

Decision to accept binding commitments
offered by Aspen
in relation to the supply of
fludrocortisone acetate 0.1 mg tablets

Case number 50455

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1. Introduction

- 1.1. In this Decision made under section 31A of the Competition Act 1998 (the 'Act'), the Competition and Markets Authority ('CMA') accepts the commitments (the 'Commitments') set out in the Schedule to this Decision (the 'Schedule') offered by Aspen Pharmacare Holdings Limited,¹ Aspen Global Inc.,² Aspen Pharma Ireland Limited³ and Aspen Pharma Trading Limited⁴ (together, 'Aspen' as defined in the Schedule⁵).
- 1.2. Aspen offered the Commitments in the context of the CMA's investigation into suspected anti-competitive agreements and conduct in the market for the supply of fludrocortisone acetate 0.1 mg tablets ('Fludrocortisone Acetate Tablets') for human use in the UK (the 'Relevant Market') (the 'Investigation', Case 50455). Specifically, the Commitments seek to address the competition concerns arising from Aspen's acquisition in October 2016 of a marketing authorisation for Fludrocortisone Acetate Tablets (the 'Acquisition'⁶), in circumstances where Aspen held the only other marketing authorisation for that drug in the UK. The CMA is concerned that this acquisition preserved and strengthened Aspen's position as sole UK supplier of Fludrocortisone Acetate Tablets in the UK. The Acquisition was implemented and took effect in October 2016 and the CMA is concerned that it continues to have effects on the conditions of competition in the Relevant Market to the present day.
- 1.3. The CMA's investigation of the Acquisition under Chapter II of the Act (the 'Chapter II prohibition') and Article 102 of the Treaty on the Functioning of the European Union ('TFEU') is one aspect of the Investigation.
- 1.4. As a result of its acceptance of the Commitments, the CMA will not continue that aspect of its Investigation. The CMA has made no final decision on whether the Acquisition amounted to an infringement of the Chapter II prohibition and Article 102 of the TFEU.⁷
- 1.5. However, acceptance of the Commitments does not prevent the CMA from taking any action in relation to competition concerns that are not addressed by the Commitments. The CMA will continue the other aspects of the Investigation relating to another agreement under Chapter I of the Act (the 'Chapter I

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, which has established a subsidiary in the UK on 12 June 2018 named Aspen Pharmacare UK Limited under company number 11411661.

³ A company incorporated in Ireland under company number IE525086 and, since 1 July 2017, which registered as an overseas company in England and Wales under registration number BR020174.

⁴ A company incorporated in Ireland under company number IE482868.

⁵ In this document, references to Aspen may also include other legal entities within the same corporate group.

⁶ The Acquisition also included the transfer to Aspen of worldwide rights over the product relating to these marketing authorisations (see Chapter 4 below).

⁷ Section 31B(2) of the Act.

prohibition’) and Article 101 of the TFEU. Those aspects of the Investigation (in relation to which other undertakings are also under investigation) are subject to separate settlement proceedings involving Aspen. The CMA has issued a Statement of Objections today relating to those aspects of the Investigation, further details of which can be found in the [press release](#). Nothing in this Decision binds the case decision group that will be appointed following the issue of the Statement of Objections in the context of their decision as to whether there has been an infringement.

- 1.6. Moreover, acceptance of the Commitments does not prevent the CMA from reopening the Investigation in relation to the Acquisition, making an infringement decision, or giving a direction in circumstances where the CMA had reasonable grounds for:
 - (a) believing that there had been a material change of circumstances since the Commitments were accepted; or
 - (b) suspecting that a person had failed to adhere to one or more of the terms of the Commitments; or
 - (c) suspecting that information which led the CMA to accept the Commitments was incomplete, false or misleading in a material particular.⁸
- 1.7. The remainder of this Decision is structured as follows:
 - (a) Chapter 2 sets out details of the Investigation and the undertaking under investigation in relation to the Acquisition.
 - (b) Chapter 3 sets out background, including the key characteristics of the Relevant Market and Aspen’s position on that market.
 - (c) Chapter 4 sets out the competition concerns identified by the CMA as arising from the Acquisition.
 - (d) Chapter 5 summarises the Commitments offered by Aspen.
 - (e) Chapter 6 sets out the CMA’s assessment of the Commitments and of the representations made in response to the CMA’s notice of intention to accept binding commitments published on 14 August 2019.
 - (f) Chapter 7 sets out the CMA’s decision to accept the Commitments.

⁸ Section 31B(4) of the Act.

- 1.8. Certain confidential information in this document has been redacted. Redacted confidential information in the text of the document is denoted by [X].

2. The CMA's investigation

The Investigation

- 2.1. On 10 October 2017, the CMA informed Aspen and other parties that it had opened a formal investigation under the Act, having determined that it had reasonable grounds to suspect that:
- (a) Aspen had infringed the Chapter II prohibition and Article 102 TFEU; and
 - (b) Aspen and other undertakings had infringed the Chapter I prohibition and Article 101 TFEU.
- 2.2. In the course of its investigation, the CMA has undertaken a number of investigative steps to gather evidence from Aspen and other parties. These steps included investigative steps under sections 26 (requests for documents), 26A (compulsory interviews), 28 (inspection of business premises under warrant) and 28A (inspection of domestic premises under warrant) of the Act. The CMA also received assistance with gathering documents held in the Netherlands and the Republic of Ireland from, respectively, the Dutch Autoriteit Consument en Markt and the Irish Competition and Consumer Protection Commission. Aspen and other parties also provided documents and took part in interviews on a voluntary basis.
- 2.3. In July 2019, Aspen indicated to the CMA that it wished to explore the possibility of offering commitments to address the CMA's competition concerns with respect to the Acquisition. Further to paragraphs 10.19 and 10.22 of *Competition Act 1998: Guidance on the CMA's investigation procedures in Competition Act 1998 cases (CMA8)* (the 'Procedural Guidance'), the CMA discussed this possibility with Aspen.

The proposed Commitments and consultation process

- 2.4. Aspen formally proposed the Commitments to the CMA on 24 July 2019. On 14 August 2019 the CMA gave notice of its intention to accept binding commitments in Case 50455 (the '[Consultation](#)') by publishing the notice and sending a copy of the notice to a number of third parties who the CMA considered appropriate for the purpose of bringing the commitments to the attention of those likely to be affected by it.⁹ The notice outlined the proposed commitments offered by Aspen, set out the reasons as to why the CMA proposed to accept those commitments and the period within which representations could be made in relation to the proposed commitments.

⁹ Schedule 6A of the Act, paragraph 8.

- 2.5. The Consultation ran from 14 August to 2 September 2019 and representations were received from four interested parties:
- the Department for Health and Social Care (the 'DHSC')
 - the Welsh Government
 - the Society for Endocrinology
 - Tiofarma B.V.
- 2.6. A summary of the responses is set out in Chapter 6.
- 2.7. Following the Consultation, and in light of the consultation responses, Aspen proposed minor operational changes¹⁰ to the Commitments, which the CMA considers do not amount to a material modification of the Commitments for the purposes of paragraphs 3 and 5 of Schedule 6A of the Act (see paragraph 6.28 below). As a result, the CMA did not give notice of the modifications.

The undertaking under investigation in relation to the Acquisition

- 2.8. Aspen is a multinational pharmaceutical group with its headquarters in South Africa. It owns a broad portfolio of branded and generic prescription products that are sold to wholesalers, hospitals and pharmacies in over 100 countries.

¹⁰ Namely, to take account of the potential need for certain elements of the Commitments to be implemented via transitional arrangements.

3. Background

Industry background

- 3.1. Fludrocortisone Acetate Tablets are a prescription-only medicine used primarily to treat 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.
- 3.2. Fludrocortisone Acetate Tablets have been off patent since 1971. Prescriptions for Fludrocortisone Acetate Tablets are usually open and without reference to brand.
- 3.3. Companies seeking to supply Fludrocortisone Acetate Tablets directly in the UK must first obtain a marketing authorisation granted by the Medicines and Healthcare Products Regulatory Authority ('MHRA').
- 3.4. In November 2014, Aspen acquired from Bristol-Myers Squibb ('BMS') a refrigerated version of Fludrocortisone Acetate Tablets ('Cold Storage Fludrocortisone' as defined in the Schedule), including intellectual property rights and a marketing authorisation for the UK related to it. This product was sold at a price of approximately 5p per tablet, until its withdrawal in 2016, until 2016 under the Florinef brand ('Florinef'). At the time, this was the only Fludrocortisone Acetate Tablets product authorised for supply in the UK. Aspen later received approval from the MHRA to sell Cold Storage Fludrocortisone as an unbranded generic product in December 2015.
- 3.5. In the UK, suppliers of unbranded generic drugs such as Fludrocortisone Acetate Tablets are normally 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 generic competitors enter, or have real concrete possibilities to enter the market within a short period of time, and compete on price. In the majority of cases, this is believed to be an effective means of securing value for money for the NHS.
- 3.6. However, effective market entry in such markets does not always occur, 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. Accordingly, the incumbent supplier (in this case Aspen) could find itself in the position of holding substantial market power in relation to an old, yet still important medicine such as Fludrocortisone Acetate Tablets.

3.7. In November 2015, Tiofarma B.V.¹¹ ('Tiofarma') obtained the first marketing authorisation for supplying in the UK a generic (heat-stable) version of Fludrocortisone Acetate Tablets ('Ambient Storage Fludrocortisone' as defined in the Schedule).¹²

The Relevant Market

3.8. In assessing the impact on competition of the Acquisition, the CMA has considered the competitive constraints faced by suppliers of Fludrocortisone Acetate Tablets in the UK.

3.9. The CMA has considered the substitutability of alternative products for Fludrocortisone Acetate Tablets, as well as the substitutability between Fludrocortisone Acetate Tablets products with different storage conditions.¹³ For prescription-only medicines such as Fludrocortisone Acetate Tablets, healthcare professionals select the relevant medicine to prescribe for the NHS patient based on what is therapeutically most appropriate and effective.

3.10. The CMA considers that:

(a) there does not appear to be a suitable alternative to Fludrocortisone Acetate Tablets for long term mineralocorticoid deficiency in primary adrenal insufficiency, so clinicians have no choice but to prescribe Fludrocortisone Acetate Tablets; and

(b) there do not appear to be any clinical barriers to switching between Fludrocortisone Acetate Tablets products with different storage conditions, and prescriptions are mostly open.

3.11. On that basis, the CMA's preliminary view is that the relevant product market is no wider than the supply of Fludrocortisone Acetate Tablets licensed for human use, and comprises both products that have been authorised for supply in the UK.

3.12. In line with its previous decisions relating to the supply of medicines, the CMA's preliminary view is that the relevant geographic market is the UK.

¹¹ A company incorporated in the Netherlands under company number KvK 23078797. Tiofarma is a Dutch company that provides services to pharmaceutical companies, including as a contract manufacturing organisation ('CMO'). Tiofarma has a longstanding relationship with another undertaking, involving the provision of development and CMO services by Tiofarma to companies owned and directed by that undertaking.

¹² Ambient Storage Fludrocortisone is superior to Cold Storage Fludrocortisone to the extent that it can be stored at room temperature indefinitely, whereas the latter can only be stored out of the fridge for up to 30 days.

¹³ The CMA's approach to market definition is set out in *Market definition* (OFT403, December 2004), adopted by the CMA Board.

Aspen's position on the Relevant Market

3.13. As noted above, Aspen has been the sole domestic supplier of Fludrocortisone Acetate Tablets since it entered the market by acquiring the marketing authorisation for Cold Storage Fludrocortisone from BMS in November 2014. In the CMA's preliminary view, since that time Aspen has held significant market power, and is likely to have been in a dominant position at the time of the Acquisition, on the basis of:

- (a) high and stable market shares (of at least 80%) and the fact that it has faced no material competitive constraint from parallel importers;
- (b) its 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 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.

4. The CMA's competition concerns

- 4.1. This section sets out the CMA's competition concerns with respect to the Acquisition. In the specific circumstances of this case, in which an SO has been issued with respect to other competition concerns, the CMA wishes to emphasise that any conclusions or findings drawn in this section (i) are only drawn for the purpose of establishing the CMA's competition concerns with respect to the Acquisition; and (ii) do not bind the Case Decision Group appointed with respect to that SO.

Relevant context to the Acquisition

- 4.2. From November 2014, Aspen was the sole supplier of Fludrocortisone Acetate Tablets in the UK. In November 2015, Tiofarma obtained a marketing authorisation for Ambient Storage Fludrocortisone.¹⁴ In the CMA's preliminary view, Ambient Storage Fludrocortisone became a source of a significant competitive threat to Aspen from November 2015 onwards, as it presented a route to market for a new entrant to the Relevant Market.
- 4.3. The CMA is concerned that as a result of the Acquisition, Aspen eliminated the threat of competition from Ambient Storage Fludrocortisone and likely extended its position as sole UK supplier of Fludrocortisone Acetate Tablets.
- 4.4. For the reasons set out below, the CMA is concerned that the Acquisition was capable of permanently precluding Ambient Storage Fludrocortisone from being used as a basis for independent entry and that this preserved and strengthened Aspen's dominant position in the Relevant Market and its resulting ability to charge supra-competitive prices.

The key relevant terms of the Acquisition

- 4.5. As from 1 October 2016, Aspen acquired the worldwide rights over Ambient Storage Fludrocortisone, including the marketing authorisations to supply the product in the UK, on a permanent basis. The key terms of the Acquisition for the purposes of this assessment are the following:
- (a) Tiofarma agreed to *'sell, assign, transfer, convey and deliver to Aspen, who purchases all rights, title and interest in'* its Ambient Storage Fludrocortisone marketing authorisations, and associated data, with effect from 1 October 2016.
 - (b) Under a non-compete clause, Tiofarma undertook for a period of five years not to *'directly or indirectly, manufacture, distribute, market or sell any*

¹⁴ Tiofarma obtained a duplicate marketing authorisation in September 2016.

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. The Product refers to 'fludrocortisone (for human use)' and refers to the two UK marketing authorisations held by Tiofarma under PL numbers 17299/0001 and 17299/0002.

(c) In addition, Tiofarma and Aspen simultaneously entered into a supply agreement, pursuant to which Tiofarma agreed to supply Ambient Storage Fludrocortisone to Aspen and Aspen agreed to purchase all its requirements of Ambient Storage Fludrocortisone only from Tiofarma for a period of five years.

4.6. The MAs for Ambient Storage Fludrocortisone (under PLs 17299/0001 and 17299/0002) held by Tiofarma were formally transferred to Aspen following the receipt of approval from the MHRA in January 2017.

The CMA's competition concerns regarding the Acquisition

4.7. At the time of the Acquisition, Aspen did not face any actual competition. The only source of a significant competitive threat to its own Cold Storage Fludrocortisone product was Ambient Storage Fludrocortisone.

4.8. Aspen's acquisition of the marketing authorisations for Ambient Storage Fludrocortisone brought both of the authorised Fludrocortisone Acetate Tablet products existing in the UK at that time permanently under Aspen's ownership. Taking into account the market context and all of the prevailing circumstances, the CMA is concerned that the Acquisition was capable of preserving and strengthening Aspen's position as sole UK supplier in the Relevant Market (leaving it with the ability to price above competitive levels) by:

(a) preventing or at least considerably delaying the emergence of competition; and

(b) removing the only source of a significant competitive threat existing in the Relevant Market at that time.

4.9. In the absence of a readily available product authorised for supply in the UK, a pharmaceutical company seeking to enter the market would have needed to undertake significant developmental and regulatory work that requires a considerable investment in resources and time. That investment had already occurred with respect to Ambient Storage Fludrocortisone, which was market-ready at the latest by March 2016.

4.10. Absent the Acquisition, or other substantially similar arrangements, it is likely that Ambient Storage Fludrocortisone would have been brought to market

independently of Aspen. As a result, there would have been at least two domestic suppliers of Fludrocortisone Acetate Tablets. The CMA is concerned that the Acquisition likely prevented or at least considerably delayed the emergence of competition, including on price, by making entry more difficult.

- 4.11. In addition, the CMA is concerned that the Acquisition, by permanently removing the then only source of a significant competitive threat to Aspen's dominant position, left Aspen free to price above competitive levels.
- 4.12. Since the Acquisition came into effect, Aspen has faced no actual or potential competition in the UK market for the supply of Fludrocortisone Acetate Tablets as no new product has been authorised for supply in the UK. Aspen continued to supply Ambient Storage Fludrocortisone at a list price of £1 per tablet until July 2017. Notwithstanding a price decrease implemented by Aspen in July 2017, the price of Ambient Storage Fludrocortisone is more than eight times higher than the price charged for Cold Storage Fludrocortisone.

5. The Commitments

- 5.1. In order to address the CMA's competition concerns (as described in Chapter 4), and without prejudice to its position that it has not infringed the Act nor the TFEU by making the Acquisition, Aspen has offered the Commitments to the CMA relating to that conduct, as set out in further detail in the Schedule and summarised below. The Commitments include in particular:
- (a) the divestment of UK rights over Ambient Storage Fludrocortisone to an independent third-party acquirer (the 'Divestment Commitments' as defined in the Schedule);
 - (b) the reintroduction and commercialisation of Cold Storage Fludrocortisone in the UK (the 'Reintroduction and Commercialisation Commitments' as defined in the Schedule); and
 - (c) payments to the Department of Health and Social Care ('DHSC') the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland totalling £8 million (the 'NHS Payment Commitments' as defined in the Schedule).

The Divestment Commitments

- 5.2. Aspen has offered to divest itself of the rights over Ambient Storage Fludrocortisone necessary to commercialise that product in the UK (the 'Product Assets' as defined in the Schedule), including the MAs for that product and any relevant proprietary data.
- 5.3. The terms of any such divestiture and the identity of any potential purchaser would need to be approved by the CMA so as to ensure that the divestment will lead to effective commercialisation of Ambient Storage Fludrocortisone in the UK independently from Aspen. Specifically, the purchaser will be required to meet the following criteria (based on the purchaser suitability criteria that would apply in the merger context¹⁵):
- (a) Independence from Aspen;
 - (b) Capability of commercialising Ambient Storage Fludrocortisone in the UK and competing with Aspen;
 - (c) Commitment to the market; and

¹⁵ See CMA Guidance: *Merger remedies* (CMA87, 13 December 2018), paragraphs 5.20 to 5.27.

(d) Absence of regulatory concerns.

- 5.4. For the purpose of assisting the CMA in approving any potential purchaser of the Product Assets, Aspen has offered to provide any information that the CMA considers necessary to reach any decision in this context. This includes providing the CMA with a timetable for the divestiture, monthly progress reports and sufficient information relating to any potential purchaser for the CMA to assess its suitability, including a written report detailing why any such potential purchaser meets the purchaser criteria set out above. The CMA will have the right to seek information directly from Aspen and any potential purchaser that it considers necessary to give effect to these commitments.
- 5.5. To facilitate any successful purchaser in becoming an effective competitor, Aspen has offered to use its best efforts to assist (to the extent necessary) that purchaser, in entering into a:
- supply agreement to procure Ambient Storage Fludrocortisone from a manufacturer, including by seeking to assign or novate its existing supply agreement with Tiofarma (see paragraph 4.5(c)); and
 - transitional supply arrangement with Tiofarma, including in the event that the purchaser seeks to rely on another source of Ambient Storage Fludrocortisone (whether a third party's or its own manufacturing facilities).
- 5.6. In the event that Aspen is unable to procure any such divestiture within the proposed period of time, Aspen would appoint a divestiture trustee to achieve divestiture of the Product Assets. The appointment of the divestiture trustee, the terms of any divestment proposed by the divestiture trustee and the identity of any potential purchaser would need to be approved by the CMA.
- 5.7. In the event that any divestiture trustee is unable to procure the divestiture of the Product Assets on that basis, it will instead seek to out-licence the Product Assets to a suitable licensee independent from Aspen nominated by the CMA. Aspen has offered to ensure, in such circumstances, that the Product Assets are licenced to a supplier on terms standard to the pharmaceutical industry for a period of 10 years from the entry into force of any such licence. The terms and duration of any licensing agreement would require approval by the CMA.
- 5.8. The CMA will ensure that the overall timeframe for completing the divestiture (or licensing) of the Product Assets, the approval of any purchaser (or licensee) and the terms of any divestment (or licensing), as well as the appointment and responsibilities of any divestiture trustee, would be consistent with the CMA's approach to divestment as set out in the its *Merger Remedies Guidance*.¹⁶

¹⁶ CMA87, section 8.

The Reintroduction and Commercialisation Commitments

- 5.9. Aspen has offered to reintroduce Cold Storage Fludrocortisone (that is the product that it was selling in the UK prior to March 2016) in the UK market as soon as practicable and in any event within a period of twelve months from the date of any decision accepting the offer of commitments. Aspen is not able to reintroduce the product immediately due to the need to complete certain required regulatory steps.
- 5.10. In addition, Aspen has offered to commercialise that product following the divestment of Ambient Storage Fludrocortisone, as soon as practicable, and for a period of at least 10 years from the effective divestiture of Ambient Storage Fludrocortisone.
- 5.11. In order to ensure that Ambient Storage Fludrocortisone and Cold Storage Fludrocortisone are supplied independently in the Relevant Market, Aspen has also offered:
- (a) not to reacquire any right or interest in the Product Assets, including any UK right to supply or distribute Ambient Storage Fludrocortisone in the UK, within a period of 10 years following the divestiture of the Product Assets;
 - (b) not to divest any rights it holds in the UK over Cold Storage Fludrocortisone within a period of two years (except with approval by the CMA), and beyond that term not to divest any such rights to any third party holding rights over, or supplying, Ambient Storage Fludrocortisone in the UK; and
 - (c) not to take any steps that would undermine the purpose of these Commitments, ie the introduction of competition between independent suppliers of Fludrocortisone Acetate Tablets in the UK.

The NHS Payment Commitments

- 5.12. Aspen has offered to make payments totalling £8 million directly to the DHSC, the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland within a period of twenty working days from the date of any decision accepting Aspen's offer of commitments.
- 5.13. The DHSC, the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland have each provided an assurance that this payment will be taken into account in the event of any follow-on damage proceedings, [X] brought against Aspen [X].

Monitoring compliance

- 5.14. In order for the CMA to effectively monitor Aspen's compliance with the Commitments, Aspen shall provide the CMA with written reports at key times such as during the implementation of the Divestment Commitments as well as any information and documents that the CMA considers necessary for that purpose from time to time.

6. The CMA's assessment of the Commitments

6.1. Following the Consultation, and for the reasons set out below, the CMA has concluded that the package of Commitments, in the terms set out in the Schedule, would address the competition concerns it has identified in relation to the Acquisition and has decided to accept the Commitments. As a result of its acceptance of the Commitments, the CMA will not continue the element of its Investigation that relates to the Acquisition only, with no decision made on whether or not the Acquisition amounted to an infringement of the Chapter II prohibition and Article 102 of the TFEU.

The CMA's Guidance

6.2. The Procedural Guidance states that the CMA is likely to consider it appropriate to accept binding commitments only in cases where (a) the competition concerns are readily identifiable, (b) the competition concerns are addressed by the commitments offered, and (c) the proposed commitments are capable of being implemented effectively and, if necessary, within a short period of time.¹⁷

6.3. However, the CMA will not accept commitments where compliance with such commitments and their effectiveness would be difficult to discern or where the CMA considers that not to complete the relevant aspect of its investigation and make a decision would undermine deterrence.¹⁸

The competition concerns are readily identifiable

6.4. The CMA's view is that the competition concerns arising from the Acquisition set out in Chapter 4 are readily identifiable. Specifically, the CMA is concerned that the Acquisition brought both of the authorised Fludrocortisone Acetate Tablet products existing in the UK at that time permanently under Aspen's ownership. The CMA considers that, absent the Acquisition, or other substantially similar arrangements, it is likely that Ambient Storage Fludrocortisone would have been brought to market, independently of Aspen, with the result that there would have been at least two domestic suppliers of Fludrocortisone Acetate Tablets. On that basis, as set out in Chapter 4 above, the CMA is concerned that the Acquisition was capable of preserving and strengthening Aspen's position as sole UK supplier in the Relevant Market (leaving it in a position to maintain prices above competitive levels) by:

¹⁷ Paragraph 10.18 of the Procedural Guidance.

¹⁸ Paragraph 10.20 of the Procedural Guidance.

- (a) preventing or at least considerably delaying the emergence of competition; and
- (b) removing the only source of a significant competitive threat existing in the Relevant Market at that time.

The Commitments would, once implemented, address the CMA's competition concerns

- 6.5. The CMA's view is that the Commitments would, once implemented, address its competition concerns with respect to the Acquisition by ending Aspen's position as sole UK supplier of Fludrocortisone Acetate Tablets and introducing competition between two independent suppliers of that product.
- 6.6. The Commitments will ensure that:
 - (a) Aspen reintroduces Cold Storage Fludrocortisone in the UK market; and
 - (b) a suitably independent third-party obtains the right to supply Ambient Storage Fludrocortisone in the UK within a short time frame, on contractual terms to be approved by the CMA.
- 6.7. Approval in relation to the divestment of the Product Assets will only be granted by the CMA if the transaction is likely to lead to the emergence of an effective competitor to Aspen. Aspen has offered to implement both commitments within a similar, and interdependent, timeframe.
- 6.8. The CMA considers that the (near) contemporaneous reintroduction of Cold Storage Fludrocortisone by Aspen and divestment of the right to supply Ambient Storage Fludrocortisone in the UK will create conditions that are conducive to competition in the Relevant Market, as two versions of Fludrocortisone Acetate Tablets will be supplied independently in the UK. This is likely to have an effect on price as competition develops in that market.
- 6.9. The Commitments include additional provisions seeking to ensure that such competition as arises from the Commitments is preserved, including by preventing Aspen from:
 - (a) re-acquiring any right or interest over Ambient Storage Fludrocortisone in the UK for the duration of the commitments;
 - (b) selling any right or interest over Cold Storage Fludrocortisone in any UK to any supplier of Ambient Storage Fludrocortisone; and
 - (c) taking any step that would undermine the purpose of the Commitments, ie to have at least two independent suppliers in the Relevant Market.

6.10. Finally, the Commitments include a total payment of £8 million to the DHSC, the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland. This is to address the CMA's concerns that, as a result of the impact of Aspen's behaviour in the Relevant Market, including the Acquisition, on the conditions of competition in that market, the NHS paid a higher price for supplies of Fludrocortisone Acetate Tablets than it would have paid absent that behaviour.

The Commitments are capable of being implemented effectively and within a short period of time

6.11. Aspen has undertaken to act in accordance with the Commitments from the date the CMA notifies Aspen of its decision to accept the Commitments. Aspen will comply with the Commitments by seeking to reintroduce Cold Storage Fludrocortisone in the UK, and divest the Product Assets, in accordance with the agreed processes set out in the Commitments, and to do this within a short period of time.

6.12. In addition, if Aspen failed to comply with its Divestment Commitments, contingency mechanisms have been offered by Aspen so as to ensure that this is completed within a reasonable timeframe. This would include the appointment of a divestiture trustee who, following directions from the CMA, will seek to divest (or out-license¹⁹) the right to supply Ambient Storage Fludrocortisone in the UK following instructions from the CMA.

6.13. The approach taken in this context, including the timeframe for divestment, is consistent with the CMA's approach to divestments in the context of merger control, as set out in the CMA's Merger Remedies Guidance.²⁰

6.14. The CMA's view is that the timescale proposed by Aspen for achieving divestment of Ambient Storage Fludrocortisone, and for the reintroduction and commercialisation of Cold Storage fludrocortisone, is reasonable and enables Aspen to comply with these commitments while protecting its legitimate commercial interests.

6.15. As regards the NHS Payment Commitments, Aspen has offered to make the payments in full within 20 working days from the date the CMA notifies Aspen of its decision to accept the Commitments, which in the CMA's provisional view is a timely implementation.

¹⁹ This option would only be undertaken if the divestiture trustee failed to identify a suitable purchaser for the Product Assets. In that event, the Divestment Commitments, as set out in the Schedule to this Decision, would ensure that the Product Assets are licensed to a suitable third-party supplier. This commitment would last for a period of ten years from the entry into force of the initial licence.

²⁰ See CMA Guidance: *Merger remedies* (CMA87, 13 December 2018).

Compliance with the Commitments and their effectiveness would not be difficult to discern

- 6.16. Aspen has offered to comply with a number of reporting obligations, including to:
- (a) provide the CMA with regular monthly reporting with respect to compliance with the Divestment Commitments and the Reintroduction and Commercialisation Commitments; and
 - (b) more generally, notify the CMA at various key milestones for implementing and complying with the Commitments.
- 6.17. In addition, if Aspen fails to comply with its Divestment Commitments to divest the Product Assets within the proposed period of time, the appointment of a divestiture trustee as a contingency mechanism will further increase the CMA's ability to direct compliance with the Divestment Commitments.
- 6.18. The CMA's view is that these reporting obligations and contingency mechanisms will ensure that the CMA remains at all times in a position to monitor effective compliance by Aspen and take appropriate enforcement steps if required.

Deterrence would not be undermined by accepting commitments in this case

- 6.19. The implications for Aspen's position in the Relevant Market from having to divest itself of Ambient Storage Fludrocortisone in order to address the CMA's competition concerns, combined with an £8 million payment to DHSC, the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland, will, in the CMA's view, send a strong signal to other businesses, deterring them from engaging in practices such as those set out in Chapter 4 above.
- 6.20. The CMA also considers that by accepting commitments in this case it is able to resolve its competition concerns quickly and bring about significant pro-competitive changes to the structure of the Relevant Market.
- 6.21. The Commitments do not preclude the CMA taking further enforcement action in relation to other suspected breaches of competition law that raise competition concerns. Indeed, the CMA is currently pursuing other aspects of the Investigation in Case 50455 under Chapter I of the Act (the 'Chapter I prohibition') and Article 101 of the TFEU. Those aspects of the Investigation, which are subject to separate settlement proceedings involving Aspen, relate

to an agreement between Aspen, Amilco Limited²¹ and Tiofarma B.V.²² that predates the Acquisition and concerns the supply and distribution of Ambient Storage Fludrocortisone in the UK. The CMA has issued today a Statement of Objections relating to those aspects of the Investigation, further details of which can be found in the [press release](#).

Assessment of the responses to the consultation

- 6.22. The DHSC and the Welsh Government expressed their support for the Commitments. The DHSC welcomed Aspen's approach and expressed a hope that it would encourage other companies to take a similar approach. The Welsh Government further noted that the Commitments as a whole should deter other pharmaceutical companies from engaging in practices which may exploit the NHS.
- 6.23. In relation to the Divestment Commitments, the DHSC welcomed Aspen's commitment to take steps to restore competition for Fludrocortisone Acetate Tablets, on the basis that increased competition normally leads to lower prices for the NHS and more resilience in the supply chain. The Welsh Government acknowledged that the Divestment Commitments should lead to significantly reduced prices. The Society for Endocrinology noted that there may be some reluctance from any potential purchaser to go through the process of purchasing or licensing the MA for Ambient Storage Fludrocortisone and enter the Relevant Market. This is because entering that market may involve a material lead time (for instance, due to the need to gain regulatory approval for the transfer of the MA). As a result, any purchaser would have to invest in the product in the knowledge that Aspen could substantially cut its prices before the purchaser is ready to launch its own product in the market.
- 6.24. The CMA notes that, following the divestment, or licensing, of Ambient Storage Fludrocortisone, Aspen would face at least a potential competitor in the Relevant Market. If, however, divestment or licensing ultimately does not take place because a purchaser or licensee cannot be found, then Aspen would have failed to adhere to the Divestment Commitments for the purposes of Section 31B(4) of the Act. In that event, and pursuant to the same provision, the CMA would consider whether to continue the Investigation in relation to the Acquisition, including whether to make an infringement decision, or give a direction to Aspen.
- 6.25. In relation to the NHS Payment Commitments, the DHSC expressed its support on the basis that they provide an immediate financial benefit and reduced the potential need for lengthy and costly litigation to seek damages following any

²¹ A company incorporated in England and Wales under registration number 08809708.

²² A company incorporated in the Netherlands under company number KvK 23078797.

final CMA decision. The Welsh Government welcomed the fact that the NHS Payment Commitments enabled the recovery of losses without the need for costly legal proceedings. The Society for Endocrinology however submitted that, while a monetary settlement was appropriate in this case, in its view a higher figure would be appropriate to reflect the cost to the NHS and the profit made by Aspen.

- 6.26. As set out above at paragraph 6.10, and having considered these representations, the CMA remains of the view that the total amount of the NHS Payment Commitments is appropriate to address the CMA's concerns that, as a result of the impact of Aspen's behaviour in the Relevant Market, including the Acquisition, on the conditions of competition in that market, the NHS paid a higher price for supplies of Fludrocortisone Acetate Tablets than it would have paid absent that behaviour. In reaching this view, the CMA noted that the NHS Payment Commitments do not restrict the ability of any of the DHSC, the Scottish Ministers, the Welsh Ministers or the Department of Health, Social Services and Public Safety for Northern Ireland to bring follow-on claims for damages against Aspen or another party to Case 50455 in relation to the supply of Fludrocortisone Acetate Tablets (subject to the assurance referred to at paragraph 5.13).
- 6.27. The Society for Endocrinology further suggested that some of the money to be paid under the NHS Payment Commitments be used to invest in patient-centred adrenal failure research. The CMA will pass this suggestion on to the responsible UK health authorities.
- 6.28. Tiofarma offered its full cooperation to any purchaser of the divested product. Tiofarma submitted, with respect to the implementation of the Divestment Commitments, that a transitional supply arrangement with any potential purchaser may be necessary in the event that such purchaser decides to rely on another source of Ambient Storage Fludrocortisone (whether its own or a third party's manufacturing facilities). To reflect this submission, Aspen proposed a minor operational change to the Commitments, offering to use its best efforts to assist (to the extent necessary) any purchaser in entering into such a transitional supply arrangement with Tiofarma (see paragraph 5.5). The CMA has decided to accept this minor operational change as it is capable of further facilitating the implementation of the Divestment Commitments.²³
- 6.29. Having carefully considered all the responses to the Consultation, and having revisited its provisional view (as set out in the Consultation document), the CMA remains of the view that the proposed package, once implemented, would

²³ As set out above at paragraph 2.7, the CMA does not consider however that this change amounts to a material modification of the Commitments for the purposes of sections 3 and 5 of Schedule 6A of the Act that would require it to further consult interested third parties.

address the competition concerns it has identified, and that it is appropriate to accept the Commitments for the reasons set out in this Chapter.

7. The CMA's Commitments decision

7.1. Having conscientiously considered all the material in its possession in the round, including the submissions received in response to the Consultation, and taking into account the reasons set out above, the CMA remains of the view that the Commitments offered by Aspen, as set out in the Schedule, once implemented, would address the competition concerns it has identified as arising from the Acquisition, and considers that it is appropriate to accept the Commitments. Therefore, the CMA has decided to accept the Commitments by means of this Decision.

Signed:

Ann Pope, Senior Responsible Officer, for and on behalf of the Competition and Markets Authority

Date: 3 October 2019

Schedule: The Commitments

Case 50455: Fludrocortisone Acetate Tablets 0.1mg

1. Introduction

1. Aspen agrees to make the following Commitments, on condition that they are accepted by the CMA in a Commitments Decision. In particular, Aspen agrees to:
 - (a) divest the UK rights over Ambient Storage Fludrocortisone to an independent third-party acquirer (the 'Divestment Commitments' set out in further detail in Section 3 of this Schedule);
 - (b) reintroduce and commercialise Cold Storage Fludrocortisone in the UK (the 'Reintroduction and Commercialisation Commitments' set out in further detail in Section 6 of this Schedule); and
 - (c) pay the Department of Health and Social Care ('DHSC'), the Scottish Ministers, the Welsh Ministers and the Department of Health, Social Services and Public Safety for Northern Ireland, a total sum of £8 million (the 'NHS Payment Commitment' set out in further detail in Section 9 of this Schedule).
2. The Commitments are being offered by Aspen under section 31A of the Act to address the CMA's competition concerns arising from the Acquisition (as defined in the accompanying Decision to Accept Binding Commitments), as set out in the CMA's Decision to Accept Binding Commitments, and should be interpreted accordingly. These Commitments seek in particular to achieve effective competition between at least two independent suppliers of Fludrocortisone Acetate Tablets in the UK and to make a payment to the NHS in relation to the CMA's competition concerns as set out in the Decision to Accept Binding Commitments.
3. The giving of the Commitments by Aspen does not constitute an admission of any wrongdoing by Aspen with respect to the aspects of the CMA's investigation relating to the Acquisition.
4. These Commitments are without prejudice to Aspen's position should the CMA or any other party commence or conduct proceedings or other legal action against Aspen in relation to the Acquisition.

2. Definitions

5. The Interpretation Act 1978 shall apply to this Schedule as it does to Acts of Parliament.
6. References in these undertakings to any English law term for any legal status, interest, concept or thing shall in respect of any jurisdiction other than England and Wales be deemed to include what most nearly approximates in that jurisdiction to the English law term.
7. In this Schedule the word "including" shall mean including without limitation or prejudice to the generality of any description, definition, term or phrase preceding that word and the word "include" and its derivatives shall be construed accordingly.
8. Any term defined in the Decision to Accept Binding Commitments shall have the same meaning in this Schedule. In addition, for the purposes of this Schedule the following definitions apply:
 - (a) **Acquisition** means Aspen's Acquisition in October 2016 of the Marketing Authorisations;
 - (b) **Ambient Storage Fludrocortisone** means Fludrocortisone Acetate Tablets 0.1mg tablets based on the Proprietary Data with proven bio-equivalence to UK licence number PL39699/0071 and/or PL00034/5072R;
 - (c) **Approved Divestiture Agreement** means a binding agreement or agreements between Aspen and an Approved Purchaser, as approved by the CMA pursuant to paragraph 9, which provides for the transfer to the Approved Purchaser of the Product Assets;
 - (d) **Approved Licensee** means any independent supplier nominated by the CMA (and reasonably acceptable to Aspen) for the purposes of bringing about Effective Licensing;
 - (e) **Approved Licensing Agreement** means a binding agreement or agreements between Aspen and an Approved Licensee which provides for the grant by Aspen, to the Approved Licensee, of a licence to use the Product Assets to the extent required for the purposes of commercialising Ambient Storage Fludrocortisone in the UK. The terms of any Licensing Agreement are to be approved by the CMA, [✂];
 - (f) **Approved Purchaser** means any purchaser approved by the CMA for the purposes of the Divestiture Commitments as meeting the Purchaser Approval Criteria set out in Annex 1 to this Schedule;

- (g) **Approved Timetable** has the meaning given in paragraph 33;
- (h) **Aspen** means Aspen Pharmacare Holdings Limited, Aspen Global Incorporated, Aspen Pharma Trading Limited and Aspen Pharma Ireland Limited and any other members of the same Group of Interconnected Bodies Corporate;
- (i) **Asset Maintenance Commitments** means the element of the Commitments set out in Section 8 of this Schedule;
- (j) **Cold Storage Fludrocortisone** means the fludrocortisone product that requires refrigeration and was manufactured for Aspen for supply in the UK by Haupt Pharma AG under PL39699/0089 until it was withdrawn from the UK market by Aspen;
- (k) **Commercialisation Period** means a period commencing either on the date that the Reintroduction Period ends or that Effective Divestiture or Effective Licencing is completed, whichever date is later, and lasting ten years, or until the Reintroduction and Commercialisation Commitments cease to have effect pursuant to paragraph 26;
- (l) **Commitments** means the commitments given by Aspen, including the Divestment Commitments, the Reintroduction and Commercialisation Commitments, the Asset Maintenance Commitments and the NHS Payment Commitments, pursuant to section 31A of the Act;
- (m) **Commitments Decision** means a formal decision by the CMA under section 31A of the Act to accept these Commitments such that section 31B of the Act applies with respect to the aspects of the CMA's investigation in Case 50455 relating to the Acquisition;
- (n) **Direction** means a written direction given to Aspen by the CMA pursuant to paragraph 62;
- (o) **Divestment Commitments** means the element of the Commitments set out in Section 3 of this Schedule;
- (p) **Divestiture Period** means a period of up to [~~3~~] beginning with the Effective Date or such longer period as the CMA may approve on request;
- (q) **Divestiture Trustee** means a person appointed in accordance with paragraphs 11, 14 or 15;
- (r) **Divestiture Trustee Obligation** means:

- (i) bringing about Effective Divestiture within [X] from the Effective Date, subject to a minimum sale price of [X] but recognizing always the need to protect the legitimate financial and business interests of Aspen, and includes the performance of all ancillary tasks as are necessary or desirable for the purpose of reaching Effective Divestiture promptly and in any event within the Divestiture Trustee Period; and
 - (ii) if the Divestiture Trustee fails to bring about Effective Divestiture within [X] from the Effective Date, assisting the CMA in identifying any suitable independent supplier for the purposes of bringing about Effective Licensing.
- (s) **Divestiture Trustee Period** means a period commencing from the date of appointment of the Divestiture Trustee to bring about Effective Divestiture and terminating within [X] from the Effective Date, to be extended by an additional period to be determined by the CMA in any Direction issued under paragraph 40 for the Divestiture Trustee to bring about Effective Divestiture or Effective Licensing;
- (t) **Divestiture Trustee Process** means the process pursuant to which the Divestiture Trustee seeks to fulfil the Divestiture Trustee Obligation within the Divestiture Trustee Period;
- (u) **Effective Date** means the date on which Aspen receives formal notification of a Commitments Decision;
- (v) **Effective Divestiture** means the completion of the divestment of the Product Assets under an Approved Divestiture Agreement to an Approved Purchaser, subject to the completion of any applicable Post-completion obligations;
- (w) **Effective Licensing** means the completion of the licensing of the Product Assets under an Approved Licensing Agreement between Aspen and an Approved Licensee;
- (x) **Effective Licensing Period** means a period of ten years commencing on the date that Effective Licensing first occurs;
- (y) **Final Divestiture** means the satisfaction and/or termination of any Post-completion obligations further to Effective Divestiture;
- (z) **Group of Interconnected Bodies Corporate** has the meaning given in section 129(2) of the Enterprise Act 2002; references to a Group of Interconnected Bodies Corporate shall be to the Group of Interconnected Bodies Corporate as constituted from time to time;

- (aa) **Marketing Authorisations** means PL17299/0001 and PL17299/0002 and any other licence granted by the UK Medicines and Healthcare Products Regulatory Agency necessary for the manufacture, import and/or commercialisation of Ambient Storage Fludrocortisone in the UK;
- (bb) **NHS** means the National Health Service;
- (cc) **NHS Payment Commitments** means the element of the Commitments set out in Section 9 of this Schedule;
- (dd) **Post-completion obligations** means all things necessary to satisfy any commercial (including any transitional arrangements that may be agreed between Aspen and the Approved Purchaser for the purposes of Effective Divestiture) and regulatory requirements (including completion of the transfer of the Marketing Authorisations to the Approved Purchaser) that have been contractually agreed with the Approved Purchaser for the purposes of implementing Effective Divestiture;
- (ee) **Purchaser Approval Criteria** means the criteria set out in Annex 1 to this Schedule;
- (ff) **Product Assets** means the Marketing Authorisations and Proprietary Data;
- (gg) **Proprietary Data** means, solely to the extent that Aspen has any proprietary rights in relation thereto, all registered or unregistered proprietary information and material relating to formulations, techniques, methodology, and source of supply relating exclusively to Ambient Storage Fludrocortisone and the UK;
- (hh) **Reintroduction and Commercialisation Commitments** means the element of the Commitments set out in Section 6 of this Schedule;
- (ii) **Reintroduction Period** means a period of up to [~~30~~] beginning with the Effective Date or such longer period as the CMA may approve on request, and which comes to an end on the date that Aspen has completed all the commercial and regulatory steps that may be required to commercialise Cold Storage Fludrocortisone in the UK;
- (jj) **Supply Agreement** means a binding agreement between an Approved Purchaser and Tiofarma or any other suitable contract manufacturing organisation pursuant to which Tiofarma or any other suitable contract manufacturing organisation agrees to sell Ambient Storage Fludrocortisone to an Approved Purchaser;

(kk) **Transitional Supply Agreement** means a binding agreement between an Approved Purchaser and Tiofarma, pursuant to which Tiofarma agrees to sell Ambient Storage Fludrocortisone to an Approved Purchaser at least until the date on which the Approved Purchaser is able to procure regular supplies of Ambient Storage Fludrocortisone for sale in the UK from another source (whether from its own or a third party's manufacturing facilities);

(ll) **UK** means the United Kingdom of Great Britain and Northern Ireland; and

(mm) **Working Day** means any day other than a Saturday, Sunday or any other day that is a public holiday in England.

3. Divestment of the Product Assets

9. To give effect to the Divestment Commitments, Aspen shall:

(a) use its best endeavours to complete the divestment of the Product Assets under an Approved Divestiture Agreement to an Approved Purchaser within the Divestiture Period, subject to the completion of any Post-completion obligations; and

(b) not enter into final terms of divestment with any potential purchaser without having first obtained confirmation from the CMA that:

(i) such potential purchaser meets the Purchaser Approval Criteria; and

(ii) the terms of divestment are compliant with the Divestment Commitments; and

(c) use its best endeavours to assist the Approved Purchaser in entering into a Supply Agreement effective from the date of Effective Divestiture, subject to approval from the CMA to implement alternative transitional arrangements, unless the Approved Purchaser does not wish to avail itself of a Supply Agreement because it elects to manufacture Ambient Storage Fludrocortisone itself. In that event, Aspen shall within the ambit of its power and ability make all reasonable commercial arrangements required for the Approved Purchaser to effectively manufacture Ambient Storage Fludrocortisone from the date of Effective Divestiture. If required to ensure supply from the date of Effective Divestiture, Aspen shall use its best endeavours to assist the Approved Purchaser in entering into a Transitional Supply Agreement.

10. Aspen shall be deemed to have completed Effective Divestiture in accordance with paragraph 9 once the CMA has confirmed in writing to Aspen that this is

the case. The CMA will confirm this is the case if, by the end of the Divestiture Period the following factors are met:

- (a) Aspen has completed the transfer of the Product Assets to the Approved Purchaser pursuant to an Approved Divestiture Agreement;
 - (b) Aspen has agreed suitable transitional arrangements with the Approved Purchaser, including to complete any relevant Post-completion obligations; and
 - (c) the Approved Purchaser has entered into a Supply Agreement (subject to approval from the CMA to implement alternative transitional arrangements) or the Approved Purchaser has commenced the manufacturing of Ambient Storage Fludrocortisone itself. Should the Approved Purchaser elect to enter into a Supply Agreement with a suitable contract manufacturing organisation other than Tiofarma, or to manufacture Ambient Storage Fludrocortisone itself, and the necessary regulatory approvals are not obtained by the end of the Divestiture Period, the CMA will consider this factor to be met if the Approved Purchaser has entered into a Transitional Supply Agreement (at the same time as entering into any Supply Agreement).
11. In the event that Effective Divestiture has not been, or in the CMA's view will not be, achieved within the Divestiture Period, Aspen shall give effect to the Divestment Commitments by initiating the Divestiture Trustee Process in compliance with any Direction issued by the CMA pursuant to paragraph 43.
12. In the event that Aspen is required to initiate the Divestiture Trustee Process, pursuant to paragraph 11, Aspen shall:
- (a) appoint, at its cost, a Divestiture Trustee, to be approved by the CMA, in accordance with paragraphs 42 to 48 below;
 - (b) accept any offer to purchase the Product Assets identified by the Divestiture Trustee from a potential purchaser which meets the CMA's Purchaser Approval Criteria, in respect of a transaction approved by the CMA, subject to a minimum sale price of [X]; and
 - (c) use its best endeavours to assist the Approved Purchaser in relation to any Post-completion obligations, and in entering into a Supply Agreement effective from the date of Effective Divestiture, subject to approval from the CMA to implement alternative transitional arrangements, unless the Approved Purchaser does not wish to avail itself of a Supply Agreement because it elects to manufacture Ambient Storage Fludrocortisone itself. In that event, Aspen shall within the ambit of its power and ability make all

reasonable commercial arrangements required for the Approved Purchaser to effectively manufacture Ambient Storage Fludrocortisone from the date of Effective Divestiture.

13. Aspen shall be deemed to have completed Effective Divestiture within the Divestiture Trustee Period in accordance with paragraph 11 once the CMA has confirmed that this is the case. The CMA will confirm that this is the case if, by the end of the Divestiture Trustee Period, the factors set out at paragraph 10 are met.
14. In the event that Effective Divestiture has not been, or in the CMA's view will not be, achieved within 12 months from the Effective Date:
 - (a) Aspen shall procure that the Product Assets are licensed to an Approved Licensee, pursuant to an Approved Licensing Agreement, for the Effective Licensing Period; and
 - (b) for that purpose, Aspen shall:
 - (i) extend the appointment of the Divestiture Trustee until the completion of Effective Licensing; and
 - (ii) accept any offer identified by the Divestiture Trustee from a potential licensee which meets the CMA's Purchaser Approval Criteria, to enter into an Approved Licensing Agreement.
15. In the event that Aspen receives notice pursuant to which the Approved Licensing Agreement will come to an end before the end of the Effective Licensing Period, Aspen shall notify the CMA as soon as practicable following receipt of that notice. At the written Direction of the CMA, Aspen shall:
 - (a) appoint a Divestiture Trustee pursuant to paragraph 12 above; and
 - (b) accept any offer identified by the Divestiture Trustee from a potential licensee which meets the CMA's Purchaser Approval Criteria, to enter into an Approved Licensing Agreement. In this event, the duration of the Approved Licensing Agreement shall not be required to extend beyond the end of the Effective Licensing Period; and
 - (c) use its best endeavours to assist any Approved Licensee in relation to any reasonable commercial arrangement that may be required for it to commercialise Ambient Storage Fludrocortisone in the UK pursuant to the Approved Licensing Agreement.
16. Aspen shall be deemed to have completed Effective Licensing once the CMA has confirmed in writing to Aspen that this is the case. The CMA will confirm

this is the case if, in accordance with paragraphs 14 and 15, the following factors are met:

- (a) Aspen has entered into an Approved Licensing Agreement in relation to the Product Assets with an Approved Licensee; and
 - (b) the Approved Licensee has entered into all reasonable commercial arrangements required for it to commercialise Ambient Storage Fludrocortisone in the UK pursuant to the Approved Licensing Agreement.
17. The Divestment Commitments shall cease to have effect following Final Divestiture or at the end of the Effective Licensing Period.

4. Approval of purchaser within the Divestiture Period

18. Aspen shall notify the CMA, in the event that it identifies a potential purchaser which made an offer to purchase the Product Assets, within five Working Days of receipt of such offer, and will advise the CMA of the identity of that potential purchaser in order to obtain the CMA's prior written approval.
19. Following any notification relating to a potential purchaser, Aspen shall:
- (a) do all things reasonable to facilitate any engagement between the CMA and that potential purchaser that the CMA considers is necessary;
 - (b) provide all information and documentation as the CMA may reasonably require for the purpose of assessing the suitability of the potential purchaser and contemplated terms of divestment; and
 - (c) make full disclosure of every material fact and matter within its knowledge that it believes is relevant to the CMA's decision on any application by it for the CMA's consent or approval.
20. The CMA will advise Aspen whether any potential purchaser is an Approved Purchaser within a reasonable time of the CMA concluding it has received sufficient information under paragraphs 18 and 19 as the case may be.

5. Procedure for consent or approval and notification

21. Any application made by Aspen for the CMA's consent or approval (including for the purposes of Section 4) shall make full disclosure of every material fact and matter within its knowledge that it believes is relevant to the CMA's decision.

22. Where the CMA grants consent or approval on the basis of misleading or incomplete information and such information materially affects its consent or approval, the consent or approval is voidable at the election of the CMA.
23. In the event that Aspen discovers that an application for consent or approval has been made without full disclosure to the CMA in accordance with paragraphs 18 and 19, Aspen shall:
 - (a) inform the CMA in writing identifying the information that it omitted to include in the application for consent within two Working Days of becoming aware that the relevant information is misleading or incomplete; and
 - (b) at the same time or not later than two Working Days starting with the date on which it has informed the CMA of the omission in accordance with the sub-paragraph above, provide to the CMA an application for consent that includes the missing information.

6. Reintroduction and commercialisation of Cold Storage Fludrocortisone in the UK

24. To give effect to the Reintroduction and Commercialisation Commitments, Aspen shall use all commercially reasonable efforts to commercialise Cold Storage Fludrocortisone in the UK independently from and in competition with any undertaking supplying Ambient Storage Fludrocortisone as soon as practicable following Effective Divestiture or Effective Licensing. This shall include, but not be limited to Aspen:
 - (a) using its best endeavours to complete, as soon as practicable and in any event within the Reintroduction Period, all necessary regulatory steps that may be required under any legislation or regulation for the purpose of commercialising Cold Storage Fludrocortisone in the UK;
 - (b) using its best endeavours to complete, as soon as practicable and in any event within the Reintroduction Period, all necessary commercial steps that may be required for Aspen to have the ability to commercialise Cold Storage Fludrocortisone in the UK; and
 - (c) once the steps in (a) and (b) are completed, commencing the sale of Cold Storage Fludrocortisone within the UK as soon as practicable following Effective Divestiture or Effective Licensing.
25. In order for the CMA to establish whether Aspen has used all commercially reasonable efforts to give effect to the Reintroduction and Commercialisation Commitments, as required under paragraph 24, Aspen shall comply with the reporting obligations set out in paragraphs 33(b), 35, 36(b), 38 and 39.

26. The Reintroduction and Commercialisation Commitments shall cease to have effect if Aspen transfers the right to commercialise, or divest the rights (including the marketing authorisations) and proprietary data it holds in relation to, Cold Storage Fludrocortisone in the UK in compliance with Section 7 below. In any event, the Reintroduction and Commercialisation Commitments shall cease to be binding on Aspen at the end of the Commercialisation Period.

7. Independence between suppliers

27. Aspen shall procure that any associated person or any member of any Group of Interconnected Bodies Corporate to which it belongs at the relevant time shall not, for a period of ten years from the date of Effective Divestiture, without the prior written consent of the CMA acquire any interest, right, licence or title relating to the Product Assets.
28. Aspen shall procure that any associated person or any member of any Group of Interconnected Bodies Corporate to which it belongs at the relevant time shall not, without the prior written consent of the CMA, grant any interest, right or title Aspen holds in relation to Cold Storage Fludrocortisone in the UK (including any exclusive licence or any right to supply or distribute Cold Storage Fludrocortisone in the UK);
- (a) for a period of two years from the Effective Date, to any third party; and
 - (b) at any time, to any undertaking holding any interest, right or title over Ambient Storage Fludrocortisone necessary to commercialise that product in the UK (including the Approved Purchaser or Approved Licensee, and any successor).

8. Asset Maintenance

29. To give effect to the Asset Maintenance Commitments, until the date of the Effective Divestiture (or the end of the Effective Licensing Period), except with the prior written consent of the CMA, Aspen shall minimise as far as possible any risk relating to the transferability or licensing of the Product Assets or to their competitive potential, and in particular ensure that it:
- (a) continues to be the owner of, and to have good and merchantable title to, all of the Product Assets, and shall be able to transfer an unencumbered title to all of the Product Assets to any Approved Purchaser;
 - (b) continues to validly hold in full force and effect the Marketing Authorisations included in the Product Assets, and continues to comply with all terms and conditions thereof;

- (c) commercialises Ambient Storage Fludrocortisone in reliance on the Product Assets as a going concern on the basis of current business plans;
 - (d) shall not transfer any Proprietary Data to any third party without the CMA's approval; and
 - (e) shall take no other action that would impair the saleability of the Product Assets, or an Approved Purchaser's (or Approved Licensee's) ability to commercialise Ambient Storage Fludrocortisone.
30. At all times until Effective Divestiture or Effective Licensing, Aspen will actively keep the CMA informed of any material developments relating to how Aspen commercialises the Product Assets in the UK, which includes, but is not limited to:
- (a) any interruption in the supply of Ambient Storage Fludrocortisone (including without limitation its procurement, production, logistics, sales) that has prevented it from operating in the ordinary course of business;
 - (b) all substantial customer volumes lost by Aspen; and
 - (c) substantial changes in the contractual arrangements or relationships with Tiofarma, key service providers and customers.

9. Payment to the NHS

31. To give effect to the NHS Payment Commitments, Aspen shall:
- (a) within a period of 20 Working Days from the Effective Date, make the following payments totalling £8 million:
 - (i) a payment of £6,485,600 to the Secretary of State for Health & Social Care;
 - (ii) a payment of £788,000 to the Scottish Ministers;
 - (iii) a payment of £455,200 to the Welsh Ministers; and
 - (iv) a payment of £271,200 to The Department of Health, Social Services and Public Safety for Northern Ireland.
 - (b) notify the CMA no later than two Working Days following completion of all of the payments described in the sub-paragraph above, providing at the same time evidence that such payments have in fact been made.

32. Aspen shall be deemed to have completed the NHS Payment Commitments in accordance with paragraph 31 once the CMA has confirmed that this is the case. The CMA will confirm that this is the case if, within a period of 22 Working Days from the Effective Date, it receives a notification from Aspen and evidence that separate payments totalling £8 million have been made to Secretary of State for Health & Social Care, the Scottish Ministers, the Welsh Ministers and The Department of Health, Social Services and Public Safety for Northern Ireland in accordance with paragraph 31(b).

10. Provision of information

33. Aspen shall provide to the CMA within a period of five Working Days from the Effective Date:
- (a) a draft timetable that it proposes to adopt, subject to the CMA's approval, to ensure that Effective Divestiture occurs within the Divestiture Period. The CMA will either approve this timetable as proposed (an 'Approved Timetable') or require reasonable amendments to it and will notify Aspen of the Approved Timetable; and
 - (b) a list of key interim milestones for the purpose of the Reintroduction and Commercialisation Commitments.
34. Aspen shall provide a written report to the CMA, within ten Working Days of the end of each month during the Divestiture Period, on all material developments relevant to bringing about Effective Divestiture. Each report will outline the progress that Aspen has made towards Effective Divestiture against the Approved Timetable, and the steps that have otherwise been taken to comply with the Divestment Commitments, and in particular shall report:
- (a) details of the measures taken by each of Aspen and its financial advisers to solicit potential purchasers for the Product Assets and on the status of any discussions that have been held with potential purchasers of the Product Assets;
 - (b) on the steps that have been taken towards reaching an Approved Divestiture Agreement and the persons to whom any draft agreement has been distributed; and
 - (c) on such other matters as may be set out in any Directions by the CMA from time to time.
35. In addition, Aspen shall provide, within ten Working Days of the end of each month during the Reintroduction Period, a written report to the CMA on all

material developments relevant to fulfilling the Reintroduction and Commercialisation Commitments.

36. In the event that Aspen:
- (a) does not meet a target date as set out in the Approved Timetable, or is otherwise delayed in implementing the divestiture of the Product Assets and believes it is unlikely to achieve Effective Divestiture within the Divestiture Period, or
 - (b) does not meet one of the key interim milestones for the purpose of the Reintroduction and Commercialisation Commitments referred to in paragraph 33 above;

Aspen shall promptly inform the CMA in writing of the occurrence and the reasons for the failure, and in any case not later than three Working Days from becoming aware of that occurrence.

37. Aspen shall notify the CMA as soon as practicable:
- (a) when any Approved Divestiture Agreement has been completed;
 - (b) when all Post-completion obligations have been completed; and
 - (c) in the event that Aspen decides to agree to transfer any interest, right or title that Aspen holds in relation to Cold Storage Fludrocortisone in the UK (including any exclusive licence or any right to supply or distribute, Cold Storage Fludrocortisone in the UK), when such decision is taken.
38. Aspen shall provide a written annual report to the CMA setting out the volumes of Cold Storage Fludrocortisone sold in the UK and its average selling price for that product:
- (a) for the first two years from the beginning of the Commercialisation Period (or for a shorter period specified in any written Direction issued pursuant to paragraph 40 below), within ten Working Days after the end of each quarter; and
 - (b) for each of the remaining years within the Commercialisation Period, within 30 Working Days following the end of each year.

39. In addition, Aspen shall furnish promptly to the CMA such information as the CMA considers necessary in relation to or in connection with the implementation and/or enforcement of and/or the compliance with the Divestment Commitments and the Reintroduction and Commercialisation Commitments, including for the avoidance of doubt, any business secrets,

know-how, commercially sensitive information, intellectual property or any other information of a confidential or proprietary nature.

11. Conditions for the appointment of a Divestiture Trustee

40. Aspen shall at the written Direction of the CMA appoint a Divestiture Trustee in accordance with paragraphs 11 or 15 (or extend the appointment of the Divestiture Trustee in accordance with paragraph 14) to initiate the Divestiture Trustee Process and give effect to the Divestiture Trustee Obligation.
41. The Divestiture Trustee shall fulfil the Divestiture Trustee Obligation and shall undertake such matters preparatory to giving effect to the Divestiture Trustee Obligation or part thereof as the CMA may specify in the written Direction referred to in paragraph 40 above.

12. Divestiture Trustee – appointment procedure

42. Aspen recognises and acknowledges that the CMA may direct the appointment of a Divestiture Trustee at any time after the expiry of the Divestiture Period, or prior to the expiry of the Divestiture Period where the CMA considers that Aspen (for whatever reason) has not complied with the Approved Timetable in such a way that Effective Divestiture may not be expected to take place within the Divestiture Period.
43. Aspen shall, at the written Direction of the CMA, submit to the CMA for approval a list of two or more persons from which it proposes to appoint a Divestiture Trustee. The proposal shall contain sufficient information for the CMA to verify that each proposed person fulfils the requirement set out in paragraph 44 below and shall include among other things:
 - (a) the full terms of the proposed mandate, which shall include all provisions necessary to enable the Divestiture Trustee once appointed to fulfil the Divestiture Trustee Obligation; and
 - (b) a schedule of the steps to be taken to give effect to the mandate.
44. Each person on the list referred to in paragraph 43 shall be independent of, and unconnected to, Aspen, possess the qualifications necessary for the performance of the mandate and shall on appointment and thereafter be free of any conflict of interest including any conflict of interest that may arise by virtue of the terms of remuneration.
45. The CMA may approve or reject any or all of the proposed Divestiture Trustees (such approval not to be unreasonably withheld) and may approve the proposed mandate subject to any modifications it deems necessary for the

Divestiture Trustee to fulfil the Divestiture Trustee Obligation. If only one name is approved, Aspen shall use its best endeavours to appoint, or cause to be appointed, the individual or institution concerned as Divestiture Trustee in accordance with the mandate approved by the CMA. If more than one name is approved, Aspen shall be free to choose the Divestiture Trustee to be appointed from among the names approved. Aspen shall, using best endeavours, appoint the Divestiture Trustee within two Working Days from the CMA's approval and on the terms of the mandate approved by the CMA.

46. If all the proposed Divestiture Trustees are rejected by the CMA, Aspen shall submit the names of at least two further persons within five Working Days starting with the date on which it was informed of the rejection, in accordance with the requirements and the procedure set out in paragraphs 43 and 44 above.
47. The provisions of paragraph 48 below shall apply only if:
 - (a) Aspen fails to nominate persons in accordance with paragraph 46 above; or
 - (b) those further persons nominated by Aspen in accordance with paragraph 46 above are rejected by the CMA; or
 - (c) Aspen is unable for any reason to conclude the appointment of the Divestiture Trustee within the time limit specified by the CMA.
48. The CMA shall nominate one or more persons to act as a Divestiture Trustee, and Aspen shall, using best endeavours, appoint or cause to be appointed such Divestiture Trustee within five Working Days starting with the date of such nomination under the terms of a Divestiture Trustee mandate approved by the CMA.

13. Divestiture Trustee – functions

49. Aspen shall enable the Divestiture Trustee to carry out the Divestiture Trustee Obligation.
50. Aspen recognises and acknowledges that:
 - (a) the CMA may, on its own initiative or at the request of the Divestiture Trustee, give written Directions or instructions to the Divestiture Trustee in order to assist it in the discharge of the Divestiture Trustee Obligation to bring about Effective Divestiture or Effective Licensing;

- (b) the CMA may include in such agreements, deeds, instruments of transfer and other instruments and documents as are necessary for the performance of the Divestiture Trustee Obligation such terms and conditions as the CMA considers appropriate; and
 - (c) the Divestiture Trustee shall protect the legitimate financial and business interests of Aspen subject to the Divestiture Trustee's overriding obligation to give effect to the Divestiture Trustee Obligation.
51. Aspen recognises and acknowledges that the Divestiture Trustee shall take such steps and measures it considers necessary to discharge the Divestiture Trustee Obligation and to that end the Divestiture Trustee may give written directions to Aspen, as applicable. Aspen shall comply with such directions or procure compliance with such directions as are within its powers and shall take such steps within its competence as the Divestiture Trustee may specify.
52. Aspen recognises and acknowledges that in the performance of the Divestiture Trustee Obligation the Divestiture Trustee shall act solely on the instructions of the CMA and shall not be bound by any instruction of Aspen. Aspen shall not seek to create or vary the obligations and duties of the Divestiture Trustee except with the CMA's prior written consent.

14. Divestiture Trustee – duties and obligations of Aspen

53. Aspen shall provide the Divestiture Trustee with such cooperation, assistance and information (including the production of financial or other information, whether or not such information is in existence at the time of the request) as the Divestiture Trustee may reasonably require in the discharge of the Divestiture Trustee Obligation.
54. Aspen recognises and acknowledges that the Divestiture Trustee shall be entitled, subject to the duty of confidentiality, to full and complete access to the books, records, documents, management or other personnel, facilities, sites and technical information necessary for the fulfilment of the Divestiture Trustee Obligation (save where material is properly the subject of legal privilege) and Aspen shall provide the Divestiture Trustee upon reasonable request with copies of any such items. On the reasonable request of the Divestiture Trustee, Aspen shall make available to the Divestiture Trustee one or more offices on its premises, and ensure personnel are available where necessary for meetings in order to provide the Divestiture Trustee with all information reasonably necessary for the performance of the Divestiture Trustee Obligation, subject in each case to the Divestiture Trustee's compliance with Aspen's internal policies.

55. Aspen shall grant reasonable comprehensive powers of attorney, duly executed, to the Divestiture Trustee to enable it to discharge the Divestiture Trustee Obligation including by the appointment of advisers that the Divestiture Trustee reasonably considers necessary or appropriate to assist with the disposal process. Aspen shall upon the reasonable request of the Divestiture Trustee execute the documents required to give effect to the Divestiture Trustee Obligation.
56. Aspen shall hold the Divestiture Trustee, its employees, agents or advisers harmless against any liabilities arising out of the proper performance of the Divestiture Trustee Obligation and Aspen recognises and acknowledges that the Divestiture Trustee, its employees, agents or advisers shall have no liability to Aspen or any of its subsidiaries for any liabilities arising out of the proper performance of the Divestiture Trustee Obligation, except to the extent that such liabilities result from the wilful default, recklessness, negligence, bad faith or breach of confidentiality of the Divestiture Trustee, its employees, agents or advisers.
57. Aspen shall cover the expenses of any advisers (in particular for corporate finance or legal advice) appointed by the Divestiture Trustee that the Divestiture Trustee reasonably considers necessary or appropriate in the discharge of the Divestiture Trustee Obligation, provided that any fees and other expenses incurred by any such advisers are reasonably incurred. Before appointing any such advisers, the Divestiture Trustee will consider using the advisers already appointed by Aspen. Should Aspen refuse to approve the advisers proposed by the Divestiture Trustee, the CMA may, after consulting with Aspen, approve and direct the appointment of such advisers.
58. Aspen shall make no objection to the divestiture or licensing of the Product Assets save on the grounds of either bad faith by the Divestiture Trustee or failure of the Divestiture Trustee reasonably to comply with this Schedule or its duty to protect the legitimate financial and business interests of Aspen, subject to the Divestiture Trustee Obligation; and where Aspen wishes to make an objection on the grounds of bad faith by the Divestiture Trustee or failure of the Divestiture Trustee reasonably to comply with this Schedule or its duty to protect the legitimate financial and business interests of Aspen, it shall submit to the CMA a notice setting out its objections within two Working Days from the day on which it became aware of the fact or facts giving rise to its objection.

15. Divestiture Trustee – replacement, discharge and reappointment

59. Aspen acknowledges that, if the Divestiture Trustee ceases to perform the Divestiture Trustee Obligation, or for any other good cause, including the exposure of the Divestiture Trustee to a conflict of interest, the CMA may, after

consulting the Divestiture Trustee, require Aspen to replace the Divestiture Trustee.

60. If the Divestiture Trustee is removed under paragraph 59 above, the Divestiture Trustee may be required to continue in post until a new Divestiture Trustee is in place to whom the Divestiture Trustee has effected a full handover of all relevant information. The new Divestiture Trustee shall be appointed in accordance with the procedure contained in paragraphs 42 to 48 above.
61. Aspen recognises and acknowledges that, other than in accordance with paragraph 59 above, the Divestiture Trustee shall cease to act as Divestiture Trustee only after the CMA has discharged it from its duties at a time at which all the obligations with which the Divestiture Trustee has been entrusted have been met.

16. Directions

62. Aspen shall comply with any written Directions the CMA may issue relating to these Commitments and will promptly take such steps as may be specified or described in the Directions for complying with these Commitments.
63. Any delay by the CMA in making a written Direction shall not affect the obligations of Aspen at such time as the CMA makes any written Direction under paragraph 62.

17. Acceptance of service

64. Aspen hereby authorises Eversheds Sutherland (International) LLP to accept service on its behalf of all documents, orders, requests, notifications or other communications connected with the Commitments (including any such document which falls to be served on or sent to Aspen in connection with proceedings in court in the United Kingdom).
65. Unless Aspen informs the CMA that Eversheds Sutherland (International) LLP has ceased to have authority and has informed the CMA of an alternative to accept and acknowledge service on its behalf, any document, order, request, notification or other communication connected with the Commitments shall be deemed to have been validly served on Aspen if it is served on Eversheds Sutherland (International) LLP (Reference: CMA Commitments, attention of Ros Kellaway), and service or receipt shall be deemed to be acknowledged by Aspen if it is acknowledged by email from Eversheds Sutherland (International) LLP to the CMA.

66. Paragraph 65 above has effect irrespective of whether, as between Eversheds Sutherland (International) LLP and Aspen, Eversheds Sutherland (International) LLP has or continues to have any authority to accept and acknowledge service on behalf of Aspen (unless Aspen informs the CMA that Eversheds Sutherland (International) LLP has ceased to have authority to accept and acknowledge service on its behalf), and no failure or mistake by Eversheds Sutherland (International) LLP (including a failure to notify Aspen of the service of any document, order, request, notification or other communication) shall invalidate any action taken in respect of the Commitments, including any proceeding or judgement pursuant to the Commitments.

18. Effect of invalidity

67. Should any provision of these Commitments be contrary to law or invalid for any reason, Aspen shall continue to observe the remaining provisions.

19. Extension of time

68. Aspen recognises and acknowledges that the CMA may, where it considers appropriate, in response to a written request from Aspen showing good cause, or otherwise at its own discretion, grant an extension of any period specified in this Schedule within which Aspen and/or the Divestiture Trustee (as the case may be) must take action.

20. Governing law

69. The Commitments shall be governed by and construed in all respects in accordance with English law.
70. Disputes arising concerning the Commitments shall be subject to the exclusive jurisdiction of the courts of England and Wales.

21. Variation, release and supersession

71. In the event that Aspen requests to vary, release or supersede these Commitments, the CMA will respond in writing as soon as is reasonably practicable having regard to the nature of the request, the aim of these Commitments and to its statutory duties. CMA shall accept all such requests that it considers reasonable.
72. The variation, release or supersession of these Commitments shall not affect the validity and enforceability of any rights or obligations that arose prior to such variation, release or supersession.

Annex 1 - Purchaser Approval Criteria

73. In order to be approved by the CMA as an Approved Purchaser, any proposed purchaser must demonstrate the satisfaction of the Purchaser Approval Criteria.

Independence

74. The proposed purchaser must have no significant connection to Aspen that may compromise the purchaser's incentives to compete with Aspen in the market for the supply of Fludrocortisone Acetate Tablets in the UK. It must further be independent of, and unconnected to, any associated person of Aspen or its Group of Interconnected Bodies Corporate.

Capability

75. The proposed purchaser must have access to appropriate financial resources, expertise and assets to effectively commercialise the Product Assets in the UK.

Commitment to the relevant market

76. The proposed purchaser must have the intention to commercialise the Product Assets in the UK in competition with Aspen. This could be demonstrated by (among other things) a suitable business plan or such other evidence as the CMA considers appropriate.

Absence of regulatory concerns

77. An Approved Purchaser should not give rise to a realistic prospect of regulatory concerns in the market for the supply of Fludrocortisone Acetate Tablets in the UK. The absence of such concerns could be demonstrated through a report setting out the ability of the Approved Purchaser to comply with the regulatory duties that apply to any supplier of pharmaceuticals in the UK.