, quality and efficacy for that product to be authorised for sale in the UK and Tiofarma had demonstrated to the MHRA that it was capable of fulfilling the necessary compliance duties to support such supply (see paragraphs 3.43 to 3.48 above).[624]

(f) Subsequent internal documents show that production of '[✂] *batches*' (equal to the official minimum order quantity of [✂] packs, or around [✂]

[620] See plans communicated by [Person 2 acting for Amilco] to [Tiofarma Employee 2] on 15 September, 29 September and 16 October 2015 (documents referred in paragraph 4.23). Document FLC3168, (see English translation in Document FLC3168.1), email chain between [Tiofarma Employee 2] and [Tiofarma Employee 6] and other employees of Tiofarma dated 17 September 2015.
[621] Document FLC3477 (See English translation in Document FLC3477.1), emails from [Tiofarma Employee 2] to [Tiofarma Employee 7], dated 17 and 29 September 2015.
[622] Document FLC3168 (English translation Document FLC3168.1), email chain between [Tiofarma Employee 2] and [Tiofarma Employee 6] and other employees of Tiofarma dated 17 September 2015.
[623] Document FLC3174 ('*Overview*' API) states: '*order sufficient API to cover 1 year worth a supply* [✂]*'.*
[624] Tiofarma must also have satisfied the MHRA that its manufacturing facilities complied with applicable regulations as it had proposed to list itself as the registered manufacturer on that MA.

tablets) began production in mid-December 2015[625] and was finished by 12 January 2016.[626] This production occurred several months prior to the SDA, and even before the Parties had signed the Term Sheet. The next [✂] batches (again equivalent to [✂] packs or around [✂] tablets) began production on 15 January 2016 (see paragraph 4.27), just before the Parties signed the Term Sheet on 19 January 2016 (and still 6 weeks before they had signed the SDA).[627] Together, these were equivalent to 9 months' worth of the forecasted sales volume under the Term Sheet).

(g) From March 2016 onwards, Tiofarma has consistently been able to procure the necessary API. During this period Tiofarma has been the manufacturer of all Fludrocortisone Acetate Tablets supplied directly in the UK, following the withdrawal of Cold Storage Fludrocortisone by Aspen, which effectively meant Tiofarma supplied all of Aspen's requirements for Fludrocortisone Acetate Tablets in the Relevant Market under the terms of the SDA.

8.63. Assessed objectively, those preparatory steps were substantial. Having already obtained an MA and begun manufacturing at scale, Amilco and Tiofarma had a generic product which was ready to be brought to the market at the time they entered into active negotiations with Aspen (as further evidenced by the fact that the product was in fact brought to market with Aspen within a few months). On that basis, the CMA finds that, at the time of the SDA, Amilco and Tiofarma had taken sufficient preparatory steps to enable the market entry of Ambient Storage Fludrocortisone.

Amilco and Tiofarma had various routes to market absent a deal with Aspen

8.64. Rather than seeking independent entry, Amilco and Tiofarma entered into the SDA. For the reasons set out below, the CMA finds that, absent the SDA, Amilco and Tiofarma would have had various route available to bring Ambient Storage Fludrocortisone to market on the basis of viable costs and without

[625] Document FLE0189, email from [Aspen Employee 21] to [Person 2 acting for Amilco] dated 25 January 2016: '*Tiofarma manufactured* [✂] *in Dec-2015 - this will cover from Apr- 2016 to mid-Jun 2016 based on our forecast in the term sheet*'. In reply, [Person 2 acting for Amilco] commented in red in an email dated 25 January 2016: '[…] *all* [✂] *batches have been manufactured and packed* […] *the packs available for sale are likely to be in the region of* [✂].'

[626] Document FLC3316 (See English translation in Document FLC3316.1), email from [Tiofarma Employee 2] to [Person 2 acting for Amilco] (acting for Amilco) dated 12 January 2016 at 13:40.

[627] Document FLE0189, email from [Person 2 acting for Amilco] to [Aspen Employee 21] dated 25 January 2016.

significant additional investment being necessary. Specifically, the CMA sets out in the following paragraphs that:

(a) Amilco and Tiofarma, working together, had the ability to identify and pursue various routes to market; and

(b) these routes to market were viable.

8.65. As set out at paragraph 8.41 and 8.42 above, the CMA is not required to demonstrate with certainty that an undertaking will in fact enter the market concerned absent the agreement, or that it will be capable thereafter of retaining its place in the market.[628] This is because the mere presence of a competitive threat creates uncertainty even prior to entry which places market incumbents under competitive pressure.[629] Accordingly, it is not necessary to assess which route to market Amilco and Tiofarma would have most likely taken in the counterfactual, nor the probability of success of each option. Instead, the CMA has assessed whether Amilco and Tiofarma could have pursued viable routes to market absent the SDA.

Amilco and Tiofarma, working together, had the ability to identify and pursue various routes to market

8.66. As explained at paragraphs 3.59 to 3.60, different routes to market are available to undertakings holding an MA and manufacturing capacity, including outsourcing or partnering with a third party taking care of downstream functions.

8.67. For the reasons set out below, the CMA's objective analysis of the facts demonstrates that, at the time of the SDA, Amilco and Tiofarma could have identified and pursued several routes to market open to them, ranging from maintaining control over all steps in the supply chain to outsourcing most or all commercial functions to third parties (and without significant investment being required from them). Amilco and Tiofarma's combined assets (including the MA and manufacturing capacity) and expertise, along with the viability of the routes for entry meant that the possibility of them bringing their product to market independently from and in competition with Aspen at that time was not merely hypothetical.

8.68. At the time of the SDA, Amilco and Tiofarma had the necessary expertise and infrastructure to identify and fill (as the case may be through reliance on a

[628] C-307/18 *Generics (UK) Ltd and Others v CMA*, EU:C:2020:28, paragraph 38. See also by analogy paragraphs 119 and 120 on the purpose of a counterfactual analysis.
[629] C-307/18 *Generics (UK) Ltd and Others v CMA*, EU:C:2020:28, paragraph 100.

third party) all of the functions required to bring the product to market in the UK:

(a) Tiofarma held all of the regulatory authorisations needed to manage a pharmaceutical supply chain (ie to manufacture the product, distribute it to customers and oversee regulatory compliance).

(b) Furthermore, Amilco [✂].[630] In addition, several ex-[Pharmaceutical Company 2] employees, with expertise relevant to supply activities, acted for Amilco in the development and supply of Ambient Storage Fludrocortisone to Aspen (see paragraph 3.11). This means that Amilco had access to the required knowledge of the possible routes to market and a wide network of contacts in the industry. This is demonstrated by the fact that [Person 1 acting for Amilco] was able to arrange a personal introduction to [Aspen Senior Executive 1] through a shared business acquaintance (see paragraph 4.52) and to give detailed input on how pricing would work under the SDA (see paragraphs 4.58 to 4.61).

(c) [Person 1 acting for Amilco]'s expertise was also confirmed by [Tiofarma Employee 1], who stated in interview that he took the risks of developing the product because he was confident that [Person 1 acting for Amilco] would utilise his '*commercial powers*' to ensure that Ambient Storage Fludrocortisone was brought to market, and that he '*had good reasons to assume that* [entry] *would work one way or the other*' so that he '*didn't worry*' or '*even think about* [this issue]'.[631]

8.69. In this context, the CMA notes that under the SDA Aspen's role in the operational aspects of the distribution of Ambient Storage Fludrocortisone did not involve any resources or capabilities that were unique to it. Indeed, as discussed in Section 3.D.II (and in particular paragraphs 3.52 to 3.56), since March 2016 Aspen had outsourced the distribution of the product to a third-party contractor, [Logistics Provider]. During the Relevant Period, [✂], and Aspen did not undertake any promotion or marketing activities in relation to Fludrocortisone Acetate Tablets during the Relevant Period (see paragraph 6.26).

The routes to market available to Amilco and Tiofarma were viable

[630] [✂].
[631] Document FLC4907, page 12 lines 6 to 7 and lines 16 to 18, Transcript of interview with [Tiofarma Employee 1] on 24 July 2018.

8.70. In addition, the analysis of the specific facts of this case strengthens the finding that, at the time of the SDA, Amilco and Tiofarma had viable routes to bring Ambient Storage Fludrocortisone to market independently from Aspen:

(a) That market entry independent of Aspen or another generic supplier was considered viable by Amilco and Tiofarma is supported by the fact that they had agreed a supply price that would facilitate entry even at the low prevailing prices in the market prior to the SDA. [Person 2 acting for Amilco] initially requested that Tiofarma lower its supply price '*to ensure that* [they] *remain competitive in the market*'.[632] In October 2015, [Tiofarma Employee 1] had agreed to produce Ambient Storage Fludrocortisone for €[✂];[633] This shows that, in order to bring its product to market, Tiofarma, which had the manufacturing capacity to supply the entire UK market, would have been willing to supply its product at a price that would have enabled competitive independent entry even at the price levels prevailing prior to the SDA, and *a fortiori* at a higher price had Aspen increased the price of Cold Storage Fludrocortisone.

(b) Ambient Storage Fludrocortisone had superior heat stability characteristics in comparison to Cold Storage Fludrocortisone, meaning the former product offered an advantage to some customers relative to the incumbent product (see paragraph 6.37(b)), which could have facilitated swift capture of market shares from the incumbent.[634] This is further supported by the fact that no marketing activity was required to supply this product in the UK (see paragraph 6.26). Indeed, Fludrocortisone Acetate Tablets is a prescription life-saving drug that pharmacists must stock to meet demand from patients; prescriptions for Fludrocortisone Acetate Tablets were generally open, without reference to supplier or brand.[635]

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[632] Document FLC3217 (see English translation in Document FLC3217.1), email from [Person 2 acting for Amilco] to [Tiofarma Employee 2] dated 21 October 2015.
[633] Document FLC3258 (see English translation in Document FLC3258.1), email from [Tiofarma Employee 2] to [Person 2 acting for Amilco] dated 22 October 2015 and Document FLC3217 referred above. This compared to Tiofarma's original request of €[✂] per 30 tablets and to the actual price included in the SDA (and SAA) of €[✂] per 30 tablets. [Tiofarma Employee 1] adopted the revised pricing specifically in response to [Person 2 acting for Amilco]'s request. In an internal email to [Tiofarma Employee 2], [Tiofarma Employee 1] explained that he had conceded such a [✂]. Document FLC3217 (see English translation in Document FLC3217.1), email from [Tiofarma Employee 1] to [Tiofarma Employee 2] dated 21 October 2015. From at least November 2014 (when Aspen purchased Florinef) until March 2016 (when Amilco and Tiofarma entered into the SDA), the Reimbursement Price for Fludrocortisone Acetate Tablets had been £5.05 per pack of 100 tablets.
[634] Aspen's analysis from October 2015 acknowledged that '*Ambient prouct* [sic] [✂] *easier to store* [✂]', concluded that '*at no change in price* [Cold Storage Fludrocortisone] *would loose* [sic] *circa* [✂]*% or more to Ambient product'* (see paragraph 8.182). See also other documents referenced in footnote 776.
[635] See paragraph 3.40.

8.71. The viability of independent entry with the Ambient Storage product is further reflected in [External Consultant 2]'s cover email to the introductory document (which was written to [External Consultant 1] but was intended to be sent on behalf of Amilco to Aspen), in which [External Consultant 2] stressed that '*This should be seen by Aspen as an opportunity, should they choose not to participate, **it will happen anyway***' (see paragraph 4.33).[636] This demonstrates that, at the time, it was expected by [External Consultant 2], who was commissioned by Amilco to approach Aspen (see paragraphs 4.30 to 4.38), that the product would come to market regardless of whether Aspen would enter into an agreement with Amilco and Tiofarma.

8.72. One plausible viable route to market consisted in Amilco and Tiofarma partnering with an existing generic supplier other than Aspen, where Tiofarma would hold the MA and manufacture the product, and the relevant supplier would handle most or all downstream supply functions.[637] Eight generic pharmaceutical companies made unsolicited approaches to Tiofarma to express their interest in distributing Ambient Storage Fludrocortisone, with two of those approaches pre-dating the SDA (see paragraphs 4.150 to 4.154). These suppliers offered different routes to market, with some offering to in-license the product (as done by Aspen under the SDA). Those companies would only have approached Tiofarma if they considered that supplying Ambient Storage Fludrocortisone in the UK was an economically viable strategy, at least in principle. The two suppliers that approached Tiofarma following the grant of the MA for Ambient Storage Fludrocortisone in November 2015[638] did so prior to the SDA and therefore before the increase in Aspen's List Price to £30 per pack of 30 tablets (see paragraph 8.62 and paragraphs 4.150 to 4.153). One of those suppliers was [Company 2], one of the largest generic drugs companies in the UK (and the world) with considerable experience in the commercialisation of pharmaceuticals,

[636] Document FLC1532, email from [External Consultant 2] to [External Consultant 1] dated 21 August 2015 (emphasis added).
[637] Tiofarma told the CMA that: '*In order to bring a new product to market in the UK, Tiofarma would need to work with: An API supplier* […] *A clinical research organisation to conduct clinical trials; A regulatory service provider to prepare and submit the marketing authorisation application; A distribution partner (and possibly wholesaler) to distribute the product and enter into commercial arrangements with pharmacy chains (and possibly the NHS trusts)*'. Document FLC2074.2, response to question 14, Annex1A, Tiofarma's response to the ACM's information request dated 10 October 2017.
[638] As set out in paragraph 4.152 below, six more pharmaceutical companies approached Tiofarma after the entry into force of the SDA in March 2016.

including within the relevant therapeutic area,[639] and in a number of foreign markets.[640]

8.73. Alternatively, Amilco and Tiofarma could have entered the market without a partnership with another generic supplier, outsourcing instead downstream supply functions as appropriate to third party contractors. For instance, they could have contracted with a pre-wholesaler which could ensure product manufactured by Tiofarma reached wholesaler customers (the MHRA has confirmed that an MA holder could outsource virtually any or all parts of the wholesaling function under a full service contract – see paragraph 3.59).

8.74. The above demonstrates that Amilco and Tiofarma, working together, had the inherent ability to enter the Relevant Market on the basis of costs which would have been economically viable through one or more available routes to market. Therefore, while the CMA accepts that partnering with the incumbent and sole UK supplier was likely to be more profitable than independent entry (and competition with the incumbent), it does not accept that the bringing Ambient Storage Fludrocortisone to market was conditional on entering into the SDA with Aspen. As set out below, potential entry could have occurred within such a period of time as would impose competitive pressure on Aspen.

The timeframe for Amilco and Tiofarma's potential entry

8.75. The CMA's analysis of the facts demonstrates that, at the time of the SDA, Amilco and Tiofarma had the ability to bring their product to market independently from Aspen sufficiently quickly to exert competitive pressure on Aspen.

8.76. As set out in paragraph 8.35, it is necessary to consider whether the steps taken by the potential entrant establish that it has a firm intention and an inherent ability to enter within such a period of time as would impose competitive pressure on the incumbent. Such steps may include the measures taken by the potential entrant to put itself in a position to have, within that period, the required MAs and an adequate stock of that medicine either through its own production or through supply contracts concluded with third parties. While the list adopted by the Court of Justice is not exhaustive (as follows from the words '*may include*') such that other factors may also be

[639] [Company 2] [✂] supplies other corticosteroids.
[640] [Company 2] repeatedly sought to partner with Tiofarma in relation to Ambient Storage Fludrocortisone both prior to and during the SDA (see paragraphs 4.152 and 4.152) and, after failing with those attempts, ultimately resorted to obtaining supplies of Fludrocortisone Acetate Tablets from a parallel importer. Document FLE0070, [✂] Portfolio update 2017, Slides 35 and 36.

relevant, the CMA considers that if an undertaking has taken these steps, it has a firm intention and inherent ability to enter the market within such a period of time as would impose competitive pressure on the incumbent.

8.77. In the present case, Amilco and Tiofarma were further advanced on all these factors than the case-law requires. In early 2016 Amilco and Tiofarma had started production at commercial scale and had the regulatory authorisations in place to enter the market. In fact, their Ambient Storage Fludrocortisone was introduced into the market by Aspen under the SDA from 1 March 2016, with Aspen making sales of that product to customers shortly thereafter. Absent the SDA, Amilco and Tiofarma could have brought their product to market in competition with Aspen within a reasonable timeframe of that date using any of the routes available to it. As set out above, no significant further investment was required from them to commercialise the product over and above the investments already made to develop the product, obtain regulatory clearance and produce at commercial scale, since they could rely on partners or service providers to commercialise their product. Two undertakings had proactively approached Tiofarma to distribute the product in the UK.

8.78. Internal Tiofarma documents from mid-September 2015 described in the previous sub-section expressed an expectation of market entry being '*in the short term*'[641] and planned for [✂][642] and with the project being '*urgent*'.[643] Those documents also detail discussions on how to ramp up production to commercial scale in keeping with that timeframe. Consistent with the above, [Tiofarma Employee 2] explained in an email to colleagues introducing them to the project that Amilco was an important new client given its potential.[644]

8.79. Furthermore, the Term Sheet signed by the Parties on 19 January 2016 contemplated a launch date of 1 March 2016 and provided that '*Tiofarma shall submit notification of the launch to the relevant authorities by no later than 31 January 2016*'.[645] This clearly shows that Aspen also expected that

[641] See also Document FLC3157 (see English translation in Document FLC3157.1), email chain between [Tiofarma Employee 2], [Tiofarma Employee 1] and others dated 10 September 2015.
[642] Document FLC3173, '*Gannt Chart*' dated 29 September 2015.
[643] Document FLC3477 (see English translation in Document FLC3477.1), email from [Tiofarma Employee 2] to [Tiofarma Employee 7], dated 29 September 2015.
[644] Document FLC3477 (see English translation in Document FLC3477.1), email from [Tiofarma Employee 2] to [Tiofarma Employee 6] and other Tiofarma colleagues dated 29 September 2015: '*This client is of major importance considering its potential*'. Document FLC3226 (see English translation in Document FLC3226.1), email from [Tiofarma Employee 2] to [✂] (trading partner of Tiofarma) dated 12 November 2015, showing that there was an expectation on the part of Tiofarma to sell 10-20M tablets per year.
[645] Document FLE0164, Term sheet between Aspen Global Incorporated, Tiofarma BV and Amilco Limited, dated 19 January 2016.

Ambient Storage Fludrocortisone was ready to come to market within a very short period.

8.80. Therefore, the CMA finds that Amilco and Tiofarma had the ability to bring their product to market sufficiently quickly to exert competitive pressure on Aspen at the time of the SDA.

8.81. Further, in the event of the termination or expiry of the SDA, the CMA considers that Amilco and Tiofarma would have had the ability to enter the market sufficiently quickly to exert competitive pressure on Aspen on the basis of the above analysis (until the implementation of the SAA in January 2017, when ownership over Ambient Storage Fludrocortisone was formally transferred to Aspen).

8.82. In light of the above, at the time of entering into the SDA, Amilco and Tiofarma had the firm intention and inherent ability to enter the Relevant Market within such a period of time as would impose competitive pressure on Aspen, as demonstrated by the steps they had taken to obtain an MA and proceed with the manufacturing of the product, and by the routes available to them to bring their product to market. The CMA therefore finds that, working together, Tiofarma and Amilco had real concrete possibilities to enter the Relevant Market at the time of the SDA.

8.83. The restrictions on entry placed on Amilco and Tiofarma by the SDA did not impact the basis, set out in this subsection, on which the CMA has found those companies had real concrete possibilities to enter the Relevant Market.

iii. There were no insurmountable barriers to entry

8.84. The CMA's analysis of the facts demonstrates that, at the time of the SDA, there were no insurmountable barriers that would have prevented Amilco and Tiofarma from bringing their product to market independently from Aspen.

8.85. There were no legal barriers to entry in the Relevant Market which would have precluded Amilco and Tiofarma's independent entry at the time of the SDA. As set out in paragraph 8.62, Tiofarma had already obtained an MA for Ambient Storage Fludrocortisone in November 2015 and had overcome any further regulatory and manufacturing hurdles at the time of the SDA.[646] It had a product it could have sold to the market within a reasonable timeframe.

[646] In any event, regulatory and manufacturing hurdles to obtaining an MA and obtaining stock ready to be sold to the market are not the same as an 'insurmountable barrier' which would have 'ruled out' potential competition. C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 31.

iv. Aspen perceived Amilco and Tiofarma as competitors

8.86. As set out in paragraph 8.49 above, the CMA may also take into account the perception of the undertaking present on the market for the purposes of assessing whether other undertakings are potential competitors.

8.87. As part of its admission of liability with respect to the Infringement, Aspen has accepted the CMA's proposed finding that it perceived Amilco and Tiofarma as potential competitors on the basis of the CMA's assessment set out in this section.

8.88. The following evidence demonstrates that Aspen perceived Amilco and Tiofarma as potential competitors prior to the SDA:

(a) The report prepared by [External Consultant 2] by which Aspen was made aware of the pending MA for Ambient Storage Fludrocortisone (August 2015) emphasised the strong competitive potential of that product as well as [Person 1 acting for Amilco]'s intentions and ability to bring that product to market. In particular, that document described Ambient Storage Fludrocortisone as a '*significant improvement on the existing product*' and controlled by '*a successful entrepreneur*' (see paragraph 4.36). At interview [Aspen Senior Executive 1] stated that, in his initial discussion with [Person 1 acting for Amilco], where Ambient Storage Fludrocortisone was offered to Aspen, [Person 1 acting for Amilco] had told him that Amilco and Tiofarma were ready to '*go out*' and that Aspen needed to respond urgently. [Aspen Senior Executive 1] further told the CMA that at the time he saw Ambient Storage Fludrocortisone as a threat to Aspen's sales of Cold Storage Fludrocortisone;[647]

(b) Contemporaneous internal Aspen documents following that approach confirm that it viewed Ambient Storage Fludrocortisone as a competitive threat to its market position prior to the SDA. An internal Aspen analysis from early October 2015 acknowledged that '[a]*mbient prouct* [sic] [✂] *easier to store* [✂]', concluding that '*at no change in price* [Cold Storage Fludrocortisone] *would loose* [sic] *circa* [✂]*% or more to Ambient product*'.[648] Consistent with the above, on 14 December 2015 (around a

[647] Document FLC4905, page 11, lines 5 to 6 and lines 20 to 22, Transcript of interview with [Aspen Senior Executive 1] on 14 May 2018.
[648] Document FLE0104 and its attachment Document FLE0105, email from [Consultant to Aspen] to [Aspen Employee 1] dated 6 October 2015 headed *'Fludrocortisone model de brand ambient product'*. The calculation was later updated. See Document FLE0134 and its attachment Document FLE0135, email from [Aspen Employee 11] to [Aspen Employee 1] and [Consultant to Aspen] dated 6 January 2016 headed *'Fludrocortisone*

month prior to the Term Sheet) [Aspen Employee 3] summarised the market conditions in an email to [Aspen Senior Executive 1], noting that '*the main Florinef competitor in the UK is already ambient*';[649] and

(c) The fact that Aspen entered into an agreement with Amilco and Tiofarma pursuant to which it replaced its own product with a product owned by Amilco and Tiofarma, thereby committing itself to sharing a significant proportion of profits within a market in which it was the sole UK supplier, is itself a strong indication that a '*competitive relationship existed*' between them.[650]

8.89. Furthermore, Aspen still perceived Tiofarma and Amilco to be potential competitors throughout the period of the SDA and even beyond. Indeed, in an email exchange negotiating the terms of the SAA, [Aspen Senior Executive 2] of Aspen requested the inclusion of a non-compete clause to cover Tiofarma, [Person 1 acting for Amilco] and Amilco (even though in its purported role as Tiofarma's '*local representative*' Amilco had not presented itself to Aspen as holding any rights or know-how relating to Ambient Storage Fludrocortisone).[651] A non-compete clause[652] was signed by Tiofarma preventing it not only from manufacturing Ambient Storage Fludrocortisone for any third party (including Amilco), but also preventing it from supporting any third party seeking to develop a competing product (see Clause 8 of the SAA).

III. Ambient Storage Fludrocortisone constituted a source of a significant competitive threat to Aspen's position as sole UK supplier

8.90. The SDA impacted the conditions of competition in the Relevant Market not only by specifically restricting the independent entry of Amilco and Tiofarma but also by more generally removing Ambient Storage Fludrocortisone as a basis for independent entry for the duration of that agreement. The CMA considers such removal of Ambient Storage Fludrocortisone to be a relevant

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generic ambient 06012016.xslx': 'Existing position at no change in price would loose [sic] *circa* [✂]*% or more to Ambient product'*. Document FLE0136 and its attachment Document FLE0137, email from [Aspen Employee 1] to [Aspen Employee 11] dated 8 January 2016: *'Existing position at no change in price would lose circa* [✂]*% or more to Ambient product overtime* [sic]'. Additional evidence is set out in paragraph 8.88.

[649] See, Document FLE0969, Email from [Aspen Employee 3] to [Aspen Senior Executive 1] dated 14 December 2015. See also Document FLC1986, page 19, line 27, to page 20, line 12, Transcript of interview with [Aspen Employee 3] on 9 November 2017.

[650] C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 33.

[651] Document FLC3398, email from [Aspen Senior Executive 2] to [Tiofarma Employee 1] of 28 September 2016: '[Aspen Senior Executive 1] *has passed the below onto me to finalise. Below please find our comments.* […] *Tiofarma and* [Person 1 acting for Amilco] *and company will accept a restraint that they will not compete with a fludro product. If you can confirm the above and below I will get a draft agreement for discussion at CPHI'.*

[652] Document FLC0344.6, Clause 8, Sale of Assets Agreement between Tiofarma and Aspen.

factor in its assessment in particular for the purposes of its assessment of the effects of the SDA.

8.91. For the reasons set out in paragraphs 8.86 to 8.89, even absent Amilco and Tiofarma working together as potential competitors, Ambient Storage Fludrocortisone (including the associated MA and other IP rights) constituted a source of a significant competitive threat to Aspen's position as sole UK supplier at least from 9 November 2015 (the date when the MHRA granted an MA for that product). This is principally because, in and of itself, it represented a market-ready product that had superior heat stability characteristics to Aspen's own offering (ie Cold Storage Fludrocortisone).

8.92. The MA for Ambient Storage Fludrocortisone could have been relied on as a basis for entry by any third party which licenced or purchased that product and which was able to perform the normal functions required of a pharmaceutical supplier in the UK (see paragraphs 8.64 to 8.83), and indeed, two credible suppliers approached Tiofarma to do so pre-SDA. The CMA considers that the significant competitive threat posed by Ambient Storage Fludrocortisone to Aspen would have been materially similar whether that product was brought to market by Amilco and Tiofarma or a third party.

B. Assessment of the object of the SDA

8.93. For the reasons set out below, the CMA concludes that the SDA had the object of preventing, restricting and/or distorting competition in the market for the supply of Fludrocortisone Acetate Tablets for human use in the UK, having regard to its:

(a) legal and economic context, in particular the fact that the Parties were potential competitors in the Relevant Market at the time of the SDA (see Sections 6 and 8.A. above); and

(b) content and objectives (see Sections 8.B.I to 8.B.II below),[653] in particular the fact that the Parties agreed that Amilco and Tiofarma would not enter the Relevant Market independently from Aspen for the duration of the SDA, thereby preventing competition between the Parties, and that in exchange, Aspen would make significant value transfers to Amilco and

[653] C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 53, citing C-32/11 *Allianz Hungaria v Commission* EU:C:2013:160, paragraph 36 and the case law cited. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 27.

Tiofarma (of a pecuniary or non-pecuniary nature) premised on that postponement of competition between the Parties.

8.94. On that basis, the CMA finds that the SDA had the object of sharing the Relevant Market.

8.95. The CMA's analysis of the Parties' respective intentions (see paragraphs 8.145 to 8.158) corroborates its conclusion on the content and objectives of the SDA.

8.96. While the Parties agreed to terminate the SDA early after seven months, this was done in order to replace that agreement with the SAA, which effectively cemented the benefits that the Parties expected to achieve (as described in paragraph 8.160) during the initial three-year term of the SDA. Since the SDA, no new MA[654] relating to Fludrocortisone Acetate Tablets has been granted by the MHRA, leaving Aspen as the sole UK supplier of that product until the divestment of Ambient Storage Fludrocortisone pursuant to the Commitments.[655]

8.97. The NHS, and ultimately patients, are considerably worse off as a result of this situation, as they failed to benefit from competition, and the lower prices that might result from competition. Until the end of February 2016, the NHS spent approximately £70,000 per month on Fludrocortisone Acetate Tablets.[656] During the Relevant Period, the costs to the NHS in England increased to approximately £1.2 million per month (approximately £9.8 million over the period of the infringement).[657]

I. Legal framework

8.98. To come within the Chapter I prohibition and/or the prohibition in Article 101 TFEU, an agreement must have '*as* [its] *object or effect'* the prevention, restriction or distortion of competition within the UK and/or the internal market. It is settled case law that certain types of coordination between undertakings reveal a sufficient degree of harm to competition, such that there is no need to

[654] Save for Tiofarma's acquisition of a duplicate MA in September 2016, which was subsequently transferred to Aspen. See www.mhra.gov.uk/spc-pil/.
[655] Document FLC0028.1 and its attachment Document FLC0036.2 (FLUDROCORTISIONE2), MHRA's response to question 1 of the CMA's section 26 notice dated 3 May 2017. No MA was granted during the period of May 2017 to March 2018. See Document FLC1126, MHRA's response to question 4 of the CMA's section 26 notice dated 28 February 2018. See also www.mhra.gov.uk/spc-pil/.
[656] In 2015, the total number of tablets dispensed by the NHS in the UK was approximately 16.8 million tablets (see paragraph 4.170) and the List Price was set at £0.05 per tablet under the PPRS.
[657] PCA data for England for months January to December 2015 to March 2016 to February 2017.

examine their effects.[658] That case law arises from the fact that certain types of coordination between undertakings can be regarded, by their very nature, as being harmful to the proper functioning of normal competition.[659]

8.99. The term '*object'* in both the Chapter I prohibition and the prohibition in Article 101 TFEU refers to the sense of '*aim'*, '*purpose'*, or '*objective'* of the coordination between undertakings in question.[660] This is assessed objectively. It is not necessary to establish that the parties jointly intended, subjectively, to pursue an anti-competitive aim – only that they had a common understanding whose terms, assessed objectively, pursue or result in such an aim.[661]

8.100. It follows that an agreement may be regarded as having an anti-competitive object even if it does not have a restriction of competition as its sole aim but also pursues other legitimate objectives. Furthermore, an agreement revealing a sufficient degree of harm may be deemed to be a restriction of competition by object irrespective of the actual, subjective aim of the parties involved, even if it those aims are legitimate.[662] Indeed, the Court of Justice has held that:

> *'even supposing it to be established that the parties to an agreement acted without any subjective intention of restricting competition* […] *such considerations are irrelevant for the purposes of applying that provision* [Article 101 TFEU]*.'*[663]

8.101. In addition, the Court of Justice has held that '*the fact that the adoption of anticompetitive behaviour may be the most cost-effective or least risky course of action for an undertaking in no way excludes the application of Article 101 TFEU*, […] *particularly if that behaviour consists in paying actual or potential competitors not to enter the market and sharing with those competitors the*

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[658] C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 26; C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 49; and *Cityhook Limited v Office of Fair Trading* [2007] CAT 18, paragraph 269.
[659] C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 26; C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 50; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), 165; and *Ping Europe Limited v Competition and Markets Authority* [2018] CAT 13, paragraph 82.
[660] See, for example, respectively: 56/64 *Consten & Grundig v Commission* EU:C:1966:41, paragraph 343; 96/82 *IAZ and Others v Commission* EU:C:1983:310, paragraph 25; C-209/07 *Competition Authority v Beef Industry Development Society* EU:C:2008:643, paragraphs 32 to 33.
[661] T-168/01 *GlaxoSmithKline Services Unlimited v Commission* EU:T:2006:265, paragraph 77 (upheld on appeal in Joined cases C-501/06P etc *GlaxoSmithKline Services Unlimited v Commission* EU:C:2009:610).
[662] C3/2018/2863 *Ping Europe Limited v Competition and Markets Authority* [2020] EWCA Civ 13, paragraph 96 and to C-209/07 *Competition Authority v Beef Industry Development Society* EU:C:2008:643, paragraph 21.
[663] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraphs 427 and 459, citing C-209/07 *Competition Authority v Beef Industry Development Society* EU:C:2008:643, paragraph 21.

profits resulting from the absence of generic medicinal products on that market, to the detriment of consumers, as in the present case.'[664]

8.102. To determine whether an agreement reveals a sufficient degree of harm such as to constitute a restriction of competition '*by object'*, regard must be had to:

(a) the content of its provisions;

(b) its objectives; and

(c) the economic and legal context of which it forms a part.[665]

8.103. It is well established that an agreement need not be implemented to fall foul of the prohibition on anti-competitive agreements, including whether it amounts to a restriction of competition by object.[666] However, evidence of the parties' conduct showing that the agreement was implemented may corroborate the assessment of its content and objectives.[667] The European Commission's Guidance on the Application of Article 101(3) TFEU states: '*The way in which an agreement is actually implemented may reveal a restriction of competition by object even where the formal agreement does not contain an express provision to that effect*'.[668]

8.104. Although the parties' subjective intention is not a necessary factor in determining whether an agreement is restrictive of competition, there is nothing prohibiting that factor from being taken into account as corroboration of the objective assessment.[669]

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[664] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraphs 380 and 459 (citing C-48/00 *Corus UK v Commission* EU:C:2003:531, paragraph 73 and T-50/00 *Dalmine v Commission* EU:T:2004:220, paragraph 211).
[665] C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 53, citing C-32/11 *Allianz Hungaria v Commission* EU:C:2013:160, paragraph 36 and the case law cited. See also C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraph 27; T-691/14 *Servier and Others v Commission* EU:T:2018:922, paragraph 221; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 165; and *Ping Europe Limited v Competition and Markets Authority* [2018] CAT 13, paragraph 82.
[666] C-277/87 *Sandoz v Commission*; *WANO Schwarzpulver*, OJ 1978 L232/26 [1979] 1 CMLR 403; Case 19/77 *Miller v Commission*, paragraphs 7 to 10. See also COMP/37750 *French Beer*, [2006] 4 CMLR 577, paragraph 68.
[667] C-49/92 P *Commission v Anic Partecipazioni SpA* EU:C:1999:356, paragraphs 81 to 94 and 109. An infringement may be proven by direct evidence and/or indirect evidence, '*for example in the form of conduct*': T-168/01 *GlaxoSmithKline Services Unlimited v* Commission EU:T:2006:265, paragraphs 82 to 83.
[668] The European Commission *Guidance on the Application of Article 101(3)*, recital 22.
[669] C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 54; and C-286/13 P *Dole v Commission* EU:C:2015:184, paragraph 118. See also C-32/11 *Allianz Hungaria v Commission* EU:C:2013:160, paragraph 37 and the case law cited. *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 165 and *Ping Europe Limited v Competition and Markets Authority* [2018] CAT 13, paragraph 82.

c. Market sharing and market exclusion

8.105. Market sharing agreements are agreements or concerted practices that have the aim of allocating markets between competitors, whether geographically,[670] by customer,[671] product,[672] or through the allocation of quotas for each competitor.[673] The Chapter I prohibition and Article 101(1) TFEU expressly apply in particular to agreements or concerted practices that '*share markets or sources of supply*' or '*limit or control production, markets, technical development or investment*'.[674]

8.106. The Court of Justice has consistently held that market sharing agreements constitute a particularly serious breach of the competition rules.[675] It has also consistently held that agreements which aim to share markets have, in themselves, an object restrictive of competition and that such an object cannot be justified by an analysis of the economic context of the anti-competitive conduct concerned.[676]

8.107. The General Court has further held that '*The **exclusion** of competitors from the market constitutes an **extreme form of market sharing** and of limitation of production*'.[677]

8.108. In the *Irish Beef* case, the Irish Competition Authority challenged a mechanism (the so-called BIDS arrangements) to reduce perceived overcapacity in the Irish beef sector. As part of the BIDS arrangements, the undertakings that stayed in the market paid financial compensation to those who agreed to leave. The Court of Justice ruled that:

'The BIDS arrangements are intended therefore, essentially, to enable several undertakings to implement a common policy which has as its object the encouragement of some of them to withdraw from the market and the reduction, as a consequence, of the overcapacity which affects their profitability by preventing them from achieving economies of scale.'

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[670] For example, Commission decision of 7 October 2009 in Case 39.129 *Power Transformers*.
[671] For example, OFT decision of 20 March 2014 in Case CE/9627/12 *Supply of care home medicines*.
[672] For example, Commission decision of 26 October 2004 in Case 38.388 *Needles*.
[673] For example, C-41/69 *ACF Chemiefarma v Commission*, EU:C:1970:71, in which the European Commission also found price fixing between the quinine and quinidine producers involved.
[674] Section 2(2)(b) and (c) of the Act and Article 101(1) TFEU.
[675] C-373/14 *Toshiba Corporation v Commission* EU:C:2016:26, paragraph 28 and the case law cited; C-449/11 *Solvay Solexis v Commission* EU:C:2013:802, paragraph 82; and C-408/12 *YKK and Others v Commission* EU:C:2014:2153, paragraph 26.
[676] C-373/14 *Toshiba Corporation v Commission* EU:C:2016:26, paragraph 28; and C-239/11, C-489/11 and C-498/11 *Siemens and Others v Commission* EU:C:2013:866, paragraph 218.
[677] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 435 (emphasis added).

'That type of arrangement conflicts patently with the concept inherent in the EC Treaty provisions relating to competition, according to which each economic operator must determine independently the policy which it intends to adopt on the common market. Article [101(1) TFEU] *is intended to prohibit any form of coordination which deliberately substitutes practical cooperation between undertakings for the risks of competition.'*

'In the context of competition, the undertakings which signed the BIDS arrangements would have, without such arrangements, no means of improving their profitability other than by intensifying their commercial rivalry or resorting to concentrations. With the BIDS arrangements it would be possible for them to avoid such a process and to share a large part of the costs involved in increasing the degree of market concentration […]*'.*[678]

8.109. The Court of Justice concluded that the arrangements in question were a restriction by object. Advocate General Trstenjak, whose Opinion the Court followed, characterised the arrangement as '*the "buying off" of competition*'.[679]

8.110. In *Cartes Bancaires*, the Court of Justice explained that '*The object of the BIDS arrangements was* […] *to change, appreciably, the structure of the market through a mechanism intended to encourage the withdrawal of competitors*'.[680]

8.111. Relying on the jurisprudence outlined above, the Commission and the CMA have issued a number of decisions finding that agreements involving incumbent pharmaceutical companies making payments (or value transfers) to potential generic entrants to delay or abandon their efforts to enter the market independently are comparable to market exclusion and constitute restrictions of competition by object: *Lundbeck*,[681] *Perindopril (Servier)*[682] and *Fentanyl*[683] in the EU and *Paroxetine*[684] in the UK. These types of agreements are commonly known as 'pay for delay' agreements.

8.112. For the purposes of assessing whether the agreements at issue in each of *Lundbeck*, *Servier* and *Fentanyl* revealed in themselves a sufficient degree of

[678] C-209/07 *Competition Authority v Beef Industry Development Society* EU:C:2008:643, paragraphs 33 to 35.
[679] Opinion of AG Trstenjak in C-209/07 *Competition Authority v Beef Industry Development Society* EU:C:2008:643, paragraph 77.
[680] C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 84.
[681] Commission decision of 19 June 2013 in Case 39.227 *Lundbeck*.
[682] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*.
[683] Commission decision of 10 December 2013 in Case 39.685 *Fentanyl*.
[684] *GSK v CMA* [2018] CAT 4 (*Paroxetine*).

harm to competition to amount to restrictions '*by object*', the European Commission took into account the following factors relating to the content, the context and the objectives of those agreements:[685]

(a) the potential entrant and the incumbent were at least potential competitors;

(b) 'the generic undertaking committed itself in the agreement to limit, for the duration of the agreement, its independent efforts to enter into one or more […] markets with a generic product'[686]; and

(c) in return, the agreements involved a value transfer, of a pecuniary or non-pecuniary nature, from the incumbent to the potential entrant.

8.113. The Commission's analysis of the agreements in *Lundbeck* and *Servier* was substantively upheld on appeal.[687] In the recent *Lundbeck* judgment, the General Court upheld the decision by the Commission that so-called 'pay for delay' agreements entered into between a patent holder and potential generic entrants were '*comparable to market exclusion agreements, which are among the most serious restrictions of competition*'.[688] In its *Servier* judgment, the General Court held with respect to such agreements that '[w]*here there is an inducement, the agreements in question must be regarded as being market exclusion agreements, in which the stayers are to compensate the goers*'.[689] In both the *Lundbeck* and *Servier* judgments, the General Court characterised these agreements as '*a buying-off of competition*'.[690] In both cases, the General Court held that these agreements were restrictions by object.[691]

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[685] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1154; Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 661; and Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 219. The CMA's decision in *Paroxetine* relied on similar factors.
[686] Or, in the Fentanyl case: '*due to the Agreement, the generic undertaking limited, for the duration of the Agreement, its independent efforts to enter the market with its generic product*'. Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 219.
[687] T-472/13 *Lundbeck v Commission* EU:T:2016:449 (currently on appeal to the EU Court of Justice); T-691/14, EU:T:2018:922; and T-677/14, T-679/14, T-680/14, T-682/14, T-701/14 and T-705/14. The only exception relates to the agreement between Servier and Krka, in respect of which the General Court annulled the Commission's decision because the agreements at issue (settlement agreements combined with ancillary licence and assignment agreements) could not be shown to contain value transfers to Krka. See T-684/14 *Krka Tovarna v Commission* EU:T:2018:918.
[688] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 435.
[689] T-679/14 *Teva v Commission* EU:T:2018:919, paragraph 233.
[690] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 352; and T-679/14 *Teva v Commission* EU:T:2018:919, paragraph 233.
[691] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 476; and T-679/14 *Teva v Commission* EU:T:2018:919, paragraph 233.

8.114. The CMA took the factors set out in paragraph 8.112 into account in its *Paroxetine* decision, in which it found that GSK and two generic companies had entered into anti-competitive agreements by object. GSK made cash payments and other value transfers to the generic companies in return for which the generic companies accepted restrictions on their ability to enter the market independently.[692]

8.115. These factors are relevant to establishing a market exclusion agreement, whether or not in a patent context. However, in the absence of a patent context, establishing a market exclusion agreement where a potential competitor agrees not to enter the market is more straightforward since it is not necessary to consider whether that agreement not to enter reflects potentially legitimate recognition of the strength of a patent.[693] For example, in *Paroxetine* the Court of Justice held that where the background to such an agreement was '*a genuine dispute relating to a process patent, that dispute being the subject of proceedings before a national court*', that agreement:

> *'cannot be regarded as … bringing to an end entirely fictitious disputes, or as designed with the sole aim of disguising a market-sharing or a market-exclusion agreement.* ***When agreements are of that nature****, they are* ***as harmful to competition as market-sharing agreements or market-exclusion agreements****, and such agreements* ***have to be characterised as 'restrictions by object'****'*[694]

8.116. Where there is no '*genuine dispute*' relating to a patent underlying an agreement involving payments from an incumbent to a potential entrant, therefore, it is more straightforward to conclude (if the evidence supports this) that the agreement is a market sharing or market exclusion agreement.

8.117. The Court of Justice also confirmed in *Paroxetine* that patent settlement agreements may be characterised as 'restrictions by object' even in cases where such agreements do not have the sole aim of disguising a market-sharing agreement or a market-exclusion agreement.

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[692] CMA decision in case CE-9531/11 *Paroxetine*, sections 6.E and 6.G.
[693] In the patent cases the agreement of the generic not to enter the market was not in dispute, since it was given as a written contractual commitment. Nor was the existence of a payment to the generic. However, it was necessary to consider whether the generic agreed not to enter in recognition of the strength of the patent (which could be legitimate) or in exchange for the payment (which would be an illegitimate buying-off of competition): whether the 'pay' was 'for delay'. See, for example, T-679/14 *Teva v Commission* EU:T:2018:919, paragraph 220; and Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraphs 604 and 660.
[694] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraph 76 (emphasis added).

8.118. Entry by an incumbent into such agreements might breach competition law '*notwithstanding the fact that it may constitute the legitimate expression of the intellectual property right attached to the patent*'. In that respect, the Court of Justice noted that '*it is necessary to assess* […] *whether those agreements may, nonetheless, be treated as equivalent to market-sharing or market-exclusion agreements*'.[695] This means that, in assessing whether the SDA should be found to constitute a 'by-object' restriction, the key issue is whether the SDA constitutes the same general 'form of collusion' as that identified in a market sharing or market exclusion agreement, with it being irrelevant whether the SDA falls within a specific 'type of agreement' that has previously been censured.[696]

8.119. In that regard, the Court further stated that, '[i]*n accordance with settled case-law, each economic operator must determine independently the policy which he intends to adopt in the internal market*'.[697] A characterisation of 'restriction by object' must be adopted when it is plain from the assessment of the agreement at issue that the transfer of value provided under the agreement '*cannot have any explanation other than the commercial interest of both* [parties] *not to engage in competition on the merits*'.*[698]*

d. Potential competition

8.120. The legal framework for potential competition is set out above in paragraphs 8.27 to 8.52.

e. Restriction on independent efforts to enter into the relevant market

8.121. A relevant question is whether a potential entrant gave a commitment not to enter the market. For example, in *Servier*, such commitments took the form of non-challenge and non-compete obligations within a patent settlement agreement.[699] In *Paroxetine*, potential entrants accepted express obligations to refrain from entering the UK paroxetine market independently of the incumbent.[700]

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[695] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraphs 76 to 79.
[696] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 438. See also *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 167: '*However, it must be emphasised that there is no exhaustive list of the categories of agreements that may constitute an infringement 'by object'. Thus, the fact that agreements of the kind in question here have never before been found to be anti-competitive is not in itself conclusive*.'
[697] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 78.
[698] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 87.
[699] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1184.
[700] CMA decision in case CE-9531/11 *Paroxetine*, paragraphs 6.88 to 6.90 and 6.152 to 6.154.

8.122. In *Lundbeck*, that commitment took many forms, including in the case of *Merck (GUK)* a commitment not to license its MA for the UK to any other generic supplier, thereby giving the incumbent certainty that no other generic undertaking could come to the UK market with the help of that MA.[701] This commitment was highly relevant to achieve total market exclusion of the relevant product in the UK, because absent this commitment, Merck (GUK) could have licensed MA duplicates to other generic companies.[702]

8.123. In *Lundbeck*, the General Court noted that the parties to the agreements at issue preferred to replace the risks inherent in the normal competitive process with the certainty that potential competitors would not enter the market with their products during the term of the agreements at issue. Specifically, these agreements eliminated that very possibility for the duration of the SDA.[703]

f. In return, payment (or value transfers) from the incumbent to the potential entrant

8.124. A further relevant factor is whether, in return for the commitment made by the potential entrant not to enter, the incumbent made payments, or value transfers, reflecting the strengthening and/or preservation of its market position. As confirmed by the Court of Justice in *Paroxetine*, endorsing AG Kokott, '*in order to assess whether transfers of value contained in* [an agreement] *can have no explanation other than the commercial interest of the parties to that agreement not to engage in competition on the merits,* […] *it is important to take into consideration all the transfers of value between the parties, whether those were pecuniary or non-pecuniary'*[704]*.*

8.125. In *Lundbeck*, the General Court noted that by eliminating the very possibility of entry by the potential competitor, the parties to the agreements at issue were able to share a part of the profits that Lundbeck continued to enjoy, to the detriment of consumers who continued to pay higher prices than those they would have paid if the generics had entered the market.[705]

8.126. Such a payment may, for example, be in cash. In some cases, cash payments have been given spurious labels, attributing them to fictitious or negligible services provided by the potential entrant. In *Fentanyl*, the payments were

[701] See Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, section 12.2.5.3.
[702] See Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 774.
[703] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 429.
[704] C-307/18 *Generics (UK) Ltd and Others v CMA,* EU:C:2020:28, paragraph 88.
[705] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 429; Commission decision of 19 June 2013 in Case 39.226 *Lundbeck,* paragraphs 644 to 646.

expressed to relate to promotional activities, though their value far exceeded that of the minimal activities carried out.[706] The Commission concluded that the parties agreed on a common plan for the purpose of '*preserving and sharing the supra-competitive profits of the incumbent undertaking and thus restricting competition between them*' that '*most probably would have arisen*' absent the agreement.[707]

8.127. In *Paroxetine*, the CAT noted that the parties' descriptions of payments as '*marketing payments*' or '*promotional allowances*' were '*simply convenient labels selected for what was part of the overall financial consideration* […] *We find it remarkable, and somewhat revealing, that the parties chose in the formal agreements to designate these payments in a manner that we find was misleading*.'[708]

8.128. A payment may also be '*through a more covert transfer of value*' which '*cannot be adequately explained by, or which considerably exceeds the value to the originator of any counter-performance of the* [potential entrant].'[709] For example, in *Paroxetine* the agreements involved the supply of limited volumes of product for the potential entrants to sell on their own account. The CAT held that '*the CMA was correct to regard the margin which the generic company was likely to earn on the specified volumes supplied as part of the consideration*'.[710] The CAT found that:

'The agreements led to the supply of limited quantities of generic paroxetine which in aggregate was significantly less than total market demand; and that demand was inelastic. Therefore the wholesalers, like the generic companies, knew they could sell all the generic paroxetine they obtained and there was no incentive for them to compete on price.'[711]

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[706] The limited promotional activities are summarised at paragraph 274 of Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*.
[707] Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, paragraph 218 (no proceedings against the decision were initiated before the General Court). See, similarly, Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 658. In that decision, the European Commission also clarified the differences between *Lundbeck* and *Irish Beef*: '*i) in the case at hand, there is no question of reducing any existing overcapacity from numerous competitors in the market, but rather of de facto preserving and sharing the supra-competitive profits of a single incumbent undertaking through the postponement of potential competition; and ii) the agreements in the case at hand were concluded against the background of patent disputes, with considerable uncertainty as to the possible outcome of potential or actual patent litigation*' (footnote 1180).
[708] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraphs 179 to 180. Compare T-208/08 *Gosselin v Commission* EU:T:2011:287, in which cartelists issued each other with invoices for common payments on rejected offers, or offers not made, '*referring to fictitious services*' (paragraph 12).
[709] Commission decision of 19 June 2013 in Case 39.226 *Lundbeck*, paragraph 660.
[710] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 184.
[711] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 184.

8.129. Similarly, in *Servier*, one of the agreements provided, in addition to cash payments, for *Servier* to supply Teva with a defined quantity of product to be distributed in Teva livery (or pay damages for non-supply).[712] In *Lundbeck*, part of the consideration for non-entry in some of the relevant agreements was the supply by Lundbeck of a limited volume of the drug citalopram at a substantial discount for GUK and Ranbaxy to sell in their territories.[713] In its judgment on *Sun Pharmaceutical Industries* and *Ranbaxy*'s appeal, the General Court agreed with the European Commission that these supplies were part of the consideration granted to Ranbaxy, and pointed out that the discount involved Lundbeck giving up the profits it would have made in selling the product itself.[714]

8.130. In *Perindopril (Krka)*, the General Court considered whether a patent settlement and related contracts (including a *prima facie* legitimate licensing agreement[715]) restricted competition by object. In its decision, the European Commission had stated on several occasions that certain side deals between parties had not been negotiated at arm's length. The General Court accepted that the concept of '*normal competitive conditions'* may be relevant in determining whether a payment in consideration of the acquisition of a right over an asset was limited to its economic value and, thus, at arm's length.[716]

8.131. In Paroxetine the Court of Justice further clarified that '*where parties to an agreement rely on its pro-competitive effects, those effects must, as elements of the context of that agreement, be duly taken into account for the purpose of its characterisation as a "restriction by object"*' (…) '*but merely to appreciate the objective seriousness of the practice concerned*'.[717] However '*the mere existence of pro-competitive effects cannot as such preclude characterisation as a 'restriction by object'. If such effects are demonstrated, relevant and specifically related to the agreement concerned, those pro-competitive effects must be sufficiently significant, so that they justify a reasonable doubt as to whether the settlement agreement concerned caused a sufficient degree of harm to competition, and, therefore as to its anticompetitive object*'.[718]

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[712] Commission decision of 9 July 2014 in Case 39.612 *Perindopril (Servier)*, paragraph 1578.
[713] T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* EU:T:2016:453, paragraphs 246 to 251.
[714] T-460/13 *Sun Pharmaceutical Industries and Ranbaxy (UK) v Commission* EU:T:2016:453, paragraph 249.
[715] T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 775; T-691/14 *Servier and Others v Commission* EU:T:2018:922, paragraph 231; European Commission's Guidelines on the application of Article 101(3) of the Treaty on the Functioning of the European Union to categories of technology transfer agreements, recital 4.
[716] T-684/14 *Krka Tovarna Zdravil d.d. v Commission* EU:T:2018:918, paragraphs 172 and 173.
[717] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraphs 103 and 104
[718] C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraphs 106 to 107.

8.132. For the reasons set out in this section, and pursuant to the legal framework set out above, the CMA concludes that, in light of its legal and economic context, in particular the fact that Tiofarma and Amilco were potential competitors of Aspen (and the absence of any other form of competition in the Relevant Market), the content and objective of the SDA was to prevent competition between the Parties for the duration of the agreement, and for the incumbent to make value transfers reflecting that postponement of competition, as follows:

(a) Amilco and Tiofarma agreed not to enter the Relevant Market independently, thereby delaying the emergence of competition between the Parties in that market; and

(b) in return, Aspen agreed to value transfers to Amilco and Tiofarma which reflected that postponement of competition. Specifically, Aspen agreed to make Tiofarma the monopoly manufacturer for supply in the UK, and to share with Amilco a fixed 30% profit margin calculated on the basis of a List Price more than 1,800% higher than its price prior to the SDA.

II. Content and objective of the SDA

8.133. The CMA has already found in the previous sections that:

(a) Amilco and Tiofarma, working together, were potential competitors to Aspen since at least November 2015 (paragraphs 8.53 to 8.89);

(b) Amilco and Tiofarma agreed not to enter the Relevant Market independently from Aspen for the duration of the SDA. They granted exclusive rights over Ambient Storage Fludrocortisone which were tantamount to a commitment by Tiofarma and Amilco not to enter the Relevant Market independently from Aspen during that period (see paragraphs 7.13 to 7.16 above);

(c) In exchange, Aspen committed to make significant value transfers to Amilco and Tiofarma (of a pecuniary or non-pecuniary nature) premised on the postponement of competition (see paragraphs 7.17 to 7.60 above and below).

8.134. For the reasons set out below, such an agreement when assessed in the relevant legal and economic context is clearly restrictive by object.

8.135. Prior to the SDA, the parties faced certain inherent risks arising from the uncertainty that flowed from the potential competition between them at that

time (see paragraphs 8.3 to 8.15). This is demonstrated most clearly by the contemporaneous evidence showing that Aspen expected independent entry to have a significant impact on its Cold Storage Fludrocortisone sales, which in turn hampered its ability successfully to implement a unilateral price increase of the magnitude observed under the SDA. Aspen had forecast internally that it would lose significant market share if Ambient Storage Fludrocortisone entered at the same price as its incumbent product (ie Cold Storage Fludrocortisone, see paragraph 8.88(b)).[719]

8.136. Instead of engaging in competition on the merits, under the SDA the Parties pursued a common commercial strategy based on substituting the risks and uncertainty of competition between them by practical cooperation. The CMA finds that the reciprocal commitments made by the Parties under the SDA (as set out in paragraph 8.133), assessed in their relevant context, were a *quid pro quo* reflecting that common commercial strategy.

8.137. Specifically, the exclusive rights over Ambient Storage Fludrocortisone granted to Aspen under the SDA prevented the emergence of competition between the Parties. This in turn meant that Aspen's position as sole UK supplier was preserved for the duration of the SDA as it was no longer constrained by the only (potential) competitors existing at that time in the Relevant Market, Amilco and Tiofarma.

8.138. The value transfers that Aspen committed to make to Amilco and Tiofarma in exchange for exclusive rights over Ambient Storage Fludrocortisone were clearly premised, and contingent, on this restriction of competition between the Parties:

(a) Making Tiofarma the sole manufacturer of Fludrocortisone Acetate Tablets in the UK for the duration of the SDA, by withdrawing Cold Storage Fludrocortisone from the UK market and purchasing all of its requirements for Fludrocortisone Acetate Tablets from Tiofarma (see paragraphs 7.19 to 7.38):[720] such an outcome was premised on the

[719] This is best illustrated by the fact that Aspen had forecast internally that it would lose significant market share if Ambient Storage Fludrocortisone entered at the same price as its incumbent product (ie Cold Storage Fludrocortisone). This is consistent with what [Aspen Senior Executive 1] stated at interview, ie that after being informed of the emergence of a new potential competitor, ie Ambient Storage Fludrocortisone, the [✂] management team had significantly revised downwards the contemplated price increase for Cold Storage Fludrocortisone to reflect the threat of competition.

[720] As set out above, [Person 1 acting for Amilco] stated at interview that Aspen's commitment to purchase 90% of its total requirements for Fludrocortisone Acetate Tablets from Tiofarma (Clause 15) was in recognition of the exclusivity the SDA offered Aspen (see paragraph 7.28). '*I think the reason why that* [minimum sales quantity clause] *was there is because they insisted on an exclusivity from us'.* Document FLC1666.2, page 94 lines 6 to 7,

Parties not competing for market shares, and ensured that benefits from their cooperation be shared between the Parties in line with the terms of the SDA.[721] [Person 1 acting for Amilco] acknowledged in interview with the CMA that the '*minimum sales quantity requirement*' was the *quid pro quo* for the exclusivity on Ambient Storage Fludrocortisone.[722] In other words, [Person 1 acting for Amilco] acknowledged that for Aspen to obtain exclusivity over Ambient Storage Fludrocortisone, Amilco and Tiofarma required the inclusion of an obligation on Aspen to acquire at least 90% of its Fludrocortisone Acetate Tablet demand from Tiofarma (and Amilco would be paid a 30% profit share element from Aspen's sale of those tablets). As explained above, the minimum sales quantity requirement in effect meant that Aspen had to purchase all of its requirements from Tiofarma. Therefore, while Tiofarma became the sole manufacturer of Fludrocortisone Acetate Tablets for Aspen, which was the sole supplier in the UK, Amilco would benefit from a 30% profit share of all sales of the product made by the sole UK supplier.

(b) Making payments to Amilco (ie a fixed Supply Price of £[✂] per pack, premised on an ASP increased to £[✂][723], subject to no third parties entering the Relevant Market): such payments could only be made as a result of the considerably higher profits that could be sustained as a result of preventing competition between the Parties for the duration of the SDA. Payments to Amilco of that magnitude would not have been sustainable for Aspen absent such postponement of competition.

8.139. On that basis, the SDA was designed to enable each Party to generate considerably higher returns than would have been the case under normal conditions of competition. In particular, given that Aspen was the sole UK

Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017. He further confirmed: '*We were tied in to supply only* [Aspen]. *So we need some sort of assurance of some sort of commercial value to this contract. So the minimum requirements were there*'. Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 101, lines 8 to 11. See also Document FLC4905, page 21, lines 3 to 9, Transcript of interview with [Aspen Senior Executive 1] on 14 May 2018.

[721] It should be noted that the CMA does not object to the withdrawal of Cold Storage Fludrocortisone *per se*, it objects to how this withdrawal contributed to Aspen making value transfers to Amilco and Tiofarma reflecting, and in exchange for, the elimination of competition between the Parties, and in that respect it is part of the common understanding between the Parties.

[722] '*I think the reason why that* [minimum sales quantity clause] *was there is because they insisted on an exclusivity from us'.* Document FLC1666.2, page 94 lines 6 to 7, Transcript of interview with [Person 1 acting for Amilco] on 14 December 2017. He further confirmed: '*We were tied in to supply only* [Aspen]. *So we need some sort of assurance of some sort of commercial value to this contract. So the minimum requirements were there.*' Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 101, lines 8 to 11. See also evidence from negotiations of the SDA at paragraph 7.34

[723] Except in the event that Aspen increased the price discount it offered to wholesalers beyond [✂], in which case Amilco's share of Aspen's revenues would be increased in line with Clause 10 of the SDA.

supplier and Ambient Storage Fludrocortisone the only potential competing product,

(a) Aspen's ability to set prices for Fludrocortisone Acetate Tablets would no longer be constrained by the only (potential) competitors existing at that time in the Relevant market, leaving it free profitably to implement significant price increases such as the one contemplated in Annexure C of the SDA.

(b) Tiofarma would at once become the sole manufacturer of Fludrocortisone Acetate Tablets in the UK (bar parallel imports), which meant that it would achieve materially higher volumes than what it would likely have achieved in competition with Aspen (see paragraphs 7.20).

(c) Amilco would be paid a share of profit on all sales of Ambient Storage Fludrocortisone, calculated on the basis of Aspen charging a retail selling price more than 1,800% higher than its price prior to the SDA; this was significantly higher than what could have been achieved if it had entered the market in competition with Aspen.

8.140. This assessment of the content and objective of the SDA is supported by the outcome of the Parties' cooperation in the Relevant Market. Indeed, in line with the ASP and projected volumes set out in Annexures B and C of the SDA, over a period of seven months (ie while the SDA remained in force) Aspen and Amilco earned significant revenues of approximately £6 million and £[0-5] million, respectively, which each far exceeded the annual total value of the Relevant Market prior to the SDA.[724]

8.141. In the light of the above, the CMA finds that the object of the SDA was to change appreciably the structure of the Relevant Market (ie preventing the only form of actual or potential competition existing at the time) through a mechanism (ie significant value transfers of a pecuniary or non-pecuniary nature) intended to encourage Amilco and Tiofarma not to enter that market independently.[725]

[724] Given the market context (ie Aspen was the sole supplier) and the content of their agreement (ie that Aspen would sell exclusively Ambient Storage Fludrocortisone at £30 per pack, absent third party entry), they were able to forecast likely prices and sales in the event that no third party entry occurred (as set out in Annexures B and C of the SDA, respectively). As no such entry ultimately occurred during that period, the forecasts set out in those annexures proved to be mostly accurate. See paragraphs 7.24 and 7.24.
[725] C-67/13 P *Groupement des Cartes Bancaires v Commission* EU:C:2014:2204, paragraph 84.

8.142. As set out in the case law, if it were possible to pay potential competitors to cease or merely delay their entry, effective competition would never take place.[726] It is therefore plain from an objective analysis of the SDA that, by entering into this agreement, the Parties substituted the risks and uncertainty of competition on the merits with practical cooperation. They pursued a common strategy which had the object of preventing the potential competition which existed between them at that time, and of sharing the resulting benefits to the detriment of the NHS.[727]

8.143. Such an object conflicts patently with the concept of competition, according to which each economic operator must determine independently the policy which it intends to adopt in the relevant market.[728] The CMA considers that there is sufficiently reliable and robust experience (as set out at paragraphs 8.105 to 8.118) showing that this form of collusion, which amounts to market sharing or market exclusion, is by its very nature harmful to the proper functioning of competition and detrimental to consumers.

8.144. Any benefit from the change in the structure of the Relevant Market caused by the SDA (including the introduction of Ambient Storage Fludrocortisone in the UK) was not due to the introduction of competition, but to a controlled reorganisation of the market engineered by the Parties. In addition, the CMA does not consider that the commercialisation of Ambient Storage Fludrocortisone was contingent on the SDA: for the reasons set out above at paragraphs 8.64 to 8.83, Amilco and Tiofarma had a number of viable routes to market open to them and the Parties could have entered into a licensing agreement on less restrictive terms. There are therefore no possible doubts as to the fact that the SDA caused a sufficient degree of harm to competition for it to be characterised as an object restriction.[729]

III. Intentions of the Parties in entering into the SDA

8.145. Although the Parties' intentions are not a necessary factor in determining whether an agreement between undertakings is restrictive, they can be an additional indication of the object of a given agreement.[730] The CMA's assessment of the content and objectives of the SDA as outlined above is

[726] T-472/13 *Lundbeck v Commission* EU:T:2016:449 paragraph 171 ; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 158.
[727] See by analogy C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraph 87.
[728] See C-209/07, *Beef Industry Development Society and Barry Brothers* EU:C:2008:643, paragraphs 33 and 34; see also discussion of those paragraphs *in* C-67/13 *Groupement des cartes bancaires (CB)* EU:C:2014:2204 at paragraph 84; and T-472/13 *Lundbeck v Commission* EU:T:2016:449 paragraph 341.
[729] See by analogy C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraphs 103 to 107.
[730] C-67/13 *Groupement des cartes bancaires (CB)* EU:C:2014:2204, paragraph 54.

supported by an analysis of the Parties' respective intentions, as set out below.

8.146. The facts set out in Section 4 show that each of the Parties was well aware of, and understood that, the main objective of the SDA (and later the SAA) was not to facilitate the bringing to market of a superior product (ie Ambient Storage Fludrocortisone). Instead, and on the basis of the evidence set out below, the CMA finds that it was the intention of each of the Parties in entering into, and implementing, those agreements to delay competition between them, and to make value transfers flowing from that postponement of competition. Specifically, each of the Parties understood that they would benefit from the SDA in the following way:

(a) Tiofarma, by becoming the sole manufacturer for Fludrocortisone Acetate Tablets in the UK; and

(b) Amilco and Aspen, by maximising and sharing supra-competitive revenues for Ambient Storage Fludrocortisone.

8.147. The evidence obtained by the CMA in the course of the Investigation shows that strategic decisions were taken for Aspen by its [✂] management ([Aspen Senior Executive 1] and [Aspen Senior Executive 2]) and for Amilco and Tiofarma by [Person 1 acting for Amilco] and [Tiofarma Employee 1] respectively. Despite the close working relationship between [Person 1 acting for Amilco] and [Tiofarma Employee 1], and their respective complementary roles in negotiations with Aspen, very few contemporaneous documents record exchanges between them (as illustrated for example by the absence of documents recording Amilco's ultimate ownership over Ambient Storage Fludrocortisone, an asset formally held by Tiofarma). As a result, there is a limited amount of evidence setting out Amilco and Tiofarma's respective intentions in entering into the SDA.

a. Aspen

8.148. The CMA finds that Aspen's intention in entering into the SDA (and later the SAA) was to maintain its position as sole UK supplier of Fludrocortisone Acetate Tablets in order to maintain a strategy seeking to maximise profits (through significant price increases) in the short-to-medium term, taking advantage of the absence of competition in the Relevant Market.

8.149. As part of its admission of liability with respect to the Infringement, Aspen has accepted that its intention in entering into the SDA was to neutralise the threat

of competition from Amilco and Tiofarma for the duration of the SDA in order to implement significant price increases in the Relevant Market.

8.150. Prior to the SDA, and shortly after the purchase of the rights to Cold Storage Fludrocortisone in the UK, the [✂] management of Aspen had already taken steps to implement a strategy relying on the absence of competition to profitably increase the price of Fludrocortisone Acetate Tablets (see paragraphs 4.5 to 4.8). Independent entry of Ambient Storage Fludrocortisone would have created uncertainty as to Aspen's ability to increase prices without losing market share. [731] By entering into the SDA, Aspen eliminated that uncertainty for the duration of the SDA.

8.151. When taking the decision to engage with Amilco, [Aspen Senior Executive 1] thought Aspen would need to '*agree a supply price with* [Amilco]*. I would think it best to lock in a gross margin'.*[732] Evidence relating to the negotiations of the Term Sheet show that Amilco and Aspen negotiated on the basis that the new List Price for Fludrocortisone Acetate Tablets would be £1 per tablet (more than 1,800% increase on the same price prior to the SDA).[733] Aspen internal documents show that forecasts contemporaneous to the Term Sheet prepared by Aspen assumed it would be able to increase the List Price while maintaining nearly all sales to NHS patients.[734] Within the context of the discussions of forecast volumes of the supply of Fludrocortisone Acetate Tablets with Amilco, [Aspen Employee 22] indicated that a challenge received from her management is that volumes should remain closer in line with the previous volumes of Florinef given that Aspen was '*the market leader with minimum competition'*.[735]

8.152. Internal documents, exchanged within Aspen's [✂] team by reference to an article in the Times about '*small drug companies hiking prices* […] *and ripping*

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[731] Document FLE0104 and its attachment Document FLE0105, email from [Consultant to Aspen] to [Aspen Employee 1] dated 6 October 2015 headed *'Fludrocortisone model de brand ambient product'*. The calculation was later updated. See Document FLE0134 and its attachment Document FLE0135, email from [Aspen Employee 11] to [Aspen Employee 1] and [Consultant to Aspen] dated 6 January 2016 headed *'Fludrocortisone generic ambient 06012016.xslx'.* Document FLE0136 and its attachment Document FLE0137, email from [Aspen Employee 1] to [Aspen Employee 11] dated 8 January 2016.
[732] Document FLE0968, email from [Aspen Senior Executive 1] to [Aspen Senior Executive 2] dated 14 December 2015. The CMA considers a plain reading of the terminology '*lock in a gross margin*' to be that Amilco would receive a fixed commission, from which Aspen would not depart.
[733] See paragraphs 4.51 to 4.63 and Document FLC1143.94, email chain between [Aspen Senior Executive 2] and [Person 1 acting for Amilco], dated 21 December 2015.
[734] Document FLE0139 and its attachment Document FLE0140 ('*UK Fludrocortisone 30 Forecast*'), email from [Aspen Employee 1] to [Aspen Senior Executive 2] and [Aspen Senior Executive 1] dated 8 January 2016.
[735] Document FLE0208, email chain between [Aspen Employee 22] and [Aspen Employee 2] dated 19 February 2016. It appears that Aspen [✂] management had not anticipated that sales to customers other than NHS customers were likely to be lost as a result of the price increase of 1 March 2016.

off NHS', shows an awareness that a strategy of price increases had been successful for [✂] (and for Aspen in other jurisdictions).[736]

8.153. Aspen's [✂] team, before and after the SDA, expected the strategy would be successful in the Relevant Market in the short-to-medium term, until the emergence of competition from third parties placed pressure on Aspen's price and market share:

(a) Discussing the prospect of the SDA on 8 January 2016, [Aspen Employee 1] told [Aspen Employee 3]: '*that's why I want us all to join hands – could be supper* [sic] *successful for 18 months before competiton* [sic] *respond'*.[737]

(b) In an email of 4 February 2016, [Aspen Employee 3] asked [Aspen Employee 1] to '*maximize this opportunity in the UK to it's* [sic] *fullest potential*.'[738]

(c) In an email of 11 March 2016 discussing the budget targets, [Aspen Employee 2] wrote to [Aspen Employee 1]: 'we have assumed in the target [✂] sales for Florinef. As a part of the budget process we will need to carefully evaluate how we can maximise this opportunity'[739].

(d) A working document setting out the status of budget preparation for 2016/2017 states:

'de-branding strategy in the UK:

Maximize the short-term opportunity with Fludrocortisone

Plan what actions to take in the medium term – after 1-2 years post de-branding, it is likely to have competition from new Gx entrants'.[740]

(e) In an internal email of July 2016, [Aspen Employee 1] explained that the plan to debrand Cold Storage Fludrocortisone and increase price was developed in the UK ('*value was created in the UK/EU'*) while the initiative taken by the Aspen's [✂] management to negotiate and enter into the

[736] Document FLE0356, messaging conversation between [Aspen Employee 11] and [Aspen Employee 2] dated 6 June 2016 at 11.42 and 12.07.
[737] Document FLE0138, messaging conversation between [Aspen Employee 1] and [Aspen Employee 2] dated 8 January 2016.
[738] Document FLE0194, email from [Aspen Employee 3] to [Aspen Employee 1] dated 4 February 2016.
[739] Document FLE0238, email from [Aspen Employee 2] to [Aspen Employee 1] dated 11 March 2016
[740] Document FLE0292, document entitled '*Priorities and Strategies Budget 2016/2017*', PDF attachment to email from [Aspen Employee 3] to [Aspen Employee 2] and others dated 18 April 2016.

SDA '*maintained this value for the medium term – until further ambient generic competition comes to the market*'.[741]

8.154. Aspen internal documents relating to the SAA provide some additional context in relation to Aspen's intention and strategy for Fludrocortisone Acetate Tablets at the time of entering into the SDA, to the extent that the SAA transaction was essentially based on the SDA: [742] The board paper prepared for the SAA transaction set out that Ambient Storage Fludrocortisone '[✂]'[743] and assumed that Aspen could sustain high prices in the UK at least for a further two and a half years (ie until the end of the initial period of the SDA).[744] This shows that Aspen's intention was to take advantage of remaining the sole UK supplier, having removed the only credible competitive threat to its position.

b. Amilco

8.155. The CMA finds that Amilco has consistently pursued a strategy seeking to partner with Aspen exclusively, with a view to achieving high profits in the short-to-medium term:

(a) The document sent on behalf of Amilco to Aspen outlined the strategy that was implemented six months later through the SDA. Specifically:

1. It offered to Aspen an exclusive licence to supply Ambient Storage Fludrocortisone (thereby precluding the possibility of competition between the Parties); and
2. It highlighted the commercial opportunity arising from the possibility to increase significantly the price of generic Fludrocortisone Acetate Tablets, identifying two benchmark products that had an NHS Drug Tariff price of c. £1 and £0.8 per tablet respectively in July 2015.[745] The CMA notes in this context that the CMA has provisionally found that one or more suppliers held significant market power in the

[741] Document FLE0387, email from [Aspen Employee 1] to [Aspen Employee 3] and [Aspen Employee 2] dated 30 July 2016.
[742] Document FLE0456, paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016.
[743] Document FLE0456, paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016. This statement about risk of generic entry originates from [Aspen Senior Executive 2] (see Document FLE1031, email from [Aspen Employee 10] to [Aspen Senior Executive 2] dated 7 October 2016 and Document FLE1032, attachment with draft board paper).
[744] The paper stated that '*the investment opportunity in the Product presents acceptable risk adjusted returns with material upside through modest sales growth during the initial term and/or a steady decline after the 3 year initial term*'. Document FLE0456, paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016.
[745] Document FLE0086, '*Fludrocortisone Acetate Tablets'* dated August 2015.

relevant market for [✂] at that time.[746] As regards [✂], the price outlined in the initial approach document was reached following a very sharp increase in April/May 2014, and subsequently began falling again from December 2016, following entry of a generic supplier by (which obtained an MA for that product in November 2016).[747]

(b) At no point prior to the SDA (or prior to SAA) did Amilco approach any supplier other than Aspen in relation to Ambient Storage Fludrocortisone. Unsolicited approaches from third parties interested in supplying Ambient Storage Fludrocortisone were dismissed outright by Tiofarma following a steer given to them by Amilco (see Section 4.E). By way of example, Amilco/ [Person 1 acting for Amilco] (and Tiofarma) decided three times not to even explore the possibility of partnering with [Company 2], generic supplier in the UK: [✂] in November 2015 and September 2016 when [Company 2] approached Tiofarma.[748]

(c) In return for entering into the SDA, Amilco successfully requested Aspen to withdraw Cold Storage Fludrocortisone and to supply exclusively Ambient Storage Fludrocortisone. During the negotiation of the SDA, Amilco's commercial position in this respect was made clear by certain comments made by Amilco's external legal counsel, who commented on a draft version of the SDA that '*Amilco's position is that Aspen should not be entitled to market their competing product while acting as exclusive distributor for the Tiofarma product unless Tiofarma materially fails to supply the Product to Aspen*.'[749]

(d) It sought to achieve a profit that reflected the postponement of potential competition between the Parties in the Relevant Market by obtaining a share of profit on all sales of Ambient Storage Fludrocortisone, calculated on the basis of Aspen charging a retail selling price more than 1,800% higher than its price prior to the SDA (see paragraphs 7.39 to 7.61).[750]

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[746] [✂].

[747] In March 2014, the net ingredient cost from pharmacy contractors for [✂] Tablets was £80,551 for 570,410 tablets, equivalent to £0.14 per tablet. In April, this went to £240,297 for 568,289 tablets (£0.42 per tablet) and in May it reached £492,837 for 591,748 tablets (£0.83 per tablet). By December 2016 it had reached £0.98 per tablet (£511,971 for 522475 tablets) but fell progressively after this. Data for dispensing doctors show the same trends. PCA data available at https://www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data.

[748] Amilco explained this decision [✂].

[749] Document FLE1812, draft SDA annotated '*Amilco mark up 8 February 2016*'.

[750] The price that [Person 1 acting for Amilco] (via Tiofarma) sought to obtain with the SAA achieved a similar goal, albeit replacing the profit share with a lump sum payment. The initial proposal that [Person 1 acting for Amilco] put forward to Aspen included an option whereby Aspen would make an upfront payment equivalent to '*a*

8.156. In the course of the investigation, Amilco provided an account of what was its intention when entering into the SDA with Aspen. According to Amilco, Aspen was best placed to commercialise Ambient Storage Fludrocortisone given its experience, size and international reach.[751] However, as set out at paragraph 8.100 above, an agreement may be regarded as having an anti-competitive object (which is the case here as set out in paragraphs 8.142 to 8.144 above) even if it pursues other legitimate objectives.

c. Tiofarma

8.157. While Tiofarma was not closely involved in negotiations that led to the conclusion of the SDA[752] it nonetheless was given the opportunity to input into the SDA and was aware that the SDA would grant a quasi-monopoly position to Tiofarma as sole manufacturer for the UK market (specifically that Aspen's ability to commercialise a competing product was constrained by the SDA).[753]

8.158. Furthermore, Tiofarma took steps to actively implement the strategy of delaying potential competition between the Parties, from which it benefited:

(a) Prior to, and after the SDA, it dismissed outright all approaches made by third parties interested in supplying Ambient Storage Fludrocortisone.

(b) It led the negotiations with Aspen of the SAA, which had the effect of preserving the market structure created by the SDA, eliminating the possibility of competition between the Parties for the duration of the SDA. Within that context, Tiofarma's intention to benefit from the postponement of competition between the Parties was evidenced by the purchase price it negotiated with Aspen. Such price reflected the expectation that

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three year profit element upfront payment'. Document FLC1143.250, email from [Person 1 acting for Amilco] to [Aspen Senior Executive 2] dated 6 September 2016. [Aspen Senior Executive 1] similarly told the CMA at interview that [Person 1 acting for Amilco] requested that Aspen pay a lump sum upfront which reflected the remaining profit share element that Amilco/Tiofarma was entitled to under the SDA. Document FLC4905, page 36, lines 7 to 14, Transcript of interview with [Aspen Senior Executive 1] on 14 May 2018.

[751] Amilco explained that when looking for a potential distributor for the product, Amilco and Tiofarma '*essentially sought a company of a decent size, with a good track record, a good understanding of the therapeutic area, and the ability to successfully commercialise the product not only in the UK, but more widely'*. Document FLC4883, Amilco's submission to the CMA dated 5 February 2019, paragraph 6.5. At interview, [Person 1 acting for Amilco] explained that the choice of Aspen was driven in part by Aspen's international reach, and in particular by its capacity to commercialise Fludrocortisone Acetate Tablets in Japan. Document FLC4925, Transcript of interview with [Person 1 acting for Amilco] on 6 December 2018, page 40, line 19, to page 41, line 17.

[752] The CMA notes in this context that the role played by an undertaking in an anti-competitive scheme is not relevant to establishing its liability and must only be taken into consideration when the gravity of the infringement is assessed, at the point of determining the fine. C-204/00 P, C-205/00 P, C-211/00 P, C-213/00 P, C-217/00 P and C-219/00 P, *Aalborg Portland and Others v Commission* EU:C:2004:6, paragraphs 85 and 86; C-49/92 P *Commission v Anic Partecipazioni SpA* EU:C:1999:356, paragraph 90.

[753] Document FLC3307, email from [Tiofarma Employee 1] to [Person 1 acting for Amilco] dated 23 February 2016, headed *'aspen agreement'*.

Aspen's market position as sole UK supplier in the Relevant Market would not be challenged in the short-to-medium term, and therefore that volumes and price would remain stable (as set out above, the purchase price was calculated on the assumption that the List Price and volumes would remain constant for the initial period of the SDA, ie three years). [754] In that context, Tiofarma justified its price to Aspen by noting that the risk of entry in the short-to-medium term was limited (and the cost to Aspen of that risk was offset by the potential for international expansion, and profits beyond that initial period, although no specific value was attached to these).[755]

IV. Conclusion on restriction by object

8.159. For the reasons given above, the CMA concludes that, having regard to its legal and economic context and its content and objectives, the SDA constitutes a market sharing agreement which had the object of preventing, restricting or distorting competition. The SDA can be regarded, by its very nature, as being harmful to the proper functioning of normal competition. In particular, the CMA finds that:

(a) Tiofarma and Amilco, working together, were potential competitors of Aspen in the Relevant Market at the time of the SDA;

(b) Amilco and Tiofarma agreed not to enter the Relevant Market independently from Aspen for the duration of the SDA; and

(c) In exchange, Aspen committed to make significant value transfers to Amilco and Tiofarma, of a pecuniary or non-pecuniary nature, premised on the postponement of competition between the Parties.

8.160. The objective of the SDA was to prevent competition between the Parties and share the benefits of postponing potential competition between them:

[754] See paragraph 4.141. While Tiofarma expressed concerns in June 2016 relating to the magnitude of the price increase implemented by Aspen, and the press reports published in the Times, it continued to supply Aspen with Ambient Storage Fludrocortisone (under its own livery) until the replacement of the SDA with the SAA, and used that price level as a legitimate basis for negotiating the SAA. By deciding to replace the SDA with the SAA, Tiofarma merely sought to discharge itself of any responsibility in relation to the List Price of Ambient Storage Fludrocortisone while maintaining its relationship as *de facto* exclusive supplier of Fludrocortisone Acetate Tablets in the UK.

[755] Document FLC1143.321, email from [Tiofarma Employee 1] to [Aspen Senior Executive 2] dated 19 September 2016. [Tiofarma Employee 1] noted: '*The risk of a potential competitor in any of the markets we believe to be well compensated by the fact Aspen will not have to renegotiate 29 months from today*'.

(a) Aspen's ability to set prices for Fludrocortisone Acetate Tablets was no longer constrained by the only (potential) competitors existing at that time in the Relevant Market, Amilco and Tiofarma;

(b) Tiofarma became the sole manufacturer of Fludrocortisone Acetate Tablets in the UK and therefore the volumes that Tiofarma could achieve under the SDA was materially higher than what Tiofarma would likely have achieved in competition with Aspen; and

(c) Amilco was entitled to a share of profit on all sales of Ambient Storage Fludrocortisone, calculated on the basis of Aspen charging a retail selling price more than 1,800% higher than its price prior to the SDA; this was significantly higher than what could have been achieved if it had entered the market in competition with Aspen.

8.161. The CMA's analysis of the Parties' respective intentions (see paragraphs 8.145 to 8.158) corroborates its assessment of the object of the SDA.

C. Assessment of the effect of the SDA

8.162. For the reasons set out below, and in light of the relevant economic and legal context (as set out above in Sections 6 and 8A), the CMA concludes that the SDA had the effect of preventing, restricting and/or distorting competition in the Relevant Market.

8.163. In particular, in light of Aspen's already significant market power and the fact that Tiofarma and Amilco were potential competitors of Aspen (see Sections 6 and 8.II above), the CMA concludes that the SDA preserved Aspen's already significant market power, ie it preserved Aspen's ability to sustain inflated prices (ie an ASP of £0.87 per tablet rather than £0.04 per tablet (see paragraph 4.159)) because it:

(a) had the actual effect of neutralising the constraint arising from the only source of potential competition to Aspen (in the form of Amilco and Tiofarma's Ambient Storage Fludrocortisone) for the duration of the SDA (see paragraphs 8.192 to 8.194);

(b) had the likely effect of considerably delaying the independent launch of Amilco and Tiofarma's Ambient Storage Fludrocortisone, which would likely have occurred in the course of 2016 (see paragraphs 8.195 to 8.201); and

In addition, the SDA had the actual effect of artificially increasing the List Price for Fludrocortisone Acetate Tablets from £0.05 to £1 per tablet, which is significantly beyond the level at which Aspen would have likely charged absent the SDA, namely a maximum of around £[✂] per tablet – the price Aspen was planning to charge *before* it entered into negotiations with Amilco in September 2015 (see paragraphs 8.202 to 8.206).

8.164. The CMA's assessment of the effects of the SDA is borne out by market developments since the entry into force of the SDA which show that Aspen has faced no actual or potential competition throughout the period of the SDA[756] and increased its prices significantly, by up to a maximum of more than 1,800% (see paragraphs 8.207 to 8.210). As set out above in paragraph 8.96, no MA relating to Fludrocortisone Acetate Tablets has been granted by the MHRA since the SDA was superseded by the SAA, leaving Aspen as the sole UK supplier of that product. The NHS, and ultimately patients, were made considerably worse off as a result of the SDA, as they failed to benefit from effective competition, and the increased choice and lower prices that would result from such competition.

I. Legal framework

8.165. The Chapter I prohibition and Article 101(1) TFEU prohibit agreements which have as their effect the prevention, restriction or distortion of competition.[757] This includes agreements which foreclose potential new entrants.[758]

8.166. In order to reach a conclusion on whether the Chapter I prohibition and Article 101 TFEU have been infringed due to its effects, it must be examined whether an agreement had or is likely to have had restrictive effects on competition.[759] The Chapter I prohibition and Article 101 TFEU apply both to actual and potential anti-competitive effects.[760]

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[756] A number of parallel importers held parallel import licences but, as noted above and in paragraph 6.44 to 6.49, these have at no point during the Relevant Period represented a material constraint on Aspen.
[757] C-23/67, *SA Brasserie de Haecht* EU:C:1967:54, page 415.
[758] T-374/94, *European Night Services* EU:T:1998:198, paragraph 137, citing Case C-234/89 *Delimitis v Henninger Bräu*:EU:C:1991:91, paragraph 27.
[759] Guidelines on the application of Article 101(3) of the Treaty (2004/C 101/08) (the Article 101(3) Guidelines), paragraph 24.
[760] C-7/95 P, *John Deere v Commission* EU:C:1998:256, paragraph 77; C-238/05, *Asnef-Equifax v Ausbanc* EU:C:2006:734, paragraph 50; C-1/12, *Ordem dos Técnicos Oficiais de Contas* EU:C:2013:127, paragraph 71, and C-345/14, *Maxima Latvija* EU:C:2015:784, paragraph 30. It follows that in the examination of the effects of an agreement, an authority must take into account not only the actual effects of clauses which are already being implemented when it adopts its decision, but also the potential effects of clauses which have not yet been implemented (T-684-14 *Krka Tovarna Zdravil d.d.* EU:T:2018:918, paragraph 346 and 347; T-691/14 *Servier*

8.167. For an agreement to be restrictive by effect it must affect (or be likely to affect) actual or potential competition to such an extent that, on the relevant market, negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability.[761] The examination of this consists essentially in taking account of the impact of the agreement on existing and potential competition and the competition situation in the absence of the agreement (known as the 'counterfactual'), those two factors being intrinsically linked.[762]

8.168. A requirement of likelihood and realism applies to the description of the competition that would have occurred in the absence of the agreement.[763] However, this element of likelihood does not mean that it is necessary to determine whether there was a more than 50% probability that the counter-factual would have materialised absent the agreement.[764] As set out by the Court of Justice in *Paroxetine* – in connection with a patent settlement agreement between an incumbent manufacturer and a potential entrant – the '*sole purpose of the counter-factual is to establish the* ***realistic possibilities*** *with respect of that manufacturer's conduct in the absence of the agreement at issue*' (emphasis added). Accordingly, the demonstration of appreciable potential or real effects on competition '*does not presuppose a finding that, in the absence of* [the] *agreement, either the* [potential entrant] *would probably have been successful in its proceedings relating to the process patent at issue, or the parties to that agreement would probably have concluded a less restrictive settlement agreement*'.[765]

8.169. In assessing the restrictive effects of an agreement, account should be taken of the actual conditions in which it produces its effects, in particular the relevant economic and legal context, the nature of the product concerned, the

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EU:T:2018:922, paragraphs 1108 and 1109; Article 101(3) Guidelines, paragraph 24; *Guidelines on Vertical Restraints* OJ 2010/C130/01, paragraph 97).

[761] Case 56-65, *Société Technique Minière v Maschinenbau Ulm GmbH* EU:C:1966:38, paragraph 249; C-382/12 *MasterCard v Commission* EU:C:2014:2201, paragraph 164 ; Article 101(3) Guidelines, paragraph 24; *Guidelines on Vertical Restraints* OJ 2010/C130/01, paragraph 97.

[762] T-328/03 *O2 (Germany) v Commission* EU:T:2006:116, paragraph 71 ; C-56/65, *STM* EU:C:1966:38, paragraph 250; Case 31/80, *NV L'Oréal and SA L'Oréal v PVBA "De Nieuwe AMCK"* ECR EU:C:1980:289, paragraph 19; C-382/12, *MasterCard and Others v Commission* EU:C:2014:2201, paragraph 161 and the case-law cited there. See also *Racecourse Association v OFT* [2005] CAT 29 at paragraph 153. This examination consists essentially in taking account of the impact of the agreement on existing and potential competition and the competition situation in the absence of the agreement, those two factors being intrinsically linked. Commission's Guidelines on horizontal cooperation agreements, (2011) OJ C11/1, paragraph 29.

[763] T-684-14 *Krka Tovarna Zdravil d.d.* EU:T:2018:918, paragraph 372, and T-691/14 *Servier* EU:T:2018:922, paragraph 1134, both under appeal.

[764] Opinion of AG Kokott in C-307/18 *Generics (UK) Ltd and Others v CMA* EU:C:2020:28, paragraphs 189 to 195.

[765] C-307/18 *Generics (UK) Ltd and Others v* CMA EU:C:2020:52, paragraphs 119 to 122.

real operating conditions and the structure of the market concerned.[766] An agreement is more likely to have restrictive effects when one of the parties has or obtains a degree of market power as a result of the agreement.[767] Factual developments subsequent to the conclusion of an agreement are relevant for establishing the sufficiently likely nature of the restrictive effects under examination.[768]

8.170. It is well-established that Article 101 TFEU is designed to protect not only the immediate interests of individual competitors or consumers '*but also to protect the structure of the market and thus competition as such*'.[769]

8.171. The Court of Justice has held that restrictive effects arise when the structure of the market is altered and the entry of a potential competitor is delayed.[770] Applying that principle, the General Court further observed in *Lundbeck* that[771]:

> *'*[…] *potential competition includes inter alia the activities of generic undertakings seeking to obtain the necessary MAs, as well as all the administrative and commercial steps required in order to prepare for entry to the market* […]. *That potential competition is protected by Article 101 TFEU. If it were possible, without infringing competition law, to pay undertakings taking the necessary steps to prepare for the launch of a generic medicinal product, including obtaining an MA, and which have made significant investments to that end, to cease or merely slow that process, effective competition would never take place, or would suffer significant delays, at the expense of consumers, that is to say, in the present case, patients or national health insurance schemes'.*

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[766] C-382/12 *MasterCard v Commission* EU:C:2014:2201, paragraph 165; T-461/07, T 461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraph 67 ; and C-307/18 *Generics (UK) Ltd and Others v* CMA EU:C:2020:52, paragraph 116.
[767] Commission Notice: Guidelines on the application of Article 81(3) of the Treaty (now Article 101(3) of the TFEU), *OJ C 101/97*, paragraph 25; *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*). The relevance of market power in assessing an agreement under Chapter I/Article 101 TFEU is set out in paragraph 169 for restrictions by 'object', and paragraph 330 for restrictions by 'effect' (referring to Commission's Guidelines on horizontal cooperation agreements, (2011) OJ C11/1, paragraphs 28 and 29).
[768] T-684-14 *Krka Tovarna Zdravil d.d.* EU:T:2018:918, paragraph 368, and T-691/14 *Servier* EU:T:2018:922, paragraph 1130, both under appeal.
[769] Case T-180/15 *ICAP v Commission* EU:T:2017:795 paragraph 55, citing C-8/08, *T-Mobile Netherlands and Others* EU:C:2009:343, paragraphs 38 and 39, and C-286/13 P, *Dole Food and Dole Fresh Fruit Europe v Commission* EU:C:2015:184, paragraph 125.
[770] Cases C-457/10 P *AstraZeneca v Commission* ECR, EU:C:2012:770, paragraph108, also cited in T-472/13 *Lundbeck v Commission* EU:T:2016:449 paragraph 163. See also Opinion of AG Kokott in C-307/18 Generics (UK) Ltd and Others v CMA EU:C:2020:28, paragraphs 197 to 200 and the case law cited.
[771] T-472/13 *Lundbeck v Commission* EU:T:2016:449 paragraph 171.

8.172. In *Toshiba* the General Court rejected an argument that an agreement could not restrict competition because Japanese producers were not competitors on the European market, stating: [772]

'[…] *Article* [101 TFEU] *protects not only actual competition, but also potential competition between undertakings.'*

8.173. In *Visa Europe,* the General Court upheld a decision of the European Commission finding that the effects of the conduct at issue was founded on the potential competition represented by the only potential entrant which had expressed its intention to enter the relevant market.[773]

II. The counterfactual to the SDA

8.174. For the reasons set out below, the CMA finds that the relevant counterfactual for the purposes of assessing the effects of the SDA contains the following elements:

(a) Aspen would have likely remained active on the market for Fludrocortisone Acetate Tablets in the UK beyond March 2016;

(b) Ambient Storage Fludrocortisone would have at least remained a source of a significant competitive threat to Aspen (in the form of potential competition);

(c) Ambient Storage Fludrocortisone would have likely been launched in the market independently of and in competition with Aspen in the course of 2016, supplied either by Amilco and Tiofarma or a third party; and

(d) the presence of actual or potential competition in the Relevant Market would have constrained Aspen's ability to sustain the prices it charged. Therefore, it is unlikely that, absent the SDA, prevailing prices in the market would have been higher than at most £[✂] per tablet, that being the level at which Aspen was planning to charge *before* it entered into negotiations with Amilco in September 2015 (see paragraphs 4.5 to 4.8).

[772] See *GSK and others v CMA* [2018] CAT 4, paragraph 91, citing T-519/09, *Toshiba v Commission* EU:T:2014:263, paragraph 230 (appeal dismissed, Case C-373/14 P *Toshiba v Commission* EU:C:2016:26, paragraphs 31 to 34). See also T 461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraph 68; T-504/93, *Tiercé Ladbroke v Commission* EU:T:1997:84, paragraph 158.
[773] T 461/07 *Visa Europe and Visa International Service v Commission* EU:T:2011:181, paragraphs 121 to 132, in particular 127, and paragraphs 175 et seq.

d. Aspen would have likely remained active on the market for Fludrocortisone Acetate Tablets in the UK beyond March 2016

8.175. The CMA finds that, had Aspen not entered into the SDA, it would have nonetheless likely remained active on the market for Fludrocortisone Acetate Tablets in the UK.

8.176. In reaching this finding, the CMA has considered the following plausible counterfactual scenarios:

(a) Aspen could have continued supplying Cold Storage Fludrocortisone. This is because the price Aspen charged for Cold Storage Fludrocortisone prior to the SDA was likely profitable (see paragraph 4.167) and Aspen had no plans to withdraw that product from the market in March 2016, absent the SDA. In fact, in parallel with the negotiations relating to the SDA, it was planning to progressively increase its price for Cold Storage Fludrocortisone after debranding that product, although not to the same level as was ultimately achieved under the SDA (namely a maximum of £[✂] per tablet/ £[✂] a pack) (see paragraphs 4.5 to 4.8).

(b) Aspen could have entered into a different supply and distribution agreement with Amilco and Tiofarma on less restrictive terms (eg licensing Ambient Storage Fludrocortisone on a non-exclusive basis), that is on terms that genuinely maintained Ambient Storage Fludrocortisone as a significant competitive constraint to Aspen (as a source of potential competition).[774]

8.177. Under either of the counterfactual scenarios described above, Aspen would have likely remained active on the market for Fludrocortisone Acetate Tablets in the UK without restricting independent entry in competition with it.

8.178. Independent of the SDA, Aspen was planning to increase its ASP for Cold Storage Fludrocortisone to £[✂] per tablet following the successful debranding of that product. It is not possible to predict to what extent Aspen would have been successful in effecting this price increase given that the threat of entry from an independent supplier of Ambient Storage Fludrocortisone would likely have constrained Aspen. In any event, the SDA led to an increase in Aspen's List Price that was significantly higher than £[✂]

[774] The CMA holds no evidence that the Parties considered entering into an SDA on less restrictive terms and, in that event, whether Aspen would have continued to sell Cold Storage Fludrocortisone in parallel to Ambient Storage Fludrocortisone. This is corroborated by the CMA's analysis of the content and objectives of the SDA (see paragraphs 8.133 to 8.144).

per tablet, namely £1 per tablet. The CMA can therefore, on a cautious approach, assess the SDA's effects on the basis of a counterfactual that includes the least competitive scenario with Aspen charging at most £[✂] per tablet.

e. Absent the SDA, Ambient Storage Fludrocortisone would have at least remained a significant competitive constraint to Aspen

8.179. The CMA finds that absent the SDA, even prior to the likely independent entry of Amilco and Tiofarma's Ambient Storage Fludrocortisone in the Relevant Market, Ambient Storage Fludrocortisone would in itself have remained a significant competitive constraint to Aspen.

8.180. As set out in more detail in paragraphs 8.90 to 8.92, Ambient Storage Fludrocortisone was a market-ready product that constituted a significant competitive threat to Aspen (ie as a source of potential competition) from at least 9 November 2015. Absent the SDA, all possible routes to enter the market independently from Aspen (as described in paragraphs 8.64 to 8.82 above) would have remained open to Amilco and Tiofarma (including through partnership with third parties[775]).

8.181. Any attempt by Aspen to increase its ASP for Fludrocortisone Acetate Tablets significantly would have provided strong incentives for Amilco and Tiofarma (or a third party) to launch Ambient Storage Fludrocortisone independently in the short term (as illustrated by the fact that eight generic pharmaceutical companies approached Tiofarma following the price increase of March 2016, see paragraphs 4.150 to 4.153 above). The threat of such entry would have constrained Aspen's expectation in relation to the degree of the price increase that it could sustain successfully (see below at paragraph 8.205). Ambient Storage Fludrocortisone would therefore have presented an important competitive constraint on Aspen in the counterfactual regardless of whether that product was launched.

8.182. This assessment is supported by contemporaneous documentary evidence which shows that, prior to the SDA, Aspen perceived Amilco and Tiofarma's Ambient Storage Fludrocortisone to represent a source of potential competition (see paragraph 8.88). In particular, Aspen staff acknowledged that '[a]*mbient prouct* [sic] [✂] *easier to store* […]', concluding that '*at no*

[775] The CMA considers that this would have been the case not only in the absence of the SDA, but also under the alternative counterfactual of a licensing agreement on less restrictive terms.

change in price [Cold Storage Fludrocortisone] *would loose* [sic] *circa* [✂]*% or more to Ambient product*'.[776]

f. Absent the SDA, it is likely that there would have been at least another supplier of Fludrocortisone Acetate Tablets competing with Aspen on price

i. Absent the SDA, Ambient Storage Fludrocortisone would have likely been launched in competition with Aspen in the course of 2016

8.183. The CMA finds that, absent the SDA, Amilco and Tiofarma or a third party would have likely independently launched Ambient Storage Fludrocortisone in competition with Aspen:

(a) Amilco and Tiofarma, working together, were potential competitors to Aspen at the time of the SDA (see paragraphs 8.53 to 8.89). They had the ability to enter the market since early 2016 and had the manufacturing capacity to supply the entire UK market demand (see paragraphs 8.32 to 8.48). They also had the incentives to ensure that Ambient Storage Fludrocortisone entered the market.[777] Indeed, [Person 1 acting for Amilco] wanted to reward Tiofarma for its assistance in developing Ambient Storage Fludrocortisone by ensuring that it would be able to manufacture the product, and Tiofarma trusted that Amilco would find a route to market. On that basis, Tiofarma had incurred substantial costs in order to prepare to enter the market, not only by obtaining an MA, but also by starting production of that product at commercial scale in December 2015 (that is, before entering into the Term Sheet with Aspen). Having already invested in developing a product authorised for sale in the UK, it is likely that Tiofarma and Amilco would have taken steps to commercialise that product through one of the available routes to market in order to generate a return on their investment. As noted in paragraphs 8.64 to 8.83, Aspen's role in the supply chain for Ambient Storage

[776] Document FLE0104 and its attachment Document FLE0105, email from [Consultant to Aspen] to [Aspen Employee 1] dated 6 October 2015 headed *'Fludrocortisone model de brand ambient product'*. The calculation was later updated. See Document FLE0134 and its attachment Document FLE0135, email from [Aspen Employee 11] to [Aspen Employee 1] and [Consultant to Aspen] dated 6 January 2016 headed *'Fludrocortisone generic ambient 06012016.xslx': 'Existing position at no change in price would loose* [sic] *circa* [✂]*% or more to Ambient product'*. Document FLE0136 and its attachment Document FLE0137, email from [Aspen Employee 1] to [Aspen Employee 11] dated 8 January 2016: *'Existing position at no change in price would lose circa* [✂]*% or more to Ambient product overtime* [sic]'.

[777] The CMA considers that this would have been the case not only in the absence of the SDA, but also under the alternative counterfactual of a licensing agreement on less restrictive terms. In particular, it was in their interest to provide their product to all pharmaceutical companies seeking to supply Fludrocortisone Acetate Tablets in the UK.

Fludrocortisone under the SDA could have been performed by another company.

(b) Amilco and Tiofarma's prospects of finding a viable route to enter the market independently from Aspen were made more likely by the following factors:

1. Prescriptions for Fludrocortisone Acetate Tablets were generally open, without reference to supplier or brand;[778]
2. Ambient Storage Fludrocortisone had superior heat stability characteristics in comparison to Cold Storage Fludrocortisone, meaning the former product offered an advantage to some customers (see paragraph 6.37(b));[779]
3. There was persistent and varied third-party interest in Ambient Storage Fludrocortisone (both before and after the launch of that product at a high price); in particular, two suppliers (including [Company 2], [✂] generic supplier in the UK) had approached Tiofarma following the grant of the MA for Ambient Storage Fludrocortisone in November 2015,[780] at a time when the price of Fludrocortisone Acetate Tablets was still £0.05 per tablet) (see paragraphs 4.150 to 4.153); and
4. No marketing activity was required to supply this product in the UK (see paragraph 6.26).

(c) The CMA has not sought to reach a finding on the precise timing when such independent entry would have been likely to occur.[781] However, on the basis of the evidence set out above (in particular Amilco and Tiofarma's ability and incentives to launch Ambient Storage Fludrocortisone and the considerable third party interest in the product, even when Aspen's ASPs were still around £0.04 per tablet), the CMA considers that such entry would have likely occurred in the course of 2016.

ii. Independent entry would have led to competition on price

[778] See paragraph 3.40.
[779] Aspen's analysis from October 2015 acknowledged that '*Ambient prouct* [sic] [✂] *easier to store* [✂]', concluding that '*at no change in price* [Cold Storage Fludrocortisone] *would loose* [sic] *circa* [✂]*% or more to Ambient product'* (see paragraph 8.182). See also other documents referenced in footnote 776.
[780] As set out in paragraph 4.152, six more pharmaceutical companies approached Tiofarma after the entry into force of the SDA in March 2016.
[781] *GSK and others v CMA* [2018] CAT 4 (*Paroxetine*), paragraph 155, citing T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 131.

8.184. As set out in paragraphs 8.2 to 8.9, competition between suppliers of generic drugs is expected to lead to lower prices and reduced market shares for the incumbent supplier. In particular, new entrants in generic markets will generally seek to enter at a lower price than the incumbent so as to capture sales from the incumbent.

8.185. For the reasons set out below, the CMA finds that independent entry of Ambient Storage Fludrocortisone would have led to competitive tension between Aspen and an independent supplier of Ambient Storage Fludrocortisone (whether Amilco and Tiofarma or a third party). There is no reason to believe that competition between Aspen and a new entrant would not have affected their respective pricing strategies:

(a) Despite Ambient Storage Fludrocortisone having superior heat stability characteristics, for the reasons set out in paragraphs 6.28 to 6.38, Cold Storage Fludrocortisone and Ambient Storage Fludrocortisone are substitutable products that would exert competitive pressure on each other if sold contemporaneously in the Relevant Market.[782] The Society for Endocrinology has submitted to the CMA that Ambient Storage Fludrocortisone's superior heat stability characteristics are only a '*minor benefit*' to patients and clinicians.[783]

(b) Under the UK reimbursement scheme there was no scope at the time of entry into the SDA for Ambient Storage Fludrocortisone to be launched in the market at a price materially higher than the prevailing price charged by Aspen for Cold Storage Fludrocortisone. This is because, until August 2016, the NHS England Reimbursement Price for Fludrocortisone Acetate Tablets was calculated solely on the basis of Aspen's List Price.[784] As a result, any pharmacist procuring Ambient Storage Fludrocortisone at a price materially higher than Aspen's List Price would have incurred a loss when dispensing the product as it would only be reimbursed at the lower NHS England Reimbursement Price.

(c) Aspen's internal documents in the period leading up to the SDA envisaged a review of the discounting strategy (from the price of £30 per

[782] The CMA notes that the issue of substitutability would in any event be irrelevant in the counterfactual scenario in which Aspen supplied Ambient Storage Fludrocortisone on the basis of a non-exclusive licence (see paragraph 8.176).
[783] Document FLC1571, response to questions 7b and 7c, Annex 1A, Society for Endocrinology's response to the CMA's section 26 notice dated 28 February 2018.
[784] This is because Fludrocortisone Acetate Tablets were in 'Category C' of the Drug Tariff (see paragraphs 3.64 to 3.66).

pack of 30 tablets) in the event of entry by a competitor.[785] This shows that the Parties anticipated that the price set under the SDA might not be sustainable in the event of independent entry.

(d) Had Ambient Storage Fludrocortisone entered the market independently of Aspen, Aspen's pricing strategy would have likely been affected by such entry (in particular given Ambient Storage Fludrocortisone's superior feature and Aspen's incentive to limit the loss of volumes supplied).

III. The restrictive effects of the SDA

8.186. The CMA has assessed the actual and likely effects of the SDA within the actual context that would occur in the absence of the agreement in dispute, that is against the counterfactual set out above.

a. The key relevant provisions of the SDA for this assessment

8.187. As set out in more detail in paragraph 4.106, under Clause 6 of the SDA Tiofarma granted Aspen the exclusive right to commercialise Ambient Storage Fludrocortisone in the UK (ie the only Fludrocortisone Acetate Tablets product other than Aspen's own Cold Storage Fludrocortisone product authorised for supply in the UK at that time).

8.188. That grant of exclusivity was tantamount to a commitment by Tiofarma and Amilco not to enter the Relevant Market independently from Aspen during that period. This is because Amilco and Tiofarma were contractually prevented, for the term of the SDA, from supplying Ambient Storage Fludrocortisone independently from Aspen in the UK, and/or from facilitating market entry by another company seeking to supply Ambient Storage Fludrocortisone in that market.[786]

8.189. As set out in paragraphs 7.13 to 7.16, Amilco and Tiofarma committed not to independently enter the Relevant Market for the duration of the SDA in return for a commitment of equal duration from Aspen to:

[785] Document FLE0394, email from [Aspen Employee 1], to [Aspen Senior Executive 2], [Aspen Employee 4], [Person 1 acting for Amilco] and other Aspen employees dated 10 February 2016: '*The trigger* [of a review of discounting strategy] *would be defined as the entry of 1 new competitor*'.
[786] A number of parallel importers held parallel import licences but, as noted above in paragraphs 6.44 to 6.49, at no point during the Relevant Period have these represented a material constraint on Aspen.

(a) Supply only Ambient Storage Fludrocortisone in that market (and, accordingly, withdraw Cold Storage Fludrocortisone from that market); and

(b) Share the benefits arising from of its sole supplier position in the UK with Amilco and Tiofarma. In particular, Aspen agreed to make Tiofarma the sole manufacturer in the Relevant Market and to pay Amilco a fixed Supply Price of £[✂] including a fixed profit margin of £[✂][787] (ie a 30% share of profits based on Aspen's ASP of £[✂]).

8.190. The commitments Aspen made to share the benefits of its sole supplier position in the UK with Amilco and Tiofarma incentivised them to grant exclusivity over Ambient Storage Fludrocortisone to Aspen.

b. The SDA preserved Aspen's already significant market power

8.191. For the reasons set out below, the CMA finds that the restrictions contained in the SDA, taken in the relevant economic and legal context and compared to the counterfactual, had the effect of preserving Aspen's already significant market power in the Relevant Market, ie it preserved Aspen's ability to sustain an artificially inflated price (ie an ASP of £0.87 per tablet rather than £0.04 per tablet (see paragraph 4.159). Specifically, the restrictions:

(a) had the actual effect of neutralising the constraint arising from the only source of potential competition to Aspen (in the form of independently supplied Ambient Storage Fludrocortisone) for the duration of the SDA; and

(b) had the likely effect of considerably delaying the independent launch of Ambient Storage Fludrocortisone in competition with Aspen (which would likely have occurred in the course of 2016 (see paragraph 8.183).

i. The SDA had the actual effect of neutralising the constraint arising from Ambient Storage Fludrocortisone for the duration of that agreement

8.192. Ambient Storage Fludrocortisone was the only market-ready version of Fludrocortisone Acetate Tablets that could have come to the UK market independently of Aspen at the time of the SDA (see paragraphs 8.90 to 8.92). As set out above at paragraphs 8.179 to 8.182, absent the SDA, Ambient Storage Fludrocortisone would have at least remained a source of a

[787] The remaining £[✂] per pack was intended to cover Tiofarma's services as manufacturer.

significant competitive threat to Aspen's position as the sole UK supplier with significant market power. The mere presence of such a source of potential competition (even prior to any actual entry) would have presented an important competitive constraint on Aspen's ability profitably to sustain significant price increases in the counterfactual regardless of whether that product was launched. It would therefore have constrained Aspen's conduct on the market (see paragraphs 8.175 to 8.178).

8.193. By granting Aspen exclusivity over Ambient Storage Fludrocortisone, the SDA prevented Amilco and Tiofarma from supplying this product independently from Aspen in the UK, and/or from facilitating market entry by another company seeking to supply the product in that market. As such, the SDA neutralised for the duration of the SDA the significant competitive constraint arising from the only source of potential competition that Aspen faced, and in particular the constraint that it exerted on Aspen's pricing. As a result, for the duration of the SDA, Aspen faced no actual or potential competition in the Relevant Market arising from that product.

8.194. The actual effect of the SDA was therefore to negatively affect the structure of the market by neutralising for the duration of the SDA the constraint arising from the only source of potential competition to Aspen that existed at that time. This preserved Aspen's position as sole UK supplier and left it free under the SDA to sustain prices above the level that it would have charged absent the SDA. As demonstrated below, this effect was borne out by the actual developments in the market.

ii. The SDA had the likely effect of considerably delaying the independent launch of Amilco and Tiofarma's Ambient Storage Fludrocortisone in the course of 2016

8.195. As set out above in paragraphs 8.183, absent the SDA, Amilco and Tiofarma (or a third party) would have likely entered the Relevant Market independently with Ambient Storage Fludrocortisone in the course of 2016 in competition with Aspen.[788]

8.196. The exclusive licence over that product granted to Aspen under Clause 6.1 of the SDA restricted Amilco and Tiofarma from doing so either by themselves or through a third party for the duration of that agreement. As stated above in paragraph 7.15, during the period of the SDA, Amilco and Tiofarma made no

[788] Even if Aspen had entered into the SDA on a non-exclusive basis, evidence suggests that a number of other (ie non-Aspen) suppliers would have been willing to sell Ambient Storage Fludrocortisone on that basis. This would have given rise at least to intra-brand competition.

attempt to commercialise Ambient Storage Fludrocortisone in the Relevant Market and Tiofarma rejected expressions of interest from several third parties concerning potential deals to distribute Tiofarma's Ambient Storage Fludrocortisone product in the UK.

8.197. The SDA therefore considerably delayed the likely independent launch of Amilco and Tiofarma's Ambient Storage Fludrocortisone until at least the end of the SDA.

8.198. This had the likely effect of delaying the emergence of actual competition between independent suppliers of Fludrocortisone Acetate Tablets in the Relevant Market because:

(a) Ambient Storage Fludrocortisone was the only alternative authorised source of Fludrocortisone Acetate Tablets existing in the UK at that time (see paragraph 8.192); and

(b) without a readily available product authorised for supply in the UK, a pharmaceutical company seeking to enter the market needs to undertake developmental and regulatory work that requires a considerable investment in resources and time. Developing a new product and obtaining an MA is expected to take at least two or three years (see paragraph 6.62).

8.199. As described above in paragraphs 8.148 to 8.154, internal documents show that Aspen expected that the SDA would delay the emergence of actual competition in the Relevant Market in the short-to-medium term as it did not foresee the entry of any other competitor following the neutralisation of the competitive threat posed by Ambient Storage Fludrocortisone. In particular:

(a) within the context of the discussions of forecast volumes of the supply of Fludrocortisone Acetate Tablets with Amilco, [Aspen Employee 22] indicated that a challenge received from her management was that volumes should remain closer in line with the previous volumes of Florinef given that Aspen was '*the market leader with minimum competition*';[789]

(b) in the context of discussing the prospect of the SDA on 8 January 2016, [Aspen Employee 1] told [Aspen Employee 3]: '*that's why I want us all to*

[789] Document FLE0208, email chain between [Aspen Employee 22] and [Aspen Employee 2] dated 19 February 2016. It appears that Aspen's [✂] management had not anticipated that sales to customers other than NHS customers were likely to be lost as a result of the price increase of 1 March 2016.

join hands – could be supper [sic] *successful for 18 months before competiton* [sic] *respond'*;[790]

(c) A working document setting out the status of budget preparation for 2016/2017 states that the 'de-branding strategy in the UK' is to 'Maximize the short-term opportunity with Fludrocortisone' and 'Plan what actions to take in the medium term – after 1-2 years post de-branding, it is likely to have competition from new Gx entrants'.[791]

(d) in an internal email of July 2016, [Aspen Employee 1] explained that the plan to debrand Cold Storage Fludrocortisone and increase price was developed in the UK ('*value was created in the UK/EU'*) while the initiative taken by the Aspen's [✂] management to negotiate and enter into the SDA '*maintained this value for the medium term – until further ambient generic competition comes to the market*'.[792]

8.200. In addition, and as described above in paragraph 8.154 and 8.158, contemporaneous documents relating to the negotiations of the SAA confirm that the Parties expected that Aspen would not face any actual competition within the short-to-medium term following that agreement (which effectively permanently removed Ambient Storage Fludrocortisone as a source of competition) and would thus remain in a position to sustain the high prices established under the SDA:

(a) The board paper prepared for the SAA transaction set out that Ambient Storage Fludrocortisone '[✂]'[793] and assumed that Aspen could sustain high prices in the UK at least for a further two and a half years (ie until the end of the initial period of the SDA); and

(b) Tiofarma negotiated the purchase price with Aspen on the basis that Aspen's market position as sole UK supplier in the Relevant Market would

[790] Document FLE0138, messaging conversation between [Aspen Employee 1] and [Aspen Employee 2] dated 8 January 2016.
[791] Document FLE0292, document entitled '*Priorities and Strategies Budget 2016/2017*', PDF attachment to email from [Aspen Employee 3] to [Aspen Employee 2] and others dated 18 April 2016.
[792] Document FLE0387, email from [Aspen Employee 1] to [Aspen Employee 3] and [Aspen Employee 2] dated 30 July 2016.
[793] Document FLE0456, paper prepared for Aspen Global Incorporated Board meeting held on 12 October 2016. This statement about risk of generic entry originates from [Aspen Senior Executive 2] (see Document FLE1031, email from [Aspen Employee 10] to [Aspen Senior Executive 2] dated 7 October 2016 and Document FLE1032, attachment with draft board paper).

not be challenged in the short-to-medium term, and therefore that volumes and price would remain stable.[794]

8.201. As such, the SDA preserved Aspen's ability to sustain prices above the level that it would have charged absent the SDA. Again, as demonstrated below, this effect was borne out by the actual developments in the market.

c. The SDA had the actual effect of artificially increasing prices for Fludrocortisone Acetate Tablets

8.202. In addition to the effects of the SDA on Aspen's already significant market power and the structure of the market, the CMA concludes that the SDA had the effect of artificially increasing Aspen's ASP for Fludrocortisone Acetate Tablets.

8.203. The pricing provisions of the SDA committed Aspen to pay to Amilco an expected Supply Price of £[✂] per pack of 30 tablets for the duration of that agreement. For the reasons set out in paragraphs 7.40, 7.42 to 7.44, the CMA finds that the Supply Price reflected a common understanding between the Parties that Aspen would be able significantly to increase and sustain an ASP for Fludrocortisone Acetate Tablets that was significantly higher than the level at which Aspen would have likely charged absent the SDA (ie to £0.87 per tablet compared to £0.04 per tablet prior to the SDA) for the purpose of sharing the benefits of the postponement of competition between the Parties for the duration of the SDA (see also paragraphs 7.39 to 7.61).

8.204. As such, Aspen's ASP (and the Supply Price[795]) under the SDA was calculated on the basis of Aspen's ability to sustain an artificially increased price in the absence of actual or potential competition following the SDA rather than on any normal commercial basis (see paragraphs 7.39 to 7.61). Aspen's significantly increased ASP was therefore a direct consequence of the SDA.

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[794] Document FLC1143.321, email from [Tiofarma Employee 1] to [Aspen Senior Executive 2] dated 19 September 2016. [Tiofarma Employee 1] noted: '*The risk of a potential competitor in any of the markets we believe to be well compensated by the fact Aspen will not have to renegotiate 29 months from today*'.

[795] As set out in section 4.F.II, the increased costs for Aspen of procuring Ambient Storage Fludrocortisone compared to Cold Storage Fludrocortisone from Haupt Pharma did not relate to any increase in manufacturing or distribution costs (other than the payment of the profit share element to Amilco). Aspen's allocation for the UK market of the price paid to purchase the rights to Cold Storage Fludrocortisone was £[✂], and therefore does not affect materially this comparison. See Document FLC0397.1C, Aspen's response to question 8 of the CMA section 26 notice dated 10 October 2017.

8.205. Aspen had already initiated a strategy to increase the price of Cold Storage Fludrocortisone prior to entering into the SDA. However, the price increases contemplated by Aspen as part of that strategy, namely to a maximum of around £[✂] per tablet/ £[✂] a pack (see paragraphs 4.5 to 4.8), were [✂] in terms of magnitude relative to those that Aspen ultimately agreed to implement under the SDA *after* it entered into negotiations with Amilco in September 2015. Moreover, as discussed above, absent the SDA, it is likely that independent entry and price competition would have emerged in the short term, which would have constrained Aspen's ability to sustain prices even at the level considered prior to the SDA (ie £[✂] per tablet/ £[✂] a pack).

8.206. Therefore, the SDA not only neutralised the competitive threat posed by Amilco and Tiofarma but also committed Aspen for the duration of that agreement to set its prices beyond the level at which Aspen would have likely charged absent the SDA. This ASP is significantly higher than the level which Aspen would have likely charged absent the SDA. As demonstrated below, this effect was borne out by the actual developments in the market as Aspen did actually charge an ASP of £0.87 per tablet / £30 a pack during the period the SDA was in force.

d. The market developments observed during and after the SDA

8.207. The CMA's proposed findings in relation to the anti-competitive effects of the SDA, as set out above, are borne out by the actual developments observed in the Relevant Market during the term of the SDA, as set out below and in more detail in Section 4.F.

8.208. There were no significant actual or potential competitive constraints faced by Aspen throughout the term of the SDA and true generic competition was prevented or at least considerably delayed (despite a significant price increase):

(a) Amilco and Tiofarma, in compliance with their contractual obligations, did not seek to commercialise Ambient Storage Fludrocortisone independently from Aspen in the UK directly or to another supplier; [796]

(b) Aspen has not faced any material actual competition for the duration of the SDA: neither Amilco, Tiofarma, nor any third party, has supplied Ambient Storage Fludrocortisone independently of Aspen directly in the

[796] While a second MA was obtained by Tiofarma in relation to Ambient Storage Fludrocortisone, this would not be used for supplying the product independently from Aspen.

UK; Aspen has continued to hold a very large market share of at least 80% (the remainder being supplied by parallel importers)[797] (see further paragraphs 6.44 to 6.49); and

(c) The CMA has no evidence that Aspen has faced any new potential competition since the entry into force of the SDA; no new MA was granted by the MHRA for the supply of Fludrocortisone Acetate Tablets in the UK.

8.209. In a context where the SDA had already produced appreciable anti-competitive effects by preserving and strengthening Aspen's significant market power for the duration of the SDA, the SAA cemented and extended those effects (beyond the original duration and geographical scope of the SDA).

8.210. Following implementation of the SDA, Aspen profitably increased and maintained high prices for Fludrocortisone Acetate Tablets (and shared the profits with Amilco), thereby significantly increasing costs to the NHS:

(a) In March 2016, Aspen launched Ambient Storage Fludrocortisone and increased its List Price for Fludrocortisone Acetate Tablets from £0.05 to £1 per tablet (an increase of more than 1,800%, in line with the List Price set out in Annexure B of the SDA), as shown in Figure 5. Aspen's ASP for Fludrocortisone Acetate Tablets remained at around £0.87 per tablet for the duration of the SDA.[798] As a result, the cost of Fludrocortisone Acetate Tablets to NHS England increased from £700,000 in the calendar year 2015 to £14.8 million in the year from March 2016 after commencement of the SDA.[799]

(b) Aspen paid a fixed supply price of £[✂] per pack of Ambient Storage Fludrocortisone to Amilco while the SDA remained in force.

(c) This strategy was highly profitable to Aspen.[800] While Aspen's volumes fell in response to the higher price set for Ambient Storage Fludrocortisone by around 50% in 2016 compared to 2015, this loss was

[797] While the volumes of Cold Storage Fludrocortisone sold in the UK by parallel importers increased following the price increase of March 2016 (up to 20% in aggregate, fragmented among several suppliers), as set out in paragraphs 6.44 to 6.49 these did not represent a material competitive threat capable of constraining the exercise by Aspen of its market power. This is because parallel importers face constraints in terms of volumes and reliability of supply of excess product volumes in other EU member states. This is exacerbated by Aspen's ownership of Cold Storage Fludrocortisone.
[798] See paragraph 6.56.
[799] PCA data for England (www.nhsbsa.nhs.uk/prescription-data/dispensing-data/prescription-cost-analysis-pca-data) for months January to December 2015 to March 2016 to February 2017.
[800] See paragraphs 4.178 to 4.179.

more than offset by the increase of its price, entailing an increase in Aspen's average monthly gross profits from approximately £42,000 to £596,000.[801]

(d) Amilco also received a share of the profit from the price increase, through the profit-sharing element of the SDA Supply Price, equivalent to approximately £[0-5] million[802] (compared to a market size prior to the SDA of less than £1 million).

(e) Tiofarma became the sole manufacturer of Fludrocortisone Acetate Tablets supplied directly in the UK.

IV. Conclusion on restriction by effect

8.211. For the reasons set out above, the CMA concludes that, considered in its relevant economic and legal context, and in particular Aspen's already significant market power and the fact that Tiofarma and Amilco were potential competitors of Aspen (see Sections 6 and 8.II above), the SDA affected (or was likely to affect) actual or potential competition to such an extent that, on the relevant market, negative effects on prices, output, innovation or the variety or quality of goods and services can be expected with a reasonable degree of probability. In particular:

(a) The SDA preserved Aspen's already significant market power, ie it preserved Aspen's ability to sustain increased prices (ie an ASP of £0.87 per tablet rather than £0.04 per tablet (see paragraph 4.159) because it:

1. had the actual effect of neutralising the constraint arising from the only source of potential competition to Aspen (in the form of independently supplied Ambient Storage Fludrocortisone) for the duration of the SDA;
2. had the likely effect of considerably delaying the likely independent launch of Amilco and Tiofarma's Ambient Storage Fludrocortisone in competition with Aspen (which would likely have occurred in the course of 2016 (see paragraphs 8.53 to 8.89); and

(b) The SDA had the actual effect of artificially increasing the List Price for Fludrocortisone Acetate Tablets (ie £1 per tablet rather than £0.05 per tablet), ie beyond the level at which Aspen would have likely charged

[801] Comparing the first 8 months of the financial year ended June 2017, with the corresponding period of the prior year. See paragraph 6.56.
[802] See paragraph 4.182.

absent the SDA (namely a maximum of around £[✂] per tablet/ £[✂] a pack – the price Aspen was planning to charge *before* it entered into negotiations with Amilco in September 2015).

8.212. The CMA considers that these effects on competition, each individually as well as in combination, prevented, restricted and/or distorted competition in the Relevant Market in breach of the Chapter I prohibition and Article 101(1) TFEU.

D. Appreciable restriction

I. Legal framework

8.213. An agreement that is restrictive of competition by '*object*' will fall within the Chapter I prohibition or Article 101 TFEU only if it has as its object an **appreciable** prevention, restriction or distortion of competition.[803]

8.214. The Court of Justice has clarified that an agreement which may affect trade between Member States and which has an anti-competitive object constitutes, by its nature and independently of any concrete effect that it may have, an appreciable restriction on competition.[804]

8.215. Appreciable anti-competitive effects are likely to occur when at least one of the parties has or obtains some degree of market power and the agreement contributes to the creation, maintenance or strengthening of that market power or allows the parties to exploit such market power.[805]

8.216. In accordance with section 60(2) of the Act,[806] these principles also apply in respect of the Chapter I prohibition and the UK for the purposes of assessing whether an agreement that may affect trade within the UK.

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[803] It is settled case law that an agreement between undertakings falls outside the Chapter I prohibition if it has only an insignificant effect on the market: see Case C-226/11 *Expedia Inc. v Autorité de la concurrence and Others* EU:C:2012:795, paragraph 16 citing, among other cases, Case 5/69 *Völk v Vervaecke* EU:C:1969:35, paragraph 7. See also *Agreements and Concerted Practices* (OFT401, December 2004), adopted by the CMA Board, paragraph 2.15.
[804] Case C-226/11 *Expedia Inc. v Autorité de la concurrence and Others* EU:C:2012:795, paragraph 37; and Commission Notice on agreements of minor importance [2014] OJ C291/01, paragraphs 2 and 13.
[805] Article 101(3) Guidelines, paragraph 25; *Guidelines on Vertical Restraints* OJ 2010/C130/01, paragraph 97.
[806] Section 60(2) of the Act provides that, when determining a question in relation to the application of Part 1 of the Act (which includes the Chapter I prohibition), the court (and the CMA) must act with a view to securing that there is no inconsistency with any relevant decision of the European Court in respect of any corresponding question arising in EU law.

II. Application to this case

8.217. The CMA has found that the Infringement had the object of preventing, restricting or distorting competition. Given that the effect on trade test is satisfied (see below), the CMA therefore concludes that the Infringement constitutes, by its very nature, an appreciable restriction of competition in the supply of Fludrocortisone Acetate Tablets in the UK for the purposes of the Chapter I prohibition and Article 101(1) TFEU.

8.218. In addition (and in the alternative), the CMA finds that the Infringement had an appreciable impact on competition for the supply of Fludrocortisone Acetate Tablets within the EU (for the purposes of Article 101 TFEU) and the UK (for the purposes of the Chapter I prohibition). This conclusion is based on the following findings:

(a) The geographic scope of the Infringement covered the whole of the UK;

(b) Aspen had a high market share throughout the Relevant Period, materially higher than the 15% share set out in the European Commission's De Minimis Notice.[807] As the sole UK supplier of Fludrocortisone Acetate Tablets active, it had at least some degree of market power and a strong position in the market throughout the Relevant Period (see paragraph 6.46).

(c) The actual and likely effects of the Infringement were significant, as it preserved Aspen's already significant market power and artificially increased prices for Fludrocortisone Acetate Tablets (see Section 8.C above). The Infringement allowed Aspen to retain a market share of at least 80% (by volume and value of the Relevant Market) despite of increasing the price of the relevant product by over 1,800% (see Figure 8). Until the end of February 2016, the NHS spent approximately £70,000 per month on Fludrocortisone Acetate Tablets.[808] During the period of the Infringement, costs to the NHS in England increased to approximately £1.2 million per month.

E. Effect on trade

8.219. For the reasons set out below, the CMA concludes that the Infringement was capable of affecting trade within both the UK, and between EU Member

[807] EU Commission, *Notice on agreements of minor importance which do not appreciably restrict competition under Article 101(1) of the Treaty on the Functioning of the European Union (De Minimis Notice)*, June 2014.
[808] See footnote 656.

States, such that Article 101 TFEU applies as well as the Chapter I prohibition.

I. Effect on trade within the UK

8.220. The Chapter I prohibition applies to agreements between undertakings which may affect trade within the UK, and have as their object or effect the prevention, restriction or distortion of competition within the UK.[809] For the purposes of the Chapter I prohibition, the UK includes, in relation to an agreement which operates or is intended to operate only in a part of the UK, that part.[810]

8.221. To infringe the Chapter I prohibition, the conduct does not actually have to affect trade as long as it is capable of doing so.[811] The concept of effect on trade is also not read as importing a requirement that the effect on trade within the UK should be appreciable.[812]

8.222. The CMA concludes that the Infringement may have affected trade in the buying and selling of drugs within the whole or part of the UK as it was implemented in the UK and was capable of:

(a) affecting the competitive structure of the Relevant Market by excluding Amilco and Tiofarma, potential competitors; and

(b) having an effect on the price paid in the UK for Fludrocortisone Acetate Tablets.

II. Effect on trade between Member States

a. Legal framework

8.223. Where the CMA applies national competition law to agreements between undertakings which restrict competition by object or effect where such conduct may have an effect on trade between EU Member States the CMA must also apply Article 101 TFEU.[813]

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[809] Section 2(1) of the Act.
[810] Section 2(7) of the Act.
[811] See, for example, T-228/97 *Irish Sugar plc v Commission* EU:T:1999:246, paragraph 170.
[812] *Aberdeen Journals Limited v Office of Fair Trading* [2003] CAT 11, paragraphs 459 and 460.
[813] Article 3 of Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (now article Articles 101 and 102).

8.224. For the purposes of assessing whether trade between EU Member States may be affected, the CMA follows the approach set out in the European Commission's Guidelines on the effect on trade concept contained in Article 81 and 82 of the TFEU (the '*Effect on Trade Guidelines*')[814] and the case law of the European Courts.

8.225. It is not necessary that the conduct actually has or had an effect on trade between Member States. It is sufficient that the conduct is '*capable'* of having an effect, ie that it may have a direct or indirect, actual or potential influence on the pattern of trade between at least two EU Member States.[815] The effect on trade between EU Member States must be appreciable.[816]

8.226. The concept of 'trade' is a wide concept that covers all cross border economic activity between EU Member States including establishment[817] and encompasses cases when practices have an effect on the competitive structure of the market, for example by eliminating or threatening to eliminate a competitor operating within the EU. When an undertaking is or risks being eliminated the competitive structure within the EU is affected and so are the economic activities in which the undertaking is engaged.[818]

8.227. The nature of the relevant products also provides an indication of whether trade between EU Member States is capable of being affected. An effect on trade between EU Member States is more likely to exist, when by their nature, products are easily traded across borders.[819] Trade between EU Member States may also be affected in cases where the relevant market is national or sub-national.[820]

8.228. In order for there to be an effect on trade between EU Member States, it is not necessary that trade is reduced. Instead, it is sufficient that an appreciable change is capable of being caused in the pattern of trade between EU Member States and this change can be positive or negative.[821]

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[814] *Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty* (Effect on Trade Guidelines), OJ C 101, 27.4.2004, p. 81 to 96.
[815] Effect on Trade Guidelines, paragraphs 21 to 26.
[816] Effect on Trade Guidelines, paragraphs 44 to 49.
[817] Effect on Trade Guidelines, paragraph 19. See also, for example, C-172/80 *Züchner v Bayerische Vereinsbank* EU:C:1981:178, paragraph 18 and C-475/99 *Ambulanz Glöckner* EU:C:2001:577, paragraph 49.
[818] Effect on Trade Guidelines, paragraph 20.
[819] Effect on Trade Guidelines, paragraph 30.
[820] Effect on Trade Guidelines, paragraph 22.
[821] Effect on Trade Guidelines, paragraphs 33 to 35 and 77; Commission decision of 29 June 2001 Case COMP/F-2/36.693 *Volkswagen*, paragraph 88.

b. Application to this case

8.229. The CMA concludes that the Infringement was capable of affecting, and did actually affect, trade between EU Member States for the following reasons:

(a) The geographic scope of the Infringement covered the whole of the UK. The UK constitutes a substantial part of the internal market, and the value of the Relevant Market is high.[822]

(b) The Infringement affected the competitive structure of the Relevant Market by excluding Amilco and Tiofarma, potential competitors.[823] This affected the competitive structure within the EU and the economic activities in which Amilco and Tiofarma were engaged.

(c) Further, an effect on trade between EU Member States is not confined to cases where a measure results in compartmentalisation of markets through restrictive or exclusionary effects. The potential for the Infringement to increase (or decrease) parallel importation exists because the Parties imposed significant price rises for Fludrocortisone Acetate Tablets in the UK over the Relevant Period. This is likely to have resulted in significant differences between the prices in the UK and the prices charged in other Member States for Fludrocortisone Acetate Tablets. Consequently, the commercial incentives for importing Fludrocortisone Acetate Tablets from other EU Member States have significantly increased while the incentive to export has decreased. Consequently, the Infringement created a change in the competitive structure of the single market and therefore they are capable of affecting trade between EU Member States.[824]

(d) The effect on trade between EU Member states arising from the Infringement is appreciable given the economic significance of the UK in the commercialisation of Fludrocortisone Acetate Tablets within the internal market, the significant position of strength enjoyed by Aspen, from which Amilco and Tiofarma were able to benefit, and the sustained and increasing high prices caused by the Infringement.

[822] See, for example, T-228/97 *Irish Sugar v Commission* EU:T:1999:246, paragraph 99.
[823] Effect on Trade Guidelines, paragraph 20.
[824] See, for example, C-6/73 *Commercial Solvents v Commission* EU:C:1974:18, paragraphs 32 and 33.

F. Exclusions

8.230. The Chapter I prohibition does not apply in any of the cases in which it is excluded by or as a result of Schedules 1 to 3 of the Act.[825]

8.231. The CMA concludes that none of the relevant exclusions set out in Schedules 1 to 3 of the Act applies to the Infringement.

G. Objectively justified transactions and ancillary restraints

8.232. A restriction of competition which is found to be objectively necessary for the existence or survival of a legitimate main operation or activity may fall outside the scope of the Chapter I prohibition and Article 101(1) TFEU.[826] Where it is claimed that an anti-competitive restriction is objectively necessary for such a main operation, it is necessary to inquire whether that operation would be impossible to carry out in the absence of the restriction in question.[827] This will be the case if such restraints cannot be dissociated from that operation or activity without jeopardising its existence and aims.[828]

8.233. The burden of demonstrating that an alleged restriction of competition is '*objectively justified*', ie necessary and proportionate to the achievement of a legitimate aim, rests with the undertaking making that assertion.[829]

8.234. The Parties have not submitted that the restrictions contained in the SDA were objectively necessary to a legitimate main operation.

8.235. The CMA therefore concludes that the SDA, and the restrictions contained therein, were neither objectively necessary for nor proportionate to the commercialisation of Ambient Storage Fludrocortisone.

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[825] Section 3 of the Act sets out the following exclusions: Schedule 1 covers mergers and concentrations; Schedule 2 covers competition scrutiny under other enactments; and Schedule 3 covers general exclusions.
[826] See, among other cases, C-382/12 *MasterCard v Commission* EU:C:2014:2201, paragraph 91. For a restrictive agreement to be 'objectively justified', it is necessary to establish a causal link between the restraint and the survival of the trade in question (see Case 107/82 *AEG v Commission* EU:C:1983:293 paragraph 71; *Ping Europe Limited v Competition and Markets Authority* [2018] CAT 13, paragraphs 63 to 69 and 73).
[827] C-382/12 *MasterCard v Commission* EU:C:2014:2201, paragraph 91.
[828] T-701/14, *Perindopril (Niche)* EU:T:2018:921, paragraph 310; *Ping Europe Limited v Competition and Markets Authority* [2018] CAT 13, paragraphs 70 to 77.
[829]See *Racecourse Association v OFT* [2005] CAT 29, paragraphs 132 and 133; see also by analogy *ASDA (and others) v MasterCard* (and others) [2017] EWHC 93 (Comm), paragraph 45; Article 101(3) Guidelines, see paragraphs 51 to 58; *Guidelines on Vertical Restraints* OJ 2010/C130/01, paragraph 47; section 9(2) of the Act.

H. Individual exemptions

8.236. Agreements falling within the scope of the Chapter I prohibition / Article 101(1) TFEU but which satisfy the criteria set out in section 9 of the Act/Article 101(3) TFEU are exempt from those prohibitions.

8.237. The burden of proof of this aspect of the legal test is on the undertakings. It is for the party claiming the benefit of exemption to adduce evidence that substantiates its claim.[830]

8.238. The Parties have not submitted that the restrictions contained in the SDA satisfy the criteria set out in section 9 of the Act/Article 101(3) TFEU.

8.239. The CMA therefore concludes that the SDA, and the restrictions contained therein, are not exempt from the Chapter 1 Prohibition/Article 101(1) TFEU.

I. Duration

8.240. The duration of the Infringement is a relevant factor for determining any financial penalties that the CMA decides to impose following a finding of infringement.

8.241. The CMA finds that the Infringement lasted from the date of the conclusion of the SDA on 1 March 2016 to its termination on 19 October 2016, following the completion of the SAA.

[830] Article 101(3) Guidelines, see paragraphs 51 to 58; *Guidelines on Vertical Restraints* OJ 2010/C130/01, paragraph 47. See also section 9(2) of the Act.

9. ATTRIBUTION OF LIABILITY

A. Legal framework

9.1. Where an undertaking infringes the competition rules, it falls to that undertaking to answer for that infringement: '*EU competition law is based on the principle of the personal liability of the economic entity which has committed the infringement.*'[831]

9.2. However, in order to enforce competition law it is necessary to attribute liability to legal persons.[832] For this reason, the CAT has confirmed that '*conceptually, the question as to the existence of an "undertaking" and the question as to the attribution of liability between different companies within an "undertaking" are distinct* […] *although* […] *the two questions are very closely related*.'[833]

9.3. The CAT therefore summarised the legal test for attributing liability as follows*:*

'a legal person may be liable for a breach of competition law:

(i) Because he, she or it has in some way participated in that breach, as a part of the single economic unit or "undertaking" that has infringed the law; and/or

(ii) Because he, she or it has exercised decisive influence over one or more of the persons within the "undertaking" who have participated in the infringement.'[834]

9.4. When attributing liability, the starting point is therefore that those legal persons that '*participated in th*[e] *breach, as a part of the single economic unit or "undertaking" that has infringed the law'* are liable.

9.5. Legal persons may also be held liable on the basis of parental liability, if they exercised decisive influence '*over one or more of the persons within the "undertaking" who have participated in the infringement*'.[835]

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[831] T-372/10 *Bolloré II* EU:T:2012:325, paragraph 52.
[832] C-97/08 P *Akzo Nobel v Commission* EU:C:2009:536, paragraphs 54 to 56.
[833] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(20). See also paragraphs 363(8) and 363(21), citing the Opinion of the Advocate General in C-231/11 P *Commission v Siemens* EU:C:2014:256, paragraphs 80 to 81.
[834] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).
[835] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

9.6. Where a parent exercises decisive influence over a subsidiary that participated in the infringement, parent and subsidiary together form a single **economic** entity in relation to the infringement. This means that the parent can be held jointly and severally liable for the infringement with the directly infringing subsidiary.[836]

9.7. The Court of Justice summarised the legal framework for attributing liability to parents in *Akzo Nobel v Commission*:

> *'It is clear from settled case-law that the conduct of a subsidiary may be imputed to the parent company in particular where, although having a separate legal personality, that subsidiary does not decide independently upon its own conduct on the market, but carries out, in all material respects, the instructions given to it by the parent company* […] *having regard in particular to the economic, organisational and legal links between those two legal* [persons].*'*[837] [838]

9.8. The legal test for parental liability is therefore that the parent entity exercises '*decisive influence'* over a directly infringing entity. The question is whether '*the parent company, by reason of the intensity of its influence, can direct the conduct of its subsidiary to such an extent that the two must be regarded as one economic unit*'.[839] If so, the parent forms part of the economic entity that

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[836] T-372/10 *Bolloré II* EU:T:2012:325, paragraphs 37, 51 to 52 and the case law cited. Compare T-69/04 *Schunk v Commission* EU:T:2008:415, paragraphs 73 and 74.

[837] C-97/08 P *Akzo Nobel v Commission* EU:C:2009:536, paragraphs 58 to 59. See also C-155/14 P *Evonik Degussa GmbH v Commission* EU:C:2016:446, paragraph 27 citing C-93/13 P and C-123/13 P *Commission and Others v Versalis and Others* EU:C:2015:150, paragraph 40; C-628/10 P and C-14/11 P *Alliance One & Others v Commission* EU:C:2012:479, paragraph 44; *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 15 to 22.

[838] Applying this legal framework '*does not in any way constitute an exception to the principle of personal responsibility, but is the expression of that very principle. That is because the parent company and the subsidiaries under its decisive influence are collectively a single undertaking for the purposes of competition law and responsible for that undertaking* […] *that gives rise to the collective personal responsibility of all the principals in the group structure, regardless of whether they are the parent company or a subsidiary* […] *As the parent company exercising decisive influence over its subsidiaries, it pulls the strings within the group of companies'*. *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(3), citing Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission* EU:C:2009:262, paragraphs 97 to 99. Nor does this legal framework infringe the right to be presumed innocent: T-419/14 *Goldman Sachs v Commission* EU:T:2018:445, paragraphs 187 to 191.

[839] T-77/08 *Dow v Commission* EU:T:2012:47, paragraph 77, upheld in C-179/12 P *Dow v Commission* EU:C:2013:605, referring to the Opinion of Advocate General Kokott in C-97/08 P *Akzo Nobel v Commission* EU:C:2009:262, paragraphs 87 to 94. The CMA is therefore not required to demonstrate that the parent was involved in, or even aware of, the infringement by its subsidiary. See C-90/09 P *General Química SA v Commission* EU:C:2011:21, paragraph 102: '*what counts is not whether the parent company encouraged its subsidiary to commit an infringement* […]*, or whether it was directly involved in the infringement committed by its subsidiary, but the fact that those two companies constitute a single economic unit and thus a single undertaking* […] *which enables the Commission to impose a fine on the parent company*'; see also C-97/08 *Akzo Nobel v Commission* EU:C:2009:536, paragraphs 59 and 77.

committed the infringement and may be held jointly and severally liable with its subsidiary for that infringement.

9.9. It is settled case law that where a parent company holds (directly or indirectly)[840] 100% (or nearly 100%)[841] of the shares or voting rights[842] in a subsidiary which has infringed the competition rules, not only is that parent company able to exercise decisive influence over the conduct of its subsidiary; but there is a rebuttable presumption that the parent company does in fact exercise such decisive influence over the conduct of its subsidiary. The two persons can therefore be regarded as a single economic unit and held jointly and severally liable for the infringement and any resulting fine.[843]

9.10. Where the presumption set out in *Akzo* applies, it suffices for the purposes of attribution of liability. In such circumstances, it is for the party in question to rebut the presumption by adducing sufficient evidence.[844]

B. Application to this case

I. Aspen

9.11. The CMA attributes liability for the Infringement to Aspen Holdings, Aspen Global Inc., Aspen Pharma Ireland Limited and Aspen Pharma Trading Limited for the period from 1 March 2016 to 19 October 2016 and holds these legal persons jointly and severally liable for any resulting financial penalties.[845]

9.12. This is because each of these legal entities were directly involved in the SDA:[846] [847]

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[840] C-90/09 P *General Química and Others* v *Commission* EU:C:2011:21, paragraphs 86 to 87.
[841] T-217/06 *Arkema France, Altuglas International SA, Altumax Europe SAS v Commission* EU:T:2011:251, paragraph 53.
[842] T-419/14 *Goldman Sachs v Commission* EU:T:2018:445, paragraphs 50 to 52 and 84.
[843] C-628/10 P and C-14/11 P *Alliance One & Others v Commission* EU:C:2012:479, paragraphs 46 to 48; C-155/14 P *Evonik Degussa GmbH v Commission* EU:C:2016:446, paragraph 28 and the case law cited; C-97/08 P *Akzo Nobel v Commission* EU:C:2009:536, paragraphs 60 to 61; see also 107/82 *Allgemeine Elektricitäts-Gesellschaft AEG-Telefunken AG v Commission* EU:C:1983:293, paragraph 50; *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 15 to 18.
[844] C-628/10 P and C-14/11 P *Alliance One & Others v Commission* EU:C:2012:479, paragraph 47, citing C-97/08 P *Akzo Nobel v Commission* EU:C:2009:536, paragraph 61; see also *Durkan v Office of Fair Trading* [2011] CAT 6, paragraphs 19 to 21.
[845] See Section 10 below on the CMA's proposed approach to imposing penalties for the Infringement.
[846] Any reference to the 'SDA' in this section refers to the concurrence of wills described in paragraph 7.10 and further detailed in the remainder of Section 7.
[847] Compare with Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, in which the European Commission attributed liability to subsidiaries that actually signed the agreement or played a prominent role in its negotiation or implementation (recitals 444 and 457).

(a) Aspen Global Inc. was the subsidiary which actually signed the agreement;

(b) Aspen Holdings and Aspen Europe (which merged in 2018 with Aspen Pharma Ireland Limited) played a prominent role in the negotiation and implementation of the SDA. Aspen Holdings is the parent company that held, at the time of the Infringement, 100% of shares in Aspen Global Inc. and Aspen Europe. Aspen Holdings still hold 100% of shares in Aspen Global Inc.

(c) Aspen Pharma Ireland Limited has been Aspen's European headquarters and merged with Aspen Europe in July 2018. Aspen Holdings held at the time of the Infringement, and still holds, 100% of shares in Aspen Pharma Ireland Limited.

(d) Aspen Pharma Trading Limited has been the holder of the MAs for Fludrocortisone Acetate Tablets (Cold and Ambient Storage).

9.13. These legal entities therefore participated in the Infringement, '*as a part of the single economic unit or "undertaking" that has infringed the law*.'[848]

II. Amilco

9.14. The CMA attributes liability for the Infringement to Amilco for the period 1 March 2016 to 19 October 2016 and proposes to hold this legal person liable for any resulting financial penalties.[849]

9.15. This is because Amilco was directly involved in the SDA:[850]

(a) Amilco was a signatory to the SDA; and

(b) Amilco, [✂], played a prominent role in the negotiation and implementation of the SDA.[851]

[848] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).
[849] See Section 10 below on the CMA's proposed approach to imposing penalties for the Infringement.
[850] Compare Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, in which the European Commission attributed liability to the subsidiaries that actually signed the agreement or played a prominent role in its negotiation or implementation (recitals 444 and 457).
[851] See Section 4.C.

III. Tiofarma

9.16. The CMA attributes liability for the Infringement to Tiofarma B.V. and Tiofarma Beheer B.V. for the period from 1 March 2016 to 19 October 2016 and proposes to hold these legal persons jointly and severally liable for any resulting financial penalties.[852]

9.17. This is because each of these persons were directly involved in the SDA:[853]

(a) Tiofarma B.V. was the subsidiary which actually signed the agreement and played a prominent role in its negotiation and implementation;

(b) Tiofarma Beheer B.V. is the parent company that held, at the time of the Infringement, 100% of shares in Tiofarma B.V. and still holds 100% of the shares in Tiofarma B.V.[854]

9.18. These persons therefore participated in the Infringement, '*as a part of the single economic unit or "undertaking" that has infringed the law*.'[855]

[852] See Section 10 below on the CMA's proposed approach to imposing penalties for the Infringement.
[853] Compare with Commission decision of 10 December 2013 in Case AT.39685 *Fentanyl*, in which the European Commission attributed liability to subsidiaries that actually signed the agreement or played a prominent role in its negotiation or implementation (recitals 444 and 457).
[854] Document FLC7772, Tiofarma's Annual report for year ending 31 December 2019.
[855] *Sainsbury's Supermarkets Ltd v MasterCard* [2016] CAT 11, paragraph 363(22).

10. THE CMA'S ACTION

A. The CMA's decision

10.1. On the basis of the evidence and analysis set out in this Decision, the CMA has concluded that Aspen, Amilco and Tiofarma infringed the Chapter I prohibition and Article 101(1) TFEU by participating, from 1 March 2016 to 19 October 2016 in the SDA (which contained the concurrence of wills between the Parties with respect to their future behaviour in the Relevant Market), because as set out in this Decision it constituted an agreement which had the object and effect of restricting competition within the UK and within the internal market and which may have affected trade within the UK and between EU Member States.

10.2. The remainder of this Section sets out the enforcement action which the CMA is taking and its reasons for taking that action.

B. Directions

10.3. The Infringement has ceased. The CMA has found that it is not necessary to give directions to any Parties in this case.[856]

C. Financial penalties

I. General

10.4. Section 36(1) of the Act provides that, on making a decision that an agreement has infringed the Chapter I prohibition or Article 101 TFEU, the CMA may require an undertaking which is a party to the agreement concerned to pay the CMA a penalty in respect of the infringement. Any penalties must be calculated by the CMA in accordance with relevant legislation[857] and, pursuant to section 38(8) of the Act, having had regard to the guidance in force at the time when setting the amount of the penalty (the **Penalties Guidance**).[858]

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[856] Section 32(1) of the Act provides that if the CMA has made a decision that an agreement (or, as appropriate, a concerted practice or a decision by an association of undertakings – see section 2(5) of the Act) infringes the Chapter I prohibition or Article 101 TFEU, it may give such person(s) as it considers appropriate such directions as it considers appropriate to bring the infringement to an end.
[857] In particular section 36 to 40 of the Act; The Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (SI 2000/309); and The Competition Act 1998 (Determination of Turnover for Penalties) (Amendment) Order 2004 (SI 2004/1259).
[858] The *CMA's guidance as to the appropriate amount of a penalty* (CMA73, April 2018).

10.5. For the reasons set out below, the CMA has concluded that the Infringement was committed intentionally or at the very least negligently by the Parties. Given the serious nature of the Infringement, and in order to deter similar conduct in the future, the CMA has found that it would be appropriate to exercise its discretion under section 36(1) of the Act to impose financial penalties in respect of the Infringement, and to attribute liability for any such penalties on the Parties.

10.6. As part of settlement, Aspen, Amilco and Tiofarma admitted their involvement in, and liability for, the Infringement. Aspen and Tiofarma furthermore agreed to pay a maximum penalty as set out in the terms of their respective settlement. For the reasons set out in Section 10.D. below, the CMA has decided to impose financial penalties on Aspen and Tiofarma in line with those terms. As regards Amilco, for the reasons explained in paragraph 10.29 below, no penalty was calculated.

II. Intention and negligence

a. Legal framework

10.7. Where the CMA has taken a decision that an undertaking's conduct infringes the Chapter I prohibition and/or Article 101(1) TFEU, it may impose a penalty on the undertaking concerned in respect of an infringement only if it is satisfied that the infringement has been committed intentionally or negligently.[859] However, the CMA is not obliged to specify whether it considers the infringement to have been intentional or merely negligent.[860]

10.8. The CAT and Court of Appeal have defined the terms 'intentionally' and 'negligently' as follows:

> *'…an infringement is committed intentionally for the purposes of section 36(3) of the Act if the undertaking must have been aware, or could not have been unaware, that its conduct had the object or would have the effect of restricting competition.*
>
> […]

[859] Section 36(3) of the Act.
[860] *Napp Pharmaceutical Holdings v OFT* [2002] CAT 1, paragraphs 453-457. See also *Argos and Littlewoods* [2005] CAT 13, paragraph 221, *Ping Europe Limited v CMA* [2020] EWCA Civ13, paragraph 117.

An infringement is committed negligently for the purposes of section 36(3) if the undertaking ought to have known that its conduct would result in a restriction or distortion of competition'.[861]

10.9. This is consistent with the approach taken by the Court of Justice which has confirmed:

'the question whether the infringements were committed intentionally or negligently…is satisfied where the undertaking concerned cannot be unaware of the anti-competitive nature of its conduct, whether or not it is aware that it is infringing the competition rules of the Treaty.'[862]

10.10. As this statement by the Court of Justice shows, the intention or negligence relates to the facts, not the law. It is not necessary to show that the undertaking knew that it was infringing the Chapter I and/or Article 101(1) TFEU.[863] Ignorance or a mistake of law does not prevent a finding of intentional (or, *a fortiori*, negligent) infringement, even where such ignorance or mistake is based on independent legal advice.[864]

10.11. In some cases, the undertaking's intention will be confirmed by internal documents. However, in other cases, and in the absence of any evidence to the contrary, the fact that certain consequences are plainly foreseeable is an element from which the requisite intention may be inferred.[865]

b. Application to this case

10.12. For the reasons set out below, the CMA has found that Aspen, Amilco and Tiofarma must have been aware, could not have been unaware, or at least ought to have known that their conduct in participating in the SDA had the object and would have the effect of restricting competition. In particular, they

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[861] *Argos Limited and Littlewoods Limited v Office of Fair Trading* [2005] CAT 13, paragraph 221. This passage was cited with approval by the Court of Appeal in *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117.
[862] Case C-280/08 P Deutsche Telekom v Commission EU:C:2010:603, paragraph 124.
[863] *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraph 456.
[864] *Ping Europe Ltd v CMA* [2020] EWCA Civ 13, paragraph 117. See also Case C-280/08 P *Deutsche Telekom v Commission* EU:C:2010:603, paragraph 124 and the Court of Justice's comments in Judgment in C-681/11*, Bundeswettbewerbsbehörde v Schenker & Co. AG* EU:C:2013:404, paragraph 38: '*the fact that the undertaking concerned has characterised wrongly in law its conduct upon which the finding of the infringement is based cannot have the effect of exempting it from imposition of a fine in so far as it could not be unaware of the anti-competitive nature of that conduct*'; and paragraph 41: '*It follows that legal advice given by a lawyer cannot, in any event, form the basis of a legitimate expectation on the part of an undertaking that its conduct does not infringe Article 101 TFEU or will not give rise to the imposition of a fine*.' See also *Guidance on Enforcement*, paragraph 5.10.
[865] *Napp Pharmaceutical Holdings Limited v Director General of Fair Trading* [2002] CAT 1, paragraph 456.

must have been aware, could not have been unaware, or at least ought to have known that:

(a) Amilco and Tiofarma, working together, were potential competitors to Aspen in the Relevant Market at the time of the SDA;

(b) the grant of an exclusive licence to Aspen over Ambient Storage Fludrocortisone for the duration of the SDA prevented Amilco and Tiofarma from entering the Relevant Market independently from Aspen during that period, thereby delaying the emergence of competition between the Parties; and

(c) in exchange for the non-entry, Aspen would make under the SDA significant value transfers to Amilco and Tiofarma, of a pecuniary or non-pecuniary nature, which reflected the postponement of competition.

and, therefore, in the light of the relevant legal and economic context, that the SDA replaced the risks of competition by cooperation between the Parties.

10.13. The Parties therefore committed the Infringement intentionally or, at the very least, negligently.

10.14. Aspen, Amilco and Tiofarma, as set out in their respective Settlement Letters, have accepted that they have infringed the Chapter I Prohibition and Article 101(1) TFEU and that they are liable to pay a penalty on the basis of the evidence and findings which were set out in the Summary Statement of Facts (Aspen) and Statement of Objections (Amilco and Tiofarma), and now in this Decision. Therefore, they do not contest the CMA's interpretation and assessment of the relevant clauses of the SDA or findings relating to its legal and economic context (including the CMA's findings on potential competition).

i. Potential competitors

10.15. Aspen, Amilco and Tiofarma must have been aware, could not have been unaware, or at least ought to have known that Amilco and Tiofarma, working together, were potential competitors to Aspen (see Section 8.A.II above).

Amilco and Tiofarma

10.16. As explained in paragraphs 8.59 to 8.63 above, at the time of entering into the SDA, Amilco and Tiofarma had made significant investments to bring that product to market. They held an MA for supplying Ambient Storage

Fludrocortisone in the UK and had started to manufacture the product. As experienced pharmaceutical businesses within the EU, they knew that an MA was the key regulatory requirement to enter a generic market. Extensive evidence confirms that Amilco and Tiofarma must have been aware, or in any event ought to have known, that the preparatory steps already taken were sufficient to enable the market entry of Ambient Storage Fludrocortisone, that there were no regulatory or commercial barriers to such entry, and that they could have pursued various routes to market absent a deal with Aspen on the basis of viable costs (including through, or with the support of, a third party).

10.17. Therefore, Amilco and Tiofarma must have been aware, could not have been unaware, or at least ought to have known that at the time of entering into the SDA they had real concrete possibilities of entering the Relevant Market and therefore that they were potential competitors to Aspen.

Aspen

10.18. As set out in paragraphs 8.86 to 8.89, Aspen perceived Amilco and Tiofarma as potential competitors prior to the SDA. Therefore, Aspen must have been aware, could not have been unaware, or at least ought to have known at the time of entering into the SDA that Amilco and Tiofarma, working together, were its potential competitors.

ii. Agreement not to enter the market

10.19. As described in Section 7.B.I. above, while the exclusivity licence granted to Aspen over Ambient Storage Fludrocortisone was not described in the SDA as a non-entry or non-compete provision, the Parties understood that granting Aspen an exclusive licence to use Tiofarma's MA for Ambient Storage Fludrocortisone was designed to achieve that outcome. Indeed, aside from reliance on that MA, which was precluded to them under the SDA, Amilco and Tiofarma had no alternative means to enter the market independently of Aspen within a reasonable timeframe (as noted above, the absence of any other MA for Fludrocortisone Acetate Tablets is a matter of public record). That commitment was contractually binding on Amilco and Tiofarma so long as Aspen fulfilled its obligations under the SDA, namely to supply exclusively Ambient Storage Fludrocortisone manufactured by Tiofarma in the UK. As a result of the SDA the only two existing MAs for this product would be controlled by Aspen, no longer facing any material actual or potential competition.

10.20. Therefore, Aspen, Amilco and Tiofarma must have been aware, could not have been unaware, or at least ought to have known that the grant of an exclusive licence to Aspen over Ambient Storage Fludrocortisone for the duration of the SDA prevented Amilco and Tiofarma from entering the Relevant Market independently from Aspen during that period, thereby delaying the emergence of competition between the Parties.

iii. Value transfers reflecting the postponement of competition in exchange for non-entry

10.21. As set out at Section 7.B.II. above, Aspen, Amilco and Tiofarma had a common understanding that, under the SDA, Aspen would make significant value transfers (of pecuniary and non-pecuniary nature) to Tiofarma and Amilco in return for their commitment not to enter the market independently.

10.22. In particular,

(a) The Parties shared a common understanding that Aspen would supply exclusively Ambient Storage Fludrocortisone in the UK, making Tiofarma the sole manufacturer of Fludrocortisone Acetate Tablets for supply in the UK; and

(b) Amilco and Aspen shared a common understanding that Aspen would pay to Amilco (as ultimate owner of the rights to Ambient Storage Fludrocortisone) a fixed profit margin on the basis of Aspen charging a List Price more than 1,800% higher than its price prior to the SDA.

10.23. As set out above in Section 7.B. and paragraphs 8.133 to 8.138 above, Aspen, Amilco and Tiofarma understood that these value transfers were the counter-performance for Amilco and Tiofarma agreeing not to enter the market independently.

10.24. Therefore, Aspen, Amilco and Tiofarma must have been aware, could not have been unaware, or at least ought to have known that, in exchange for non-entry, Aspen would make significant value transfers (of pecuniary or non-pecuniary nature) to Amilco and Tiofarma under the SDA which reflected the postponement of competition.

III. Small agreements

10.25. Section 39 of the Act (which provides that a party to a 'small agreement'[866] is immune from financial penalties for infringements of the Chapter I prohibition) does not apply in this case on the basis that the combined applicable turnover of the Parties exceeded the relevant threshold. Moreover, section 39 of the Act does not apply in respect of infringements of Article 101 TFEU.

IV. The CMA's margin of appreciation in determining the appropriate penalty

10.26. Provided the penalties it imposes in a particular case are (i) within the range of penalties permitted by section 36(8) of the Act and the Competition Act 1998 (Determination of Turnover for Penalties) Order 2000 (the '**2000 Order**'),[867] and (ii) the CMA has had regard to the Penalties Guidance in accordance with section 36(8) of the Act, the CMA has a margin of appreciation when determining the appropriate amount of a penalty under the Act.[868]

10.27. The CMA is not bound by its decisions in relation to the calculation of financial penalties in previous cases.[869] Rather, the CMA makes its assessment on a case-by-case basis,[870] having regard to all the relevant circumstances and the twin objectives of the CMA's policy on financial penalties, namely:

(a) to impose penalties on infringing undertakings which reflect the seriousness of the infringement; and

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[866] Competition Act 1998 (Small Agreements and Conduct of Minor Significance) Regulations 2000 (SI 2000/262), Regulation 3. A 'small agreement' is an agreement between undertakings whose combined applicable turnover does not exceed £20 million for the business year ending in the calendar year preceding the one during which the infringement occurred. The term 'applicable turnover' means the turnover determined in accordance with the Schedule to the Regulations.
[867] SI 2000/309, as amended by the Competition Act (Determination of Turnover for Penalties) (Amendment) Order 2004, SI 2004/1259.
[868] *Argos Limited and Littlewoods Limited v OFT* [2005] CAT 13, paragraph 168 and *Umbro Holdings and Manchester United and JJB Sports and Allsports v OFT* [2005] CAT 22, paragraph 102.
[869] See, for example, *Eden Brown and Others v OFT* [2011] CAT 8, paragraph 78.
[870] See, for example, *Kier Group and Others v OFT* [2011] CAT 3, paragraph 116 where the CAT noted that *'other than in matters of legal principle there is limited precedent value in other decisions relating to penalties, where the maxim that each case stands on its own facts is particularly pertinent'*. See also *Eden Brown and Others v OFT* [2011] CAT 8, paragraph 97 where the CAT observed that '[d]*ecisions by this Tribunal on penalty appeals are very closely related to the particular facts of the case*'.

(b) to ensure that the threat of penalties will deter both the infringing undertaking and other undertakings from engaging in anti-competitive activities.[871]

10.28. Aspen and Tiofarma have admitted their involvement in, and liability for the Infringement and agreed to pay a maximum penalty. Accordingly:

(a) Aspen has agreed to pay a maximum penalty of £2,101,954;[872]

(b) Tiofarma has agreed to pay a maximum penalty of £186,442.[873]

10.29. As set out in paragraph 3.13 above, Amilco achieved no worldwide turnover in the last business year.[874] Given that, as set out in section 36(8) of the Act, the financial penalty may not exceed the maximum penalty of 10% of the worldwide turnover of an undertaking in its last business year, the maximum financial penalty that the CMA could impose on Amilco under the Act is nil. As a result, the CMA has decided not to impose on Amilco a penalty under section 36(1) of the Act despite finding that Amilco committed the Infringement intentionally or, at the very least, negligently.

D. Calculation of the penalties

10.30. When setting the amount of the penalty, the CMA must have regard to the guidance on penalties in force at that time. The Penalties Guidance establishes a six-step approach for calculating the penalty. Their application in this case are set out below.

Step 1 - starting point

10.31. The starting point for determining the level of financial penalty is calculated having regard to:

(a) the relevant turnover of the undertaking; and

(b) the seriousness of the infringement and the need for general deterrence.[875]

[871] Section 36(7A) of the Act and Penalties Guidance, paragraph 1.4.
[872] Aspen's Settlement Letter dated 24 July 2019.
[873] Tiofarma's Settlement Letter dated 18 December 2019.
[874] Document FLC7765, and its attachment Document FLC7766, letter from Amilco's accountants.
[875] Penalties Guidance, paragraph 2.3 to 2.15.

a. Relevant turnover

10.32. An undertaking's *'relevant turnover'* is defined in the Penalties Guidance as the turnover of the undertaking in the relevant product market and relevant geographic market affected by the infringement in the undertaking's last business year. In this context, an undertaking's last business year is the financial year preceding the date when the infringement ended.[876] Relevant turnover is a measure of the 'scale and impact of the infringing activity for the purpose of calculating the appropriate penalty'.[877]

10.33. While the CMA is obliged to have regard to the Penalties Guidance pursuant to section 38(8) of the Act, the CMA may depart from the approach set out in the Penalties Guidance where appropriate. The CMA considers that it is appropriate to exercise its discretion where necessary in order to give effect to the requirement that the relevant turnover reflect the undertaking's real economic situation at the time the infringement was committed.

10.34. As set out above in this Decision, the CMA has found that the relevant market for these purposes is the supply of Fludrocortisone Acetate Tablets for human use in the UK, and that the Parties' participation in the Infringement lasted seven months, from 1 March 2016 and to 19 October 2016.

i. Aspen

10.35. Aspen's last financial year preceding the date when the Infringement ended is the financial year ending 30 June 2016. Aspen began supplying Ambient Storage Fludrocortisone under the SDA in March 2016 at the List Price of £1 per tablet. Prior to Infringement, for the first eight months of the financial year finishing 30 June 2016 (ie between July 2015 to February 2016), Aspen supplied Cold Storage Fludrocortisone at the much lower List Price of £0.05 per tablet. Although volumes sold in the relevant market decreased following the price increase, Aspen's turnover in the relevant market increased significantly from 1 March 2016 as set out in paragraphs 4.178 and 4.179 above, specifically:

(a) in the first eight months of that financial year (ie before the Infringement started), Aspen turnover was £309,244; and

[876] Penalties Guidance, paragraph 2.11.
[877] *Eden Brown and Others v OFT* [2011] CAT 8, paragraph 55.

(b) in the last four months of that financial year (ie after the Infringement started), Aspen's turnover was £4,298,282.

10.36. The timing of Aspen's financial years means that the relevant turnover achieved in the financial year preceding the end of the Infringement would only capture four months of Aspen's sales under the SDA (ie eight months pre-SDA and four months during the SDA).

10.37. Having had regard to the Penalties Guidance and to the particular circumstances of this case, the CMA considers that a more appropriate approach is to use the 12-month period immediately preceding the end of the Infringement as a basis for relevant turnover (ie the seven months of the SDA period and the five months preceding the SDA). Aspen's relevant turnover in this 12-month period (from 1 October 2015 to 30 September 2016) was £7,155,346.[878]

10.38. This period gives a more accurate reflection of the true scale and impact of Aspen's activity in the Relevant Market under the SDA as it captures the turnover achieved during the entire duration of the Infringement. It is therefore more appropriate as compared to alternative approaches, such as using the turnover achieved in the financial year preceding the end of the infringement (as set out above, this would capture only part of the duration of the infringement but instead eight months – rather than only five – pre-SDA), or in the four month period of turnover to June 2016 grossed up to a full 12 month period.

10.39. On the basis of the approach above, the CMA considers it is appropriate to use the figure of £7,155,346 as the relevant turnover for Aspen.

ii. Tiofarma

10.40. Tiofarma's last financial year preceding the end of the infringing activity is the financial year finishing 31 December 2015. Tiofarma began supplying Ambient Storage Fludrocortisone under the SDA in March 2016. Prior to that, Tiofarma had no activity in the Relevant Market and therefore a nil turnover.

10.41. The timing of Tiofarma's financial year means that applying the relevant turnover from the period indicated by the Penalties Guidance would not capture any of the sales made by Tiofarma under the SDA. The CMA therefore does not consider that the approach envisaged by paragraph 2.11 of the Penalties Guidance would be an accurate reflection of the scale and

[878] See Document FLC1836, Aspen's response to question 1 of the CMA's section 26 notice dated 19 April 2018.

impact of Tiofarma's activity in the Relevant Market under the SDA since as a new entrant Tiofarma would have no turnover.

10.42. Having had regard to the Penalties Guidance and the particular circumstances of this case, the CMA considers that a more appropriate approach is to use the turnover in the financial year ending 31 December 2016. Tiofarma's relevant turnover in this period was £465,000.[879] This period gives a more accurate reflection of the true scale and impact of Tiofarma's activity in the Relevant Market under the SDA as it captures the turnover achieved during the duration of the Infringement.

10.43. On the basis of the approach above, the CMA considers it is appropriate to use the figure of £465,000 as the relevant turnover for Tiofarma.

b. Seriousness of the infringement

10.44. The CMA will apply starting point of up to 30% to an undertaking's relevant turnover in order to reflect adequately the seriousness of the particular infringement. A starting point of 21 to 30% will be used for the most serious infringements of competition law, including hardcore cartel activity. A starting point between 10 and 20% is more likely to be appropriate for certain, less serious object infringements, and for infringements by effect.[880] In applying the starting point, the CMA will also reflect the need to deter the infringing undertaking and other undertakings generally from engaging in that type of infringement in future.[881]

10.45. The CMA will then consider whether it is appropriate to adjust the starting point upwards or downwards to take account of specific circumstances of the case. When making this assessment, the CMA will consider a number of factors, including the nature of the product, the structure of the market, the market coverage of the infringement, and the effect on competitors and third parties. The extent and likelihood of damage to consumers, whether directly or indirectly, will also be an important consideration. The assessment will be made on a case-by-case basis for all types of infringement, taking account of all the circumstances of the case.[882]

[879] See Document SET120, email from [Tiofarma's External Legal Adviser] [✂] to [CMA] dated 28 November 2019.
[880] Penalties Guidance, paragraph 2.6.
[881] Penalties Guidance, paragraph 2.4.
[882] Penalties Guidance, paragraph 2.6.

10.46. Finally, the CMA will consider whether the starting point for a particular infringement is sufficient for the purpose of general deterrence. In particular the CMA will consider the need to deter other undertakings, whether in the same market or more broadly, from engaging in the same or similar conduct.[883]

i. Application in this case

10.47. Having taken account of the below factors in the round, the CMA considers that the appropriate starting point for the Infringement is 27%.

10.48. The CMA considers that the following specific circumstances of the case are relevant in assessing the extent and likelihood of harm to competition (and ultimately to consumers) and justify a starting point at the upper end of the 21-30% range:

The likelihood that the type of infringement at issue will, by its nature, cause harm to competition

10.49. The Infringement involves a market sharing agreement, one of the most serious type of breach of competition law[884], pursuant to which Amilco and Tiofarma agreed not to enter the Relevant Market for the duration of the SDA in exchange for significant value transfers, of a pecuniary or non-pecuniary nature, reflecting the postponement of competition (see Sections 7.B. and 8.B.II.).

10.50. Therefore, the Infringement can be regarded, by its very nature, as being harmful to the proper functioning of normal competition, such that the CMA would generally use a starting point in the 21% to 30% range.

The extent and/or likelihood of harm to competition in the specific relevant circumstances in this case

The nature of the product

10.51. The CMA notes that Fludrocortisone Acetate Tablets is a vital, life-saving drug for patients and the NHS with no alternative treatment.

The structure of the market and coverage of the Infringement

[883] Penalties Guidance, paragraph 2.9.
[884] Agreements intended to exclude potential competitors from the market during their terms fall within the scope of the serious infringements referred to explicitly in section 2 of the Competition Act 1998 (CA98). See, by reference to Article 101 TFEU, T-472/13 *Lundbeck v Commission* EU:T:2016:449, paragraph 832.

10.52. The Infringement was implemented in the whole of the UK.

10.53. Prior to entering into the SDA, Aspen was the sole supplier of Fludrocortisone Acetate Tablets in the UK, facing no material competitive pressure. Any company seeking to supply this product in the UK must first obtain an MA. Tiofarma is the only pharmaceutical company to have obtained an MA for supplying Fludrocortisone Acetate Tablets in the UK other than Aspen, and as such was the first and only source of potential competition to Aspen.

The actual or potential effect of the Infringement on competitors

10.54. The SDA affected the competitive structure of the market by preventing, or at least considerably delaying entry of Tiofarma. As such, the SDA neutralised the constraint arising from the only source of potential competition to Aspen (in the form of independently supplied Ambient Storage Fludrocortisone) for the duration of the SDA.

10.55. Independent entry to the Relevant Market would have been expected to result in competitive pressure on Aspen's sales volumes and/or pricing strategy. Instead, the SDA preserved Aspen's position as sole supplier of Fludrocortisone Acetate Tablets.

The actual harm or potential harm caused to the NHS and consumers

10.56. As explained in Section 8.C.III., the CMA has found that the SDA not only neutralised the competitive threat posed by Amilco and Tiofarma, thereby preserving Aspen's ability to sustain prices above the level that it would have charged absent the SDA, but also had the actual effect of artificially increasing the List Price for Fludrocortisone Acetate Tablets beyond that level.

10.57. As a result, the cost of Fludrocortisone Acetate Tablets to the NHS increased from approximately £70,000 per month pre-SDA to approximately £1.2 million (in England) per month during the period of the Infringement. The Infringement therefore resulted in significant harm to the NHS and, indirectly, to consumers and taxpayers.

ii. Sufficiency of the starting point and conclusion

10.58. The CMA considers that a starting point of 27% is sufficient for the purpose of general deterrence, and in particular, to deter other undertakings from engaging in the same or similar conduct.

10.59. At the end of step 1, the penalties are as follows:

Party	Penalty
Aspen	£1,931,943
Tiofarma	£125,550

Step 2 – adjustment for duration

10.60. The starting point under step 1 may be increased, or in particular circumstances decreased, to take into account the duration of an infringement. Where the total duration of an infringement is less than one year, the CMA will treat that duration as a full year for the purpose of calculating the number of years of the infringement. In exceptional circumstances, the starting point may be decreased where the duration of the infringement is less than one year.[885]

10.61. The CMA has found that the Infringement lasted from 1 March 2016 to 19 October 2016. The duration of the Infringement was therefore 7 months and 19 day. Given that Aspen and Tiofarma participated in the Infringement for less than one year, the CMA has applied a multiplier of 1 to the figures reached for both Parties at the end of step 1.

Step 3 – adjustment for aggravating and mitigating factors

10.62. The CMA may, at step 3, increase a penalty where there are aggravating factors, and/or decrease it where there are mitigating factors. A non-exhaustive list of aggravating and mitigating factors is set out in the Penalty Guidance.[886] In the circumstances of this case, the CMA has adjusted the penalties at step 3 to take account of the factors set out below.

c. Aggravating factor – involvement of directors or senior management

10.63. The involvement of directors or senior management in an infringement can be an aggravating factor.[887]

10.64. In this case, the SDA was set up and/or operated by the directors and/or senior management of Aspen and Tiofarma. Given the direct and active involvement of directors and/or senior management in the Infringement, as set

[885] Penalties Guidance, paragraph 2.16.
[886] Penalties Guidance, paragraphs 2.18 and 2.19.
[887] Penalties Guidance, paragraph 2.18.

out in Section 4 of this Decision, the CMA considers that it is appropriate to apply an uplift of 10% to the penalties of Aspen and Tiofarma.

d. Mitigating factor – cooperation

10.65. The CMA may decrease the penalty at step 3 for cooperation which enables the enforcement process to be concluded more effectively and/or speedily. The Penalties Guidance provides that, for these purposes, what is expected is cooperation over and above respecting time limits specified or otherwise agreed (which will be a necessary but not sufficient criterion to merit a reduction at step 3).[888]

10.66. In this case, Aspen provided cooperation during the Investigation, including by:

(a) agreeing to a more expedient process for the CMA to gather and identify relevant evidence which led to savings of time and resources, including in relation to documents held on servers and in the context of a formal information request issued by the CCPC (on behalf of the CMA);

(b) producing voluntarily a significant number of documents relating to certain custodians based in South Africa in connection with an information request addressed by the CMA to group companies based in the EU; these documents assisted the CMA's Investigation; and

(c) making a number of its employees available for voluntary interviews, including directors based in South Africa; these interviews assisted the CMA's Investigation.

10.67. The CMA therefore considers that a 15% reduction for cooperation for Aspen is appropriate in the circumstances of this case.

e. Mitigating factor – compliance policy

10.68. The CMA may decrease the penalty at step 3 where adequate steps have been taken by an undertaking with a view to ensuring future compliance with competition law.[889] To qualify, an undertaking has to provide evidence of adequate steps taken to achieve a clear and unambiguous commitment to competition law compliance throughout the organisation, from the top down, together with appropriate steps relating to competition compliance risk

[888] Penalties Guidance, paragraph 2.19 and footnote 35.
[889] Penalties Guidance, paragraph 2.19.

identification, risk assessment, risk mitigation and review activities. The CMA will consider carefully whether evidence presented of an undertaking's compliance activities in a particular case merits a discount to the penalty of up to 10%.

10.69. Following the CMA's Investigation and the settlement discussions in the present case, Aspen has engaged constructively with the CMA to introduce a number of enhancements to its competition law compliance programme. The CMA considers that the enhancements to compliance activities by Aspen demonstrate a clear and unambiguous commitment to competition law compliance throughout its companies from the top down, in that it has engaged in appropriate steps relating to risk identification, assessment, mitigation and review to which its Board has fully committed.

10.70. In particular, the CMA has been provided with evidence that, prior to this Decision, Aspen has rolled out an updated competition law compliance policy and annual training. In terms of its public commitment, Aspen has published clear statements on its website regarding its commitment to compliance. Aspen has also committed to submitting a report to the CMA on its compliance activities every year, for the next three years.

10.71. The CMA therefore considers that it is appropriate to decrease Aspen's penalty for the Infringement by a further 10% to reflect Aspen's enhanced compliance activities. At the end of step 3, the penalties are as follows:

Party	**Penalty**
Aspen	£1,642,152
Tiofarma	£138,105

Step 4 – adjustment for specific deterrence and proportionality

10.72. The penalty may be adjusted at this step to achieve the objective of specific deterrence (namely, ensuring that the penalty imposed on the undertaking in question will deter it from engaging in anti-competitive practices in the future), or to ensure that a penalty is proportionate, having regard to the appropriate indicators of the size and financial position of the relevant undertaking as well as any other relevant circumstances of the case.[890] At step 4, the CMA will

[890] Penalties Guidance, paragraph 2.20 to 2.24.

assess whether, in its view, the overall penalty is proportionate in the round.[891]

10.73. Adjustment to the penalty at step 4 may result in either an increase or a decrease to the penalty. The assessment of the need to adjust the penalty will be made on a case-by-case basis for each individual infringing undertaking.[892]

10.74. The penalty may be increased at step 4 for specific deterrence. Increases to the penalty figure at step 4 will generally be limited to situations in which an undertaking has a significant proportion of its turnover outside the relevant market, or where the CMA has evidence that the infringing undertaking has made or is likely to make an economic or financial benefit from the infringement that is above the level of the penalty reached at the end of step 3.[893] In considering the appropriate level of uplift for specific deterrence, the CMA will ensure that the uplift does not result in a penalty that is disproportionate or excessive having regard to the infringing undertaking's size and financial position and the nature of the infringement.[894]

10.75. Where necessary, the penalty may be decreased at step 4 to ensure that the level of penalty is not disproportionate or excessive. In carrying out this assessment of whether a penalty is proportionate, the CMA will have regard to the undertaking's size and financial position, the nature of the infringement, the role of the undertaking in the infringement and the impact of the infringing activity on competition.[895]

10.76. As explained in the Penalties Guidance, it is appropriate to assess the proportionality and deterrence effect of a penalty by reference to a particular undertaking's size and financial position. Undertakings can vary in size and financial position, such that variation between uplifts applied at step 4 in the penalty calculation in multi-party cases does not, in itself, demonstrate a failure to observe the principle of equal treatment.[896]

10.77. The CMA's consideration of step 4 in calculating the financial penalties for Aspen and Tiofarma is set out below.

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[891] Penalties Guidance, paragraph 2.24.
[892] Penalties Guidance, paragraph 2.21.
[893] Penalties Guidance, paragraph 2.21.
[894] Penalties Guidance, paragraph 2.23.
[895] Penalties Guidance, paragraph 2.24.
[896] Penalties Guidance, paragraph 2.1, footnote 17.

f. Application to Aspen

10.78. The penalty for Aspen at the end of step 3 is £1,642,152. Taking into account the serious nature of the Infringement, Aspen's participation in it and the impact of Aspen's infringing activity on competition, the CMA considers that Aspen's penalty after step 3 should be increased by 100%, to £3,284,304 to ensure that the penalty to be imposed on Aspen will deter it from breaching competition law in the future, given its specific size and financial position and any other relevant circumstances of the case.

10.79. While Aspen's profits in the Relevant Market increased above the level of the penalty after Step 3 as a result of the Infringement, the CMA has not considered it appropriate to add an uplift for specific deterrence on the basis of the financial benefits made by Aspen as a result of the Infringement. This is because under the Commitments Aspen made a total payment of £8 million to the Department of Health and Social Care and the devolved administrations. As set out at paragraph 6.10 of the Commitments decision, this payment addressed the CMA's concerns that, as a result of the impact of Aspen's behaviour in the Relevant Market (including the Infringement), Aspen charged the NHS a higher price for supplies of Fludrocortisone Acetate Tablets than it would have charged absent that behaviour.

10.80. Nonetheless the CMA's view is that an 100% uplift for specific deterrence is appropriate having regard to:

(a) the fact that Aspen generates a significant proportion of its turnover outside the relevant market; and

(b) various indicators of Aspen's size and financial position.

10.81. With the uplift, based on Aspen's financial results for the financial year ended 30 June 2019,[897] the penalty represents:

(a) 0.1% of Aspen's global turnover;

(b) 1.0 % of Aspen's global operating profit; and

(c) 0.1% of Aspen's global net assets.

[897] Document PD0046, Integrated Annual Report 2019 - Aspen Pharmacare.

10.82. Assessing the resulting penalty in the round, the CMA considers that the adjusted penalty of £3,284,304 at Step 4 is appropriate in this case for deterrence purposes without being disproportionate or excessive.

g. Application to Tiofarma

10.83. The penalty for Tiofarma at the end of step 3 is £138,105. Taking into account the serious nature of the Infringement, Tiofarma's participation in it and the impact of Tiofarma's infringing activity on competition, the CMA considers that Tiofarma's penalty after step 3 should be increased by 50%, to £207,158 to ensure that the penalty to be imposed on Tiofarma will deter it from breaching competition law in the future, given its specific size and financial position and any other relevant circumstances of the case.

10.84. The CMA's view is that this increase is appropriate having regard to:

(a) the fact that Tiofarma generates a significant proportion of its turnover outside the relevant market; and

(b) various indicators of Tiofarma's size and financial position.

10.85. With the uplift, based on Tiofarma's financial results for the financial year ended 31 December 2019,[898] the penalty represents:

(a) 0.5% of Tiofarma's global turnover;

(b) 3.3% of Tiofarma's global operating profit; and

(c) 0.7% of Tiofarma's global net assets.

10.86. Assessing the resulting penalty in the round, the CMA considers that the adjusted penalty of £207,158 at Step 4 is appropriate in this case for deterrence purposes without being disproportionate or excessive.

10.87. At the end of Step 4, the penalties are as follows:

Party	**Penalty**
Aspen	£3,284,304
Tiofarma	£207,158

[898] Document FLC7772, Tiofarma's Annual report for year ending 31 December 2019, CMA convenience translation from Dutch original.

Step 5 – adjustment to prevent the maximum penalty from being exceeded and to avoid double jeopardy

10.88. The CMA may not impose a penalty for an infringement that exceeds 10% of an undertaking's '*applicable turnover*'; that is, the worldwide turnover of the undertaking in the business year preceding the date of the CMA's decision or, of figures are not available for that business year, the one immediately preceding it.[899]

10.89. The CMA has assessed Aspen and Tiofarma's penalties at step 4 against this threshold and concluded that no adjustments are necessary.

10.90. In addition, the CMA must, when setting the amount of a penalty for a particular agreement or conduct, take into account any penalty or fine that has been imposed by the European Commission, or by a court or other body in another EU Member State in respect of the same agreement or conduct.[900] No such penalty has been imposed in respect of the Infringement.

Step 6 – application of reductions for leniency, settlement or voluntary redress

10.91. The CMA will reduce an undertaking's penalty at step 6 where an undertaking has a leniency agreement with the CMA or agrees to settle the case with the CMA.[901] The CMA may also apply a penalty reduction where an undertaking obtains approval for a voluntary redress scheme.[902]

10.92. Reductions for leniency are not applicable to any of the Parties in this case.

a. Settlement

10.93. Aspen and Tiofarma expressed a genuine interest and willingness to enter into settlement discussions with the CMA. As set out above at paragraphs 2.6 and 2.16, as part of settlement, Aspen and Tiofarma have admitted their involvement in, and liability for the Infringement, and cooperated with the CMA thereby expediting the process for concluding the Investigation.

10.94. In the light of these considerations, the CMA considers it appropriate (provided that they each continue to comply with the continuing requirements

[899] Section 36(8) of the Act, the 2000 Order, as amended; Penalties Guidance, paragraph 2.25.
[900] Penalties Guidance, paragraph 2.28.
[901] Penalties Guidance, paragraphs 2.29 and 2.30.
[902] Penalties Guidance, paragraphs 2.31.

of settlement as set out in their respective settlement agreements with the CMA):

(a) to grant Aspen a 20% discount to reflect the savings achieved as a result of entering into settlement before the CMA issued the Statement of Objections, including the fact that Aspen agreed to a streamlined access to file procedure whereby it only had access to the documents on the case file referred to in the Statement of Objections and that it was limited to identifying manifest factual inaccuracies in the Summary Statement of Facts and the Statement of Objections;

(b) to grant Tiofarma a 10% discount to reflect the savings achieved as a result of entering into settlement shortly after the CMA issued the Statement of Objections, including the fact that Tiofarma was limited to identifying manifest factual inaccuracies in the Statement of Objections (which are reflected in this Decision).

b. Further reduction in light of payment made to the Department of Health and Social Care by Aspen

10.95. As part of the Commitments offered by Aspen and accepted by the CMA to resolve the competition concerns identified by the CMA as arising from the SAA,[903] Aspen has paid £8 million to the DHSC and the devolved administrations. The DHSC and the devolved administrations have provided an assurance to Aspen that they would offset the payment against any potential future damages action.

10.96. In recognition of this payment, including the administrative savings for the NHS in pursuing damages actions through Courts, and in the specific circumstances of this case, the CMA has further reduced the financial penalty imposed on Aspen by 20%. This is equivalent to the maximum discount that the CMA is likely to apply in circumstances where a company obtains approval for a voluntary redress scheme.[904]

10.97. At the end of Step 6, the penalties are as follows:

Party	Penalty
Aspen	£2,101,954

[903] See the CMA's decision to accept binding commitments offered by Aspen at https://assets.publishing.service.gov.uk/media/5d94c607ed915d5540d5b093/Case_50455_-_Commitments_Decision.pdf.
[904] See *Guidance on the approval of voluntary redress schemes for infringements of competition law* (CMA40), paragraphs 3.30 and 3.32.

Tiofarma	£186,442

E. Payment of the penalties

10.98. The following table sets out a summary of the penalty calculations and the penalties that the CMA requires Aspen and Tiofarma to pay in relation to the Infringement, namely:

(a) the total penalty imposed on Aspen is £2,101,954; and

(b) the total penalty imposed on Tiofarma is £186,442.

Step	Description		Aspen	Tiofarma
	Relevant turnover		**£7,155,346**	**£465,000**
1	Starting point as a percentage of relevant turnover		27%	27%
2	Adjustment for duration		1	1
3	Adjustment for aggravating or mitigating factors	*Aggravating: Director involvement*	+10%	+10%
		Mitigating: Co-operation	-15%	N/A
		Mitigating: Compliance programme	-10%	N/A
4	Adjustment for specific deterrence or proportionality		+100%	+50%
	Interim penalty at end of step 4		£3,284,304	£207,158
5	Adjustment to take account of the statutory maximum penalty		N/A	N/A
6	Leniency discount		N/A	N/A
	Settlement discount		-20%	-10%
	Further discount reflecting payment to the NHS		-20	N/A
	Penalty payable		**£2,101,954**	**£186,442**

10.99. Aspen and Tiofarma's penalties will become due to the CMA in their entirety on 10 September 2020[905] and must be paid to the CMA by close of banking business on that date.[906]

9 July 2020

SIGNED

[✂]

- Howard Cartlidge, Senior Director, Cartels, (Chair of the Case Decision Group), for and on behalf of the Competition and Markets Authority

[✂]

- Maria da Cunha, CMA Panel Member, for and on behalf of the Competition and Markets Authority

[✂]

- Stuart McIntosh, CMA Panel Member, for and on behalf of the Competition and Markets Authority

All of whom are the members of, and who together constitute, the Case Decision Group.

[905] The next working day two calendar months from the expected date of receipt of the Decision.
[906] Details on how to pay the penalty are set out in the letter accompanying this Decision.

ANNEX 1: GLOSSARY

TERM	DEFINITION
ACM	Autoriteit Consument en Markt (Authority for Consumers and Markets): The Dutch competition authority.
Act	The Competition Act 1998.
Ambient Storage Fludrocortisone	The generic, heat-stable, Fludrocortisone Acetate Tablets manufactured by Tiofarma and introduced into the UK in March 2016.
Amilco	Amilco Limited, a privately-owned company [✂].
Amilco Settlement Letter	The settlement letter confirming Amilco's agreement to the terms of settlement signed on 29 June 2020.
API	Active Pharmaceutical Ingredient: The chemical substance contained in a pharmaceutical product, which is responsible for its therapeutic effect. Some pharmaceutical products contain more than one active ingredient (combination product).
ASP	Average Selling Price. In this Decision, ASP refers to the monthly average of Aspen's selling price.
Aspen	An undertaking formed of: Aspen Pharmacare Holdings Limited, Aspen Global Incorporated, Aspen Europe GmbH, Aspen Pharma Ireland Limited and Aspen Pharma Trading Limited.
Aspen Europe	Aspen Europe GmbH: A former Aspen company incorporated in Germany (which was registered as an overseas company in England and Wales) which formally merged with Aspen Pharma Ireland Limited effective from 1 July 2018.

TERM	DEFINITION
Aspen Global Inc.	Aspen Global Incorporated: The holding company for Aspen's international business which established a subsidiary in the UK on 12 June 2018 named Aspen Pharmacare UK Limited.
Aspen Holdings	Aspen Pharmacare Holdings Limited: Aspen's parent company listed in South Africa.
Aspen Pharma Ireland Limited	Aspen's European headquarters registered as an overseas company in England and Wales.
Aspen Pharma Trading Limited	The holder of the MAs for Fludrocortisone Acetate Tablets (Cold and Ambient Storage).
Aspen Settlement Letter	The settlement letter confirming Aspen's agreement to the terms of settlement and final draft maximum penalty, signed by Aspen on 24 July 2019.
ATC	Anatomical Therapeutic Chemical: The ATC classification system was developed by the World Health Organisation (WHO) and divides active substances into groups according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.
BGMA	British Generic Manufacturers Association.
BMS	Bristol-Myers Squibb Pharmaceuticals Limited: The original holder of the MA for Cold Storage Fludrocortisone in the UK.
CCGs	Clinical Commissioning Groups: Responsible for the commission of most of the NHS services in the areas for which they are responsible in England. There are equivalent bodies in the devolved nations.

TERM	DEFINITION
CCPC	Competition and Consumer Protection Commission: An independent statutory body with a dual mandate to enforce competition and consumer protection law in Ireland.
Chapter I prohibition	The prohibition contained in section 2 of the Act.
Chapter II prohibition	The prohibition contained in section 18 of the Act.
CMA	Competition and Markets Authority.
CMO	Contract Manufacturing Organisation: An entity which produces pharmaceuticals and sells them to an entity holding a product licence.
Cold Storage Fludrocortisone	The fludrocortisone product that requires refrigeration and was manufactured by Haupt Pharma AG until it was withdrawn from the UK market by Aspen.
Commitments	Commitments offered by Aspen to resolve the competition concerns identified by the CMA arising from the SAA.
COGs	Cost of Goods.
Court of Justice	The Court of Justice of the European Union.
Dechra	Dechra Veterinary Products Limited.
Decision	This Decision dated 9 July 2020.
DHSC	Department of Health and Social Care.
DM&D	NHS Directory of Medicines and Devices: An online dictionary of descriptions and codes which represent medicines and devices in use across the NHS.

TERM	DEFINITION
Drug Tariff	A monthly publication of Drug Tariff Prices. There is a common Drug Tariff in England and Wales. Separate Drug Tariffs are published in Scotland and Northern Ireland.
Drug Tariff Price	The basic price of medicines and appliances listed in the Drug Tariff. In this Decision the Drug Tariff Price refers to the basic price of Fludrocortisone Acetate Tablets as listed in the Drug Tariff for England and Wales and used to calculate the NHS England Reimbursement Price.
EU	The European Union.
Focal Product	Fludrocortisone Acetate Tablets licensed for human use.
Florinef	The brand name of Cold Storage Fludrocortisone supplied by Aspen in the UK until it was withdrawn from the UK market in February 2016.
Fludrocortisone Acetate Tablets	Fludrocortisone acetate 0.1 mg (100 microgram) tablets containing the API fludrocortisone acetate.
General Court	The General Court of the European Union.
Haupt Pharma	Haupt Pharma AG and its subsidiaries. Haupt Pharma was the registered manufacturer and CMO for Cold Storage Fludrocortisone in the UK under the Florinef brand until it was withdrawn from the UK market by Aspen.
Infringement	The finding in this Decision that the Parties entered into an SDA that had the object and the effect of preventing, restricting or distorting competition in breach of the Chapter I prohibition and Article 101 TFEU.

TERM	DEFINITION
Investigation	The formal investigation opened by the CMA on 10 October 2017 into the matters that are the subject of this Decision.
List Price	The basic price for supplying a drug as published by the manufacturer, wholesaler or supplier. In this Decision it is also referred to as the retail selling price.
MA	Marketing Authorisation.
MHRA	Medicines and Healthcare products Regulatory Agency.
the NHS Act	National Health Service Act 2006 (as amended).
NHS England Reimbursement Price	The price that is reimbursed to the dispenser for fulfilling prescription items in England.
NICE	National Institute for Health and Care Excellence.
NPH	Neurogenic (or neuropathic) Postural Hypotension.
Parties	The collective addressees of this Decision.
Party	Each individual addressee of this Decision.
PCA data	Prescription Cost Analysis data: National prescription data for medicines and appliances dispensed. Separate PCA data is published for each devolved nation.
PPRS	Pharmaceutical Price Regulation Scheme: A voluntary scheme that regulates branded drug prices.
PSNC	Pharmaceutical Services Negotiating Committee: The body recognised by the Secretary of State for Health and Social Care as representing NHS pharmacy contractors in England.
Relevant Market	The market for the supply of Fludrocortisone Acetate Tablets for human use in the UK.

TERM	DEFINITION
Relevant Period	The period from 1 March 2016 to 19 October 2016 inclusive.
[Healthcare Business Consultants]	The trading name of the healthcare consultancy business operated by [External Consultant 1].
SAA	Sale of Assets Agreement signed by Tiofarma and Aspen on 19 October 2016, with a retroactive implementation date of 1 October 2016.
SDA	Supply and Distribution Agreement entered into by the Parties and implemented from 1 March 2016. The SDA was terminated on 19 October 2016.
Statement of Objections	The Statement of Objections issued to the Parties on 3 October 2019.
Summary Statement of Facts	The Summary Statement of Facts issued to Aspen on 5 July 2019.
Supply Agreement	Supply Agreement between Tiofarma and Aspen signed on 17 October 2016 and in force from 1 October 2016.
Supply Price	The price payable by Aspen for each pack of Fludrocortisone Acetate Tablets supplied by Tiofarma in accordance with the provisions of the SDA.
Term Sheet	The non-binding agreement in relation to the supply of Fludrocortisone Acetate Tablets signed by the Parties on 19 January 2016.
Tiofarma Settlement Letter	The settlement letter confirming Tiofarma's agreement to the terms of settlement and final draft maximum penalty, signed by Tiofarma on 18 December 2019.
TFEU	Treaty on the Functioning of the European Union.

TERM	DEFINITION
Tiofarma	An undertaking, formed from at least 1 March 2016, comprising Tiofarma B.V. and Tiofarma Beheer B.V.
WDA	Wholesale Distribution Authorisation: A license required by a wholesale distributor to sell or supply medicines.

ANNEX 2: KEY INDIVIDUALS REFERRED TO IN THE DECISION

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